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2017 Benefit Year Protocols

PPACA HHS Risk Adjustment Data Validation

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1.0	5/21/18	CMS/CCIIO	Initial Draft with Process Clarifications and Updates
2.0	08/10/18	CMS/CCIIO	General Process Clarifications and Updates

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Section 1

HHS Risk Adjustment Data Validation Protocols

Overview

Preface

The purpose of the Department of Health and Human Services Risk Adjustment Data Validation (HHS-RADV) program is to validate the accuracy of data submitted by issuers to their External Data Gathering Environment (EDGE) servers for use in risk adjustment calculations where HHS is operating risk adjustment on a State's behalf.[1] It is important for issuers and their Initial Validation Audit (IVA) Entities to understand the EDGE Server Business Rules (ESBR) and understand the data in the HHS-RADV sampling reports. The following resource documents are available in the Registration for Technical Assistance Portal (REGTAP) Library:

- EDGE Server Business Rules (ESBR) Version 8.0
- EDGE Server XML and XSD Zip File Contents Job Aid (8/3/18)
- Interface Control Document - Risk Adjustment and Reinsurance Addendum Version 05.00.19 (8/3/18)
- Job Aid for Validation of RADVPS Reports (4/20/18)
- Job Aid for Validation of RADVPSF Report (5/21/18)
- Job Aid for Validation of RADVIVAS Reports (5/21/18)

[1] Starting with the 2017 benefit year, no State has elected to operate a risk adjustment program. Therefore, HHS operates risk adjustment in all States.

1 HHS Risk Adjustment Data Validation Overview

1.1 Purpose

The Risk Adjustment (RA) program is a premium stabilization program established by the Patient Protection and Affordable Care Act (PPACA). The overall goal of RA 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 Exchange(s). RA accomplishes this by transferring funds from issuers with lower risk enrollees to plans with higher risk enrollees. To ensure the integrity of the RA program, the Centers for Medicare & Medicaid Services (CMS) will perform Department of Health and Human Services (HHS) risk adjustment data validation (RADV) for each benefit year on behalf of any State that chooses not to implement its own State-operated risk adjustment program.

CMS conducted two (2) pilot years for HHS-RADV, benefit years 2015 and 2016. The results, of benefit years 2015 and 2016 HHS-RADV, were not applied to adjust RA risk scores and resulting payments and charges. However, the 2017 benefit year HHS-RADV results will be used to make RA payment adjustments. CMS has incorporated feedback from issuers and their IVA Entities on the 2015 and the 2016 benefit year HHS-RADV and has implemented process refinements for the 2017 benefit year HHS-RADV. This document defines protocols and guidance for the HHS-RADV process, and provides background, regulations, roles and responsibilities, process summaries, and activity timelines. This guidance is effective May 21, 2018 and specific to the 2017 benefit year HHS-RADV. CMS will communicate all updates and amendments to the protocols as they become available. For questions regarding the HHS-RADV protocols, contact HHS-RADV Operations at CCIIOACARADataValidation@cms.hhs.gov.

For the 2017 benefit year HHS-RADV, CMS has revised the error estimation methodology used to calculate issuer error rates consistent with the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule. Under the new methodology, CMS will determine if a risk score will be adjusted by comparing the health status of an issuer's enrollee population based on data submissions for RA calculations against its peers and applying an adjustment to issuers who statistically deviate from the norm. The results of 2017 benefit year HHS-RADV will be used to adjust risk scores, payments and charges, and we anticipate these adjustments will occur in June 2019. Refer to Section 7 – Error Estimation for additional detail related to the revised Hierarchical Condition Category (HCC) error estimation methodology, henceforth referred to as the "HCC failure rate methodology".

The HHS Notice of Benefit and Payment Parameters for 2019 Final Rule establishes an exemption for small issuers with 500 billable member months or fewer Statewide (that is, combining an issuer's enrollment in a State's individual and small group markets), as of the April 30, 2018 EDGE data submission deadline, from the 2017 benefit year HHS-RADV participation.

The HHS Notice of Benefit and Payment Parameters for 2019 Final Rule also delayed the implementation of the materiality threshold until the 2018 benefit year HHS-RADV. That is, issuers with total annual premiums at or below $15 million (calculated based on the premiums of the benefit year being audited) will not be subject to annual IVA requirements beginning with the 2018 benefit year HHS-RADV; however, these issuers are subject to the 2017 benefit year HHS-RADV, unless another exemption applies, and will be subject to an IVA approximately every three (3) years thereafter.

Issuers receiving a risk adjustment default charge (RADC) pursuant to 45 C.F.R. § 153.740(b) as a result of insufficient EDGE data are exempt from the requirements of HHS-RADV in the markets for which the issuer is receiving a RADC. CMS intends to propose in future rulemaking an exemption from the requirement to hire an IVA and submit IVA results for

issuers in liquidation or entering liquidation.[2]

CMS will assess the performance of an issuer's HHS-RADV effort for the 2017 benefit year and will consider efforts in medical record retrieval and good faith compliance with HHS-RADV requirements when considering enforcement action under 45 C.F.R. § 153.630(b)(9). If an issuer does not engage an IVA Entity or submit the results of an IVA to CMS, CMS may impose civil monetary penalties (CMPs) under 45 C.F.R. § 153.630(b)(9). Additionally, CMS has authority to assess CMPs if an issuer engages in misconduct or substantial non-compliance with the HHS-RADV standards and requirements or intentionally, or recklessly, misrepresents or falsifies information that it furnishes to CMS. Under 45 C.F.R. § 153.630(e), CMS may also adjust RA payments and charges for issuers that do not comply with audit requirements and standards.

1.2 Regulatory References

The Secretary of HHS has designated CMS to implement the HHS-RADV program in accordance with regulations 45 C.F.R. §§ 153.350 and 153.630, as well as the following final rules:

- *Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Final Rule*, 77 FR 17220 (March 23, 2012);
- *HHS Notice of Benefit and Payment Parameters for 2014* Final Rule, 78 FR 15410 (March 11, 2013);
- *HHS PPACA Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards*; *Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 Part II, Final Rule*, 78 FR 65046 (October 30, 2013);
- *HHS Notice of Benefit and Payment Parameters for 2015* Final Rule, 79 FR 13744 (March 11, 2014);
- *HHS Notice of Benefit and Payment Parameters for 2018* Final Rule, 81 FR 94056 (Dec. 22, 2016); and
- *HHS Notice of Benefit and Payment Parameters for 2019* Final Rule, 83 FR 16930 (April 17, 2018).

1.3 HHS-RADV Participants, Roles, and Responsibilities

The HHS-RADV process requires active participation and coordination between multiple stakeholders, including: CMS, issuers of RA covered plans, IVA Entities, and the Second Validation Audit (SVA) Entity.[3] This section provides an overview of HHS-RADV program participants' roles and responsibilities.

[2] Please refer to https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf for additional information.

[3] For the purpose of this document, the terms "IVA Entity" and "SVA Entity" refer to the auditors performing the HHS-RADV audit steps. The terms "IVA" and "SVA" refer to the audits.

1.3.1 CMS

CMS is responsible for implementing RA data validation in states where HHS operates the RA program. CMS will perform the following to implement HHS-RADV:

- Regulate HHS-RADV process for the HHS-operated RA program;
- Develop, implement, and approve actions associated with the EDGE server, HHS-RADV protocols, and the HHS-RADV Audit Tool;
- Acknowledge submission from each IVA Entity;
- Provide validation logic for selecting the sample of enrollees to issuers;
- Oversee and conduct the SVA;
- Communicate all HHS-RADV updates; and
- Provide HHS-RADV training to all applicable entities.

1.3.2 Issuers

Issuers are insurance companies that are required to be licensed to engage in the business of insurance in a State and are subject to State laws that regulate insurance. RA covered plans is defined as health insurance coverage offered in the individual or small group markets, both inside and outside the Exchanges, with the exception of grandfathered health plans, excepted benefit health insurance coverage described in 45 C.F.R. § 146.145(c) and § 148.220, and any plan determined not to be an RA covered plan in the applicable Federally certified RA methodology. Issuers are identified by a Health Insurance Oversight System Identification (HIOS ID), which is unique to the issuer and a State. The issuers' responsibilities for the HHS-RADV program are grouped into programmatic responsibilities and Audit Tool responsibilities.

Issuers' Programmatic Responsibilities

- Engage an independent auditor that is reasonably capable of performing the IVA;
- Ensure that the IVA Entity applies HHS-RADV protocols in conducting the IVA;
- Attest that the selected IVA Entity is reasonably free of conflicts of interest and able to conduct the IVA in an impartial manner with its impartiality not reasonably open to question;
- Provide the IVA Entity access to applicable systems, processes and source documentation for enrollment, premiums, claims and/or medical records, and any required attestations for sampled enrollees;
- Ensure the IVA results and requested supporting source documentation are submitted to CMS in the manner and time frame established by CMS;
- Substantiate results of the IVA;
- Attend all required training related to the HHS-RADV program as specified by CMS;
- Review all published documents related to the 2017 HHS-RADV; and
- Read and comprehend the HHS-RADV Protocols.

Issuers' Audit Tool Responsibilities

- Register for and obtain access to the HHS-RADV Audit Tool;
- Designate the IVA Entity through the IVA Designation Form in the HHS-RADV Audit Tool;
- Review and approve the RADV Population Summary Statistics (RADVPS) Report and submit discrepancies to CMS, as necessary;
- Review and approve the RADV Population Summary Statistics Final (RADVPSF) Report and RADV sampling reports and submit discrepancies to CMS, as necessary;
- Discuss IVA findings with IVA Entity prior to submission and complete sign-off in the HHS-RADV Audit Tool; and
- Resolve disputes while maintaining the integrity of the IVA Entity's independence.

To fulfill the issuers' Audit Tool responsibilities, issuers must designate an Issuer Senior Official (SO) in the HHS-RADV Audit Tool. Issuers also have the ability to select a backup Issuer SO and an Issuer Coordinator (CO) in the HHS-RADV Audit Tool. For additional detail on electing Issuer SOs and COs, as well as performing Audit Tool responsibilities, see the HHS-RADV IVA Submission User Manual.

1.3.3 IVA Entity

The IVA Entity is an independent organization hired by an issuer to conduct the validation of sampled enrollees' demographic and enrollment data, and health status information derived from diagnosis data submitted by issuers to the EDGE servers for use in RA calculations. The IVA Entity must conduct the validation independently and within the time frame specified by HHS. The issuer must engage an IVA Entity and submit their information to CMS for review and approval. The IVA Entity must conduct the validation of demographic and enrollment information and health status information. Once the IVA Entity completes the audit, the results, along with supporting documentation, are uploaded to the Audit Tool. Section 5 details the audit execution and submission requirements for the HHS-RADV program. The IVA Entity's responsibilities for the HHS-RADV program are grouped into programmatic responsibilities and Audit Tool responsibilities.

IVA Entity's Programmatic Responsibilities

- Provide qualified personnel to perform data validation steps, demographic reviews, claim reviews, and health status data validations;
- Ensure that at least two (2) certified medical coders are available to perform medical record reviews, with at least one (1) of them being a Senior Coder with five (5) years of experience;
- Ensure medical coders maintain current certifications;
- Conduct the IVA independently and in accordance with the protocols for HHS-RADV;
- Perform Inter-rater Reliability (IRR) assessments between medical coders for quality assurance; and
- Attend all required training related to the HHS-RADV program as specified by CMS and review the HHS-RADV Protocols and other published documents related to the 2017 benefit year HHS-RADV program.

IVA Entity's Audit Tool Responsibilities

- Register for and obtain access to the HHS-RADV Audit Tool;
- Submit HHS-RADV findings to the Audit Tool;
- Discuss IVA findings with issuer prior to submission;
- Submit IVA findings to Audit Tool prior to issuer sign-off in the HHS-RADV Audit Tool; and
- Resolve disputes while maintaining the integrity of the IVA Entity's independence.

To fulfill the IVA Entity's Audit Tool responsibilities, the IVA Entity must register a primary IVA Entity SO and a backup IVA Entity SO in the HHS-RADV Audit Tool. The IVA Entity also has the ability to register an IVA Entity CO in the HHS-RADV Audit Tool. For further detail on registering IVA Entity SOs and IVA Entity COs, as well as performing Audit Tool responsibilities, see the HHS-RADV IVA Submission User Manual.

1.3.4 SVA Entity

The SVA Entity validates the issuer's demographic and enrollment (D&E) data and health status on a subsample of the IVA sampled enrollees for all IVA submissions. The SVA validation of health status information for the subsamples follows the steps and requirements outlined in Section 5. For HHS-RADV, the SVA Entity's responsibilities include, but are not limited to, the following:

- Validate and approve RADV Sample Reports;

- Conduct the SVA independently and in accordance with the protocols for HHS-RADV; and
- Perform IRR assessments between medical coders as part of quality assurance.

1.3.5 IVA and SVA Entity Personnel

EDGE server data validations should be completed by personnel within the IVA Entities and the SVA Entity that are qualified to perform the validation activity. Experience requirements vary for individuals performing D&E and health status data validations. Two (2) primary groups of personnel exist:

- Primary and Senior Reviewers - NO REQUIRED certification or minimum years of experience.
- Primary and Senior Coders - REQUIRED medical record coding certification and minimum five (5) years of experience for Senior Coders.

Sections 1.3.5.1 and Section 1.3.5.2 specify the roles for Reviewers and Coders, along with experience requirements as defined by CMS.

1.3.5.1 Primary and Senior Reviewers

Primary and Senior Reviewers' responsibilities include performing the D&E Data Validation and conducting the medical record intake portion of the Health Status Validation, as specified in Section 5.6. Errors identified in the D&E Data Validation by Primary Reviewers must be confirmed by Senior Reviewers. There are no experience or certification requirements for Primary or Senior Reviewers.

1.3.5.2 Primary and Senior Coders

The IVA Entity and SVA Entity must be staffed with at least one (1) Primary Coder and one (1) Senior Coder. Health Status Data Validation activities (see Section 5.6) are required to be completed by certified medical coders, with the exception of medical record intake which may be completed by Primary or Senior Reviewers. Senior Coders are also essential to performing IRR (see Section 6). Table 1 (below) outlines the role, experience requirements, and activities specific to Primary and Senior Coders.

Table 1: Primary and Senior Coder Information

	Primary Coder	Senior Coder
Role	Perform coder-specific Health Status Data Validation activities.	Re-perform validation steps when Primary Coder results do not match the EDGE server data and note any findings of an RA data error. Senior Coder re-review is used to confirm or refute RA data error findings identified by Primary Coders. Perform IRR over Primary Coder results.
Certification Requirements	Must be certified after examination by a nationally recognized accrediting agency for medical coding, such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC).	Must be certified after examination by a nationally recognized accrediting agency for medical coding, such as AHIMA or AAPC.
Experience Requirements	None	Must be a certified coder with at least five (5) years of experience.
In Scope Data Validation Activities	Health Status Data Validation Activities[4] (Section 5.6)	Health Status Data Validation Activities (Section 5.6) IRR - Senior Coder performs IRR on a sample of medical records for all Primary Coders in order to determine whether they meet the required accuracy rate.

1.4 HHS-RADV Process

HHS-RADV includes six (6) process stages – sample selection, IVA, SVA, error estimation, final results discrepancies and administrative appeals, and error rate adjustments to RA risk scores and calculated RA payments and charges - that are discussed in further detail throughout this document.

1.4.1 Sample Selection

The first stage in the HHS-RADV process is the selection of a sample of an issuer's enrollees. CMS applies a sampling methodology, described in Section 4, to select each issuer's sample of enrollees such that the estimated risk score errors are statistically valid and the enrollee-level risk score distributions reflect enrollee characteristics for each issuer. CMS uses the data submitted to an issuer's EDGE server for RA and applies the sampling methodology, as described in Section 4, to select each issuer's sample of enrollees. CMS provides the sample to issuers and IVA Entities for review.

1.4.2 IVA

The second stage of the HHS-RADV process is the IVA. In this stage, issuers are required to engage an IVA Entity to perform the D&E Data Validation and the validation of health status information for the CMS-defined sample of enrollees. As part of this process, the IVA Entity will also measure and report their IRR. Once the IVA has been completed, the IVA Entity submits the results to CMS via the Audit Tool. The IVA process for HHS-RADV is discussed in further detail in Section 5. Execution of IRR is discussed in detail in Section 6. Recording and submission of IVA results is discussed in detail in Section 5.7.

1.4.3 SVA

[4] For the purposes of HHS-RADV, an individual who meets the requirements for the Primary or Senior Coder role may also serve as a Primary Reviewer or Senior Reviewer, as no experience or coding requirements are specified. As such, Primary or Senior Coders may perform all Primary Reviewer and Senior Reviewer data validation activities, including Enrollment Data Validation, and Claims Data Validation.

The third stage of the HHS-RADV process is the SVA. The objective of this phase is to verify the accuracy of the IVA results. The SVA Entity validates a subsample of issuers' D&E data and health status data across all IVA submissions. The SVA steps and requirements are outlined in Section 5. The SVA uses pairwise means testing to determine if IVA and SVA results are statistically different and expands the number of enrollees reviewed as required.[5]

1.4.4 Error Estimation

The fourth stage in the HHS-RADV process is error estimation. Upon completion of the SVA process, CMS will calculate the failure rate for each HCC across all issuers' IVA samples. HCC failure rates are the probability of an assigned HCC being found to be incorrect based on HHS-RADV findings. All HCCs will then be grouped into low, medium, and high failure rate groups based on each HCC's failure rate. Next, CMS will compare each issuer's Group Failure Rate to the weighted mean failure rate for that HCC group to assess each issuer's performance relative to the total population of issuers participating in HHS-RADV. If an issuer's Group Failure Rate falls outside the confidence interval for the weighted mean failure rate for the HCC group, the failure rate for the issuer's HCCs in that group would be considered an outlier. When an issuer's Group Failure Rate is an outlier, CMS will adjust the sample enrollees' applicable HCC risk scores and calculate the issuer's risk score error rate. The Error Estimation process is discussed in detail in Section 7.

1.4.5 Final Results Discrepancy and Administrative Appeals

The fifth stage in the HHS-RADV process is the final results discrepancy and administrative appeals process, wherein issuers may submit discrepancies with CMS' final HHS-RADV determinations. The Final Results Discrepancy and Administrative Appeals process is discussed in detail in Section 8.

1.4.6 RA Payment Transfer Adjustments

In the sixth stage of the HHS-RADV process, CMS will apply the 2017 benefit year HHS-RADV risk score error rate to the 2018 benefit year RA risk scores and calculate the 2018 benefit year RA payment and charges using the adjusted risk score(s) in June 2019, with one (1) exemption. CMS will adjust the 2017 benefit year risk adjustment risk scores and transfers in the event that an issuer of RA covered plans exits the market in the 2018 benefit year and is found to have an outlier error rate in the 2017 benefit year HHS-RADV. Adjustments to 2017 benefit year risk scores and transfers for exiting issuers will also occur in June 2019.

1.5 HHS-RADV Process Activities Timeline

CMS will deliver training for issuers and IVA Entities covering the HHS-RADV process and the applicable standards for performing the IVA. CMS will review "lessons learned" during the HHS-RADV process and consider applying information to future HHS-RADV benefit years. The submission of IVA findings is referred to as Package 1 and the submission of medical records for the SVA subsample is referred to as Package 2.

For the 2017 benefit year HHS-RADV, CMS may potentially expand the SVA sample to include the entire IVA sample if, after executing a pairwise means test, insufficient agreement between IVA and SVA findings is determined. The submission of the additional medical records for review by the SVA due to insufficient agreement between IVA and SVA findings is referred to as Package 3. Package 3 is similar to Package 2 but contains medical records that were not submitted during Package 2 submission. Medical records submitted in Package 3 must align with the medical records captured in the *IVA Entity Audit Results Submission XML*.

[5] Pairwise Means Test: A statistical means test, which is a hypothesis-testing procedure to determine if two (2) population means are different when there is a one-to-one (1:1) correspondence between the values in the two (2) samples.

Figure 1 below details the planned activities and an estimated timeline for the HHS-RADV process for the 2017 benefit year. Note that this timeline is subject to change. Refer to https://www.REGTAP.info/ for HHS-RADV Timeline activities and corresponding deadlines for the applicable benefit year.

Figure 1: HHS-RADV Process Activities Timeline for the 2017 Benefit Year

Ongoing	Issuers contractually select IVA Entities.
March 28, 2018	IVA Entities elect to participate in the 2017 benefit year HHS-RADV using the CMS web form.
Beginning April 16, 2018	**NEW RADV issuers only –** Issuers designate their HHS-RADV SO using CMS web form. After SO designation is complete, Issuer SOs receive a CMS generated email inviting them to start the registration process in the Audit Tool.
Beginning April 16, 2018	Issuers designate IVA Entities within the HHS-RADV Audit Tool.
April 30, 2018	2017 benefit year RA final EDGE server data submission deadline. Last day for IVA Entity to elect participation in the 2017 benefit year HHS-RADV.
Late May 2018	2017 benefit year HHS-RADV Protocols are released.
May 2018	1. May 11, 2018 12:01 a.m. ET., CMS pushes RADV sampling command to EDGE servers. Issuers should execute the command by 10:00 a.m. ET. 2. Reports are provided to CMS for validation. Reports are NOT available to issuers. 3. May 21, 2018 CMS pushes final RADV command to EDGE servers for release to issuers. 4. The 15-day RADV sample discrepancy window opens May 22, 2018 to June 6, 2018.
June 2018 – January 25, 2019	IVA is conducted.
December 2018 – January 2019	CMS releases the SVA subsample to IVA Entities, upon issuer signoff of Package 1.
January 11, 2019	Deadline for IVA Entities to submit Package 1 audit findings. This closes the window for the 2017 benefit year HHS-RADV audit submission process.
January 25, 2019	Final day for IVA Entity to submit Package 2 medical records to CMS for the SVA subsample and final issuer sign-off.
January 25, 2019	IVA Entity Inter-rater Reliability (IRR) results submission deadline.
January 2019 – April 2019	SVA is conducted and pairwise means tests are executed to determine if Package 3 submission is necessary. If Package 3 is required, the IVA Entity must submit and the Issuer SO must sign off within seven (7) calendar days from CMS notification.
May 2019 – June 2019	CMS releases 2017 benefit year HHS-RADV error rates to issuers.

Package 1 submissions may be submitted from December 2018 until January 11, 2019. Package 1 submissions should include the IVA Entity Audit Results Submission XML and all D&E data for enrollees selected by CMS in the D&E Subsample Report. After the Issuer SO signs off on Package 1 in the Audit Tool, CMS will release the SVA subsample to IVA Entities. Package 1 submission must be successfully completed, including review and sign off by the Issuer SO by January 11, 2019.

Package 2 submission must be successfully completed, including review and issuer sign off, by January 25, 2019. Package 2 submission should include all medical records and non-EDGE claim information for enrollees selected in the HHS-RADV IVA sample. CMS is not requiring Package 2 be submitted immediately after issuer sign-off of Package 1, but strongly encourages IVA Entities to submit Package 2 well before January 25, 2019 to allow time for resolution of issues that may arise, related to the submission process.

Upon CMS request, Package 3 submission should include all medical records for the additional enrollees in the IVA Sample that were not submitted during Package 2 submission. If CMS requests the submission of Package 3, the IVA Entity and issuer will have seven (7) calendar days to submit the additional records. Please note the seven (7) calendar day submission window includes Issuer SO sign off on the Package 3 submission.

1.6 Record Retention Policy

An issuer that offers RA covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable RA standards (which includes HHS-RADV) for each benefit year for at least ten (10) years, and must make those documents and records available upon request to HHS, the Office of Inspector General (OIG), the Comptroller General, or their designees for purposes of verification, investigation, audit or other review (See 45 C.F.R. § 153.620[b]).

1.7 Protected Health Information Security

The Health Insurance Portability and Accountability Act (HIPAA) Security Rule requires covered entities and their business associates to implement appropriate administrative, technical, and physical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information (PHI). The HIPAA Privacy Rule requires appropriate safeguards to protect the privacy of medical records and other PHI and limits the permissible uses and disclosures of PHI without patient authorization. The HIPAA Privacy and Security rules, which are found in 45 C.F.R. parts 160 and 164, apply to issuers and certain service providers of issuers, including IVA Entities, to the extent they qualify as covered entities or business associates under HIPAA. The Privacy Act of 1974 governs the collection, maintenance, and use of certain information about individuals that is personally identifiable information (PII) by agencies of the Federal government. The requirements of the Privacy Act extend to certain governmental contractors through contractual provisions, including the SVA Entity.

Section 2

HHS Risk Adjustment Data Validation Protocols
IVA Entity Selection

2 IVA Entity Selection

2.1 Purpose

The purpose of this section is to outline requirements and provide guidance for issuers and IVA Entities regarding the IVA Entity selection process.

2.2 IVA Entity Selection Participants

2.2.1 Issuers

Issuers in states where HHS is operating the RA program are required to engage an IVA Entity to perform an IVA for HHS-RADV. The issuer must document the IVA Entity's capability of performing an IVA and document that the IVA Entity, and its staff, are not subject to any conflicts of interest. CMS has defined conflicts of interest standards between an issuer and IVA Entity in Section 2.5.

The issuer must register in the Audit Tool and complete the IVA Entity Designation process within the Audit Tool. CMS will review and provide a final decision based on § 153.630(b)(1). See Section 2.2.3 (below) for further information regarding CMS's oversight methods and review of the IVA Entity selection.

2.2.2 IVA Entity

Any IVA Entity electing to participate in the 2017 benefit year HHS-RADV process must complete the IVA Entity Election Web Form and be registered for the applicable benefit year with CMS in order to be listed as an available IVA Entity in the Audit Tool. This will allow issuers to designate the IVA Entity for the 2017 benefit year HHS-RADV audit program.

The IVA Entity must provide an issuer with details regarding their technical capabilities, approach to performing the IVA and submitting its findings in the time frame specified by CMS, and information regarding its independence.

2.2.3 CMS

CMS monitors and reviews IVA Entity registration and election to participate within the Audit Tool by verifying their information against the OIG exclusions list.[6] CMS reviews the issuer's designation of an IVA Entity, along with the issuer's attestation verifying the IVA Entity and issuer are free of conflicts of interest (COI). CMS will either accept or reject the issuer's IVA Entity designation within the Audit Tool.

CMS also details the protocols that the IVA Entity follows as covered in Section 5. These protocols are used by the issuer to assess a potential IVA Entity's capability to conduct an IVA.

2.3 IVA Entity Requirements

Issuers have considerable autonomy in selecting their IVA Entity. In accordance with section 45 C.F.R. § 153.630(b)(2), (3), and (5). Issuers must ensure that the IVA Entity meets the following criteria:

- Is reasonably capable of performing the IVA and validating the accuracy of the RA data in accordance with CMS defined audit standards;

[6] This CMS check does not in any way reduce the issuer's separate obligation to confirm as part of the required conflict of interest review that no key individuals involved in supervising or performing the IVA have been excluded from working with either the Medicare or Medicaid program, are on the OIG exclusion list or, to its knowledge, are under investigation with respect to any HHS programs.

- Is reasonably free of COI for the entity and the individual working on the IVA, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question; and
- Employs medical coders to conduct the IVA who are certified and in good standing by a nationally recognized accrediting agency such as the AHIMA or the AAPC.

2.4 Timeline of IVA Entity Selection

For each benefit year, CMS instructs issuers and IVA Entities to begin preparing for the selection process, and communicates timing requirements via https://www.REGTAP.info/. Refer to https://www.REGTAP.info/ for the HHS-RADV timeline and corresponding deadlines for the applicable benefit year, or to Section 1.5: HHS-RADV Process Activities Timeline.

2.5 Criteria for Assessing IVA Entity Capabilities

The issuer is responsible for ensuring that the IVA Entity is reasonably capable of performing an IVA. IVA Entities may include organizations that perform independent reviews, assessments, validations, and analyses. They are expected to have expertise in medical diagnosis coding and other skills necessary to evaluate the validity of medical records. The issuer must retain documentation from the selection and review process that demonstrates the IVA Entity meets regulatory requirements. CMS may request documentation regarding the issuer's IVA Entity selection process and the IVA Entity's compliance with applicable requirements.

Each year, the issuer will complete and provide CMS with an attestation stating that they have used a documented process to ensure that there is no COI between the issuer and the IVA Entity. This attestation can be downloaded from the Audit Tool by the Issuer SO and must be signed by the issuer's chief executive officer (CEO), chief financial officer (CFO), or a person who is authorized to legally and financially bind the organization, for the 2017 benefit year HHS-RADV. The Issuer SO must then upload the signed COI Attestation to the Audit Tool. The IVA Entity must certify that there is an absence of COI, at both the organization and staff levels, and must provide signed documentation to the issuer.

In addition to a review of the COI Attestation provided by the issuer's CEO or CFO, CMS may gather information through external reporting and analysis of public and private data about any relationship between an issuer and the IVA Entity that may result in a potential COI.

The following section outlines requirements which should be used by issuers to evaluate the IVA Entity's potential conflicts as stated in the HHS Notice of Benefit and Payment Parameters for 2015 Final Rule.

Conflict of Interest (COI) Requirements:

- The IVA Entity certifies that there is an absence of a COI between the issuer and the IVA Entity.

- Neither the IVA Entity nor any member of its management team or data validation audit team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the issuer, such that the financial success of the issuer could be reasonably seen as materially affecting the financial success of the IVA Entity or management team or audit team member (or immediate family member) and the impartiality of the IVA process could reasonably be called into question, or such that the IVA Entity or management or audit team member (or immediate family member) could be seen as having the ability to influence the decision-making of the issuer. Immediate family is defined as a person's smallest family unit, consisting of the closest relatives, such as parents, siblings, and children.

- Neither the issuer nor any member of its management team (or any member of the

immediate family of such a member) may have any material financial or ownership interest in the IVA Entity, such that the financial success of the IVA Entity could be seen as materially affecting the financial success of the issuer or management team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called into question, or such that the issuer or management team member (or immediate family member) could be reasonably seen as having the ability to influence the decision making of the IVA Entity.

- Owners, directors, and officers of the issuer may not be owners, directors, or officers of the IVA Entity, and vice versa.
- Members of the data validation team of the IVA Entity may not be married to, in a domestic partnership with, or otherwise in the same immediate family as an owner, director, officer, or employee of the issuer.
- The IVA Entity may not have a role in establishing any relevant internal controls for the issuer related to RA or the IVA process or serve in any capacity as an advisor to the issuer regarding the RA process or IVA.
- The IVA Entity may not perform any SVA activities on behalf of CMS.

2.6 Additional Reasons for IVA Entity Exclusion

A potential IVA Entity must be excluded from conducting an IVA for any of the following reasons:

- The IVA Entity, its owners, or staff engaged to work on the IVA are listed on the HHS OIG Exclusions List;
- The IVA Entity has been declared ineligible to receive Federal contracts and is on the Office of Federal Contract Compliance Programs (OFCCP) list of federally debarred entities, as identified per the instructions; and/or
- The IVA Entity is listed on a State's OIG Exclusions List.

2.7 Required Documentation for IVA Entity Selection by an Issuer

Issuers are required to complete the HHS-RADV IVA Entity Designation and Maintenance Form within the Audit Tool regarding their designation of an IVA Entity. On the web form, the issuer will select from a dropdown list of available IVA Entities who have elected to participate for the applicable HHS-RADV benefit year and select the issuer HIOS IDs that will be represented by the IVA Entity. If the IVA Entity cannot be located from the dropdown list, issuers should contact the IVA Entity directly to ensure they have completed the HHS-RADV IVA Entity election web form for the current benefit year.

Additionally, the issuer will confirm compliance with the following criteria in the COI Attestation:

Table 2: Criteria Categories for IVA Entity Selection

1. Ensure IVA Entity is Reasonably Capable of Performing Risk Adjustment Data Validation and has Certified Medical Coders 45 C.F.R. § 153.630(b)(2), and (b)(5)-(8):	a) The designated IVA Entity is reasonably capable of the performing risk adjustment data validation in accordance with CMS defined audit standards under 45 C.F.R. § 153.630(b)(2) and (b)(5)-(8), and in accordance with HHS-RADV audit protocols.
	b) The designated IVA Entity has medical coders with relevant skills as demonstrated through certification after examination by a nationally recognized accrediting agency for medical coding, such as the AHIMA or the AAPC, in addition to relevant professional experience. A medical coder can have other certifications besides AHIMA or AAPC, but other certifications must meet the same standards. However, the IVA Entity cannot utilize coders who are only certified through Practice Management Institute (PMI) or a similar certifying entity.
	c) The IVA Entity must ensure that the coders are able to perform work on inpatient, outpatient, and/or professional records. If a coder is only certified for inpatient or outpatient coding, then the coder can only review files for the setting for which they are certified. The issuer will be providing medical records and claims on both inpatient and outpatient/professional encounters. The IVA Entity must have coders trained and certified for inpatient, outpatient, and professional settings.
2. Ensure IVA Entity is Free of Conflicts of Interest, IVA Entity is not excluded from Medicare or Medicaid and IVA Entity is not the Issuer's Third-Party Administrator (TPA):	a) The designated IVA Entity is reasonably free of conflicts, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question (refer to HHS-RADV Conflict of Interest Guidelines). The issuer attests they have performed a reasonable investigation into COI and they have obtained equivalent representation from the IVA Entity regarding conflicts of interest.
	b) No key individuals involved in supervising or performing the initial validation audit have been excluded from working with either the Medicare program or the Medicaid program, are on the Federal OIG exclusion list, or are under investigation with respect to any CMS program.
	c) The IVA Entity designated did not have a role in establishing any relevant internal controls for our issuer organization related to the HHS-RADV process or serves in any capacity as an advisor to our issuer organization regarding the IVA. Additionally, the nominated IVA Entity is not this issuer's TPA.
3. Ensure Performance of HHS-RADV Audit [45 C.F.R. § 153.630(b)(1), (2), and (4)]	a) The issuer of an RA covered plan engages one (1) or more independent auditors to perform the IVA of a sample of its RA data selected by CMS.
	b) The issuer ensures that the IVA Entity auditors are reasonably capable of performing the IVA according to the standards established by CMS and ensures that the audit is performed according to those standards.
	c) The issuer ensures validation of the accuracy of the RA data for a sample of enrollees selected by CMS.
	d) The issuer ensures that the IVA findings are submitted to CMS in a manner and timeframe specified by CMS.

In addition to the COI Attestation, the issuer should detail the scope or duties of the IVA Entity in a written agreement with the IVA Entity, and it must maintain a copy of the documentation that the IVA Entity submitted to CMS according to CMS regulations and guidance.

CMS will review the issuer's IVA Entity designation in the Audit Tool and either accept or reject the designation within the Audit Tool. CMS may reject a designation or exclude an IVA Entity based on the criteria above. In the event that CMS has rejected an issuer's designation or excluded an IVA Entity, the issuer must procure the services of a different IVA Entity that meets all applicable requirements. CMS will communicate to the issuer the outcome of the review in order to assist the issuer in selecting an eligible IVA Entity. Refer to https://www.REGTAP.info for the HHS-RADV timeline activities and corresponding deadlines for the applicable benefit year.

2.8 Implications of Non-Selection

An issuer of an RA covered plan must engage an independent auditor to perform an IVA of a sample of its RA data selected by CMS. An issuer is also required to provide CMS with the identity of the IVA Entity, and attest to the absence of conflicts of interest between the IVA Entity (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), in a time frame and manner to be specified by CMS. Please refer to https://www.REGTAP.info/ for HHS-RADV timeline activities for the applicable benefit year.

If an issuer of an RA covered plan fails to engage an IVA Entity, CMS will impose a default data validation charge and may take other action (as appropriate). This default charge is calculated based on the same methodology as the default charge to issuers for failure to establish an EDGE server or failure to provide CMS with access to the required data (see 45 C.F.R. §§ 153.630(b)(10) and 153.710).

Section 3

HHS Risk Adjustment Data Validation Protocols

Audit Tool Overview

3 Audit Tool Overview

3.1 Purpose

The HHS-RADV Audit Tool is a Salesforce tool built in accordance with CMS Technical Reference Architecture and CMS Information Security (IS) Acceptable Risk Safeguards (ARS)[7] to maintain and protect PHI and PII. The HHS-RADV Audit Tool will comprise externally facing web-based forms (or "Visualforce" pages) and a Salesforce Community area accessed with login credentials.

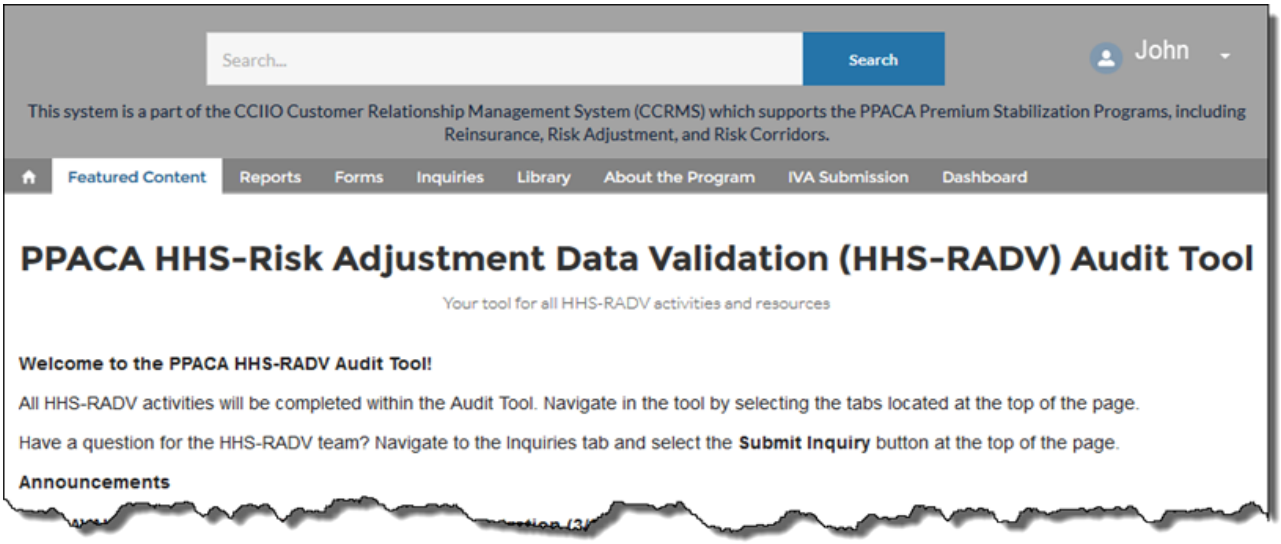
Reference Documentation

The Visualforce pages will allow issuers and IVA Entities to submit initial registration information related to participation, including identifying issuer and IVA Entity SOs, as necessary. Upon SO designation, Issuer SOs will receive a custom email with a brief introduction to Salesforce and instructions for registering and logging into the Salesforce Community area for the first time. Issuer SOs designate the selected IVA Entity within the Salesforce Community. Following designation by an issuer and CMS review, identified IVA Entity SOs will be given access to the Salesforce Community to complete audit tasks and upload the results of the IVA.

The Salesforce Community provides reporting and dashboard capabilities, hosts a library of programmatic information, and provides issuers and IVA Entities with technical assistance. It allows for the processing of stakeholder inquiries from issuers and IVA Entities, disseminates email messages to issuers and IVA Entities, and provides a secure environment through use of multi-factor authentication and adherence to CMS security protocols.

The Audit Tool will display announcements that may be related to RADV program information on the "Featured Content" tab.

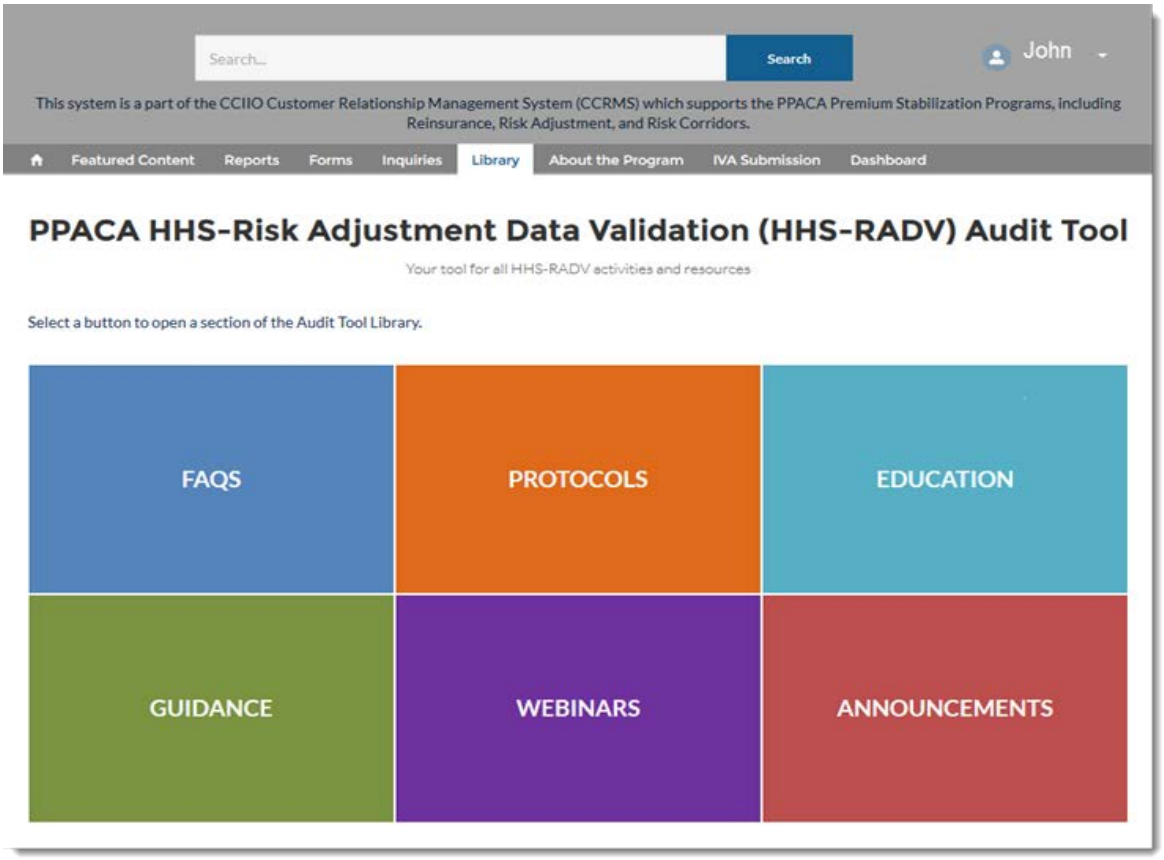
Featured Content Tab in the Audit Tool



[7] CMS' Information Security and Privacy Library can be found at: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html

The Audit Tool contains a Library tab that includes six (6) sections where various HHS-RADV program materials are available. These sections include Announcements, Education, FAQs, Guidance, Protocols, and Webinars.

Library Tab in the Audit Tool



The SVA Entity will perform the SVA within the Audit Tool, including producing error rates to be provided to issuers and CMS.

The following e-mail address will be utilized for all HHS-RADV communications: CCIIOACARADataValidation@cms.hhs.gov. Users will receive an auto-generated confirmation message from this address upon submission of their inquiry with an assigned case number.

Specific instructions on the functionality of the Audit Tool are provided in user guides located within the library of the audit tool, and are available after logging in here:

https://ccrms-rari.force.com/HHSRADVAuditTool/ .

Section 4

HHS Risk Adjustment Data Validation Protocols Sampling

4 Sampling

4.1 Purpose

CMS will select a sample of 200 enrollees for each issuer[8] participating in the 2017 benefit year HHS-RADV. This process will help ensure that the HHS-RADV process reviews an adequate sample of enrollees for each issuer so that estimated risk score errors will be statistically sound and the sample will adequately cover applicable subpopulations. The following four (4) major sections describe the main sampling procedures in greater detail:

- Sample Design (Section 4.2): explains the data used to make stratified sampling design assumptions, population assumptions, and other error rate and variance assumptions.
- Sample Size (Section 4.3): provides the rationale for selecting the sample size of 200 and discussion of precision analysis.
- Future Years' Sample Size Refinement (Section 4.4): discusses how the initial year assumptions may be updated in future years once there is concrete data available.
- Review of Sampling Reports (Section 4.5): explains how CMS will verify the risk scores of an issuer's sample.

4.2 Sample Design

To design the sampling approach for the initial years of HHS-RADV, CMS applied proxy sampling assumptions for error rates and population statistics as described in the following subsections:

- Stratification – discusses how and why CMS stratified the sample
- Proxy Sampling Frame – discusses how CMS initially created an assumed average issuer population
- Actual Population – discusses what assumptions will change once CMS has actual issuer populations and RADV payment years' data.

4.2.1 Stratification

To account for variation in risk scores, each issuer population is divided into mutually exclusive groups or "strata" based on recorded risk scores, age, and presence of HCCs. This achieves sampling efficiencies by dividing the issuer population into homogeneous groups. Statistical theory indicates that for a given level of confidence and precision, stratification of a population into homogeneous groups (or strata) results in a smaller sample size, relative to a simple random sample for which no stratification is performed. Based on the available data, CMS will calculate the sample size for a given benefit year by dividing the relevant population into a number of strata, representing different demographic and risk score bands.

Each issuer's enrollee population will be grouped into 10 strata based on presence of HCCs, risk adjustment age model, and risk level. Table 3 provides a listing of assigned strata by risk level for each age group.

[8] Lower sample sizes may be calculated for issuers with a small number of enrollees. See Section 4.3.3

Strata 1 – 3 represent low-, medium-, and high-risk adults with the presence of at least one (1) HCC.

Strata 4 – 6 represent low-, medium-, and high-risk children with the presence of at least one (1) HCC.

Strata 7 – 9 represent low-, medium-, and high-risk infants with the presence of at least one (1) HCC.

Stratum 10 consists of the No-HCC population and is not further stratified by age or risk level because it is assumed to have a uniformly low error rate.

Table 3: Stratification Mapping

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

CMS will use this simple age and risk score stratification for at least the initial years of HHS-RADV, and may consider other sampling strategies in the future as experience with this population increases.

4.2.2 Proxy Issuer Population

This section discusses the processes and data used to develop estimated risk scores for an assumed issuer population to determine an acceptable sample size.

CMS originally used 2014 summary data from the EDGE server as a proxy population for the sample design. The EDGE server summary data included the stratified populations of each issuer. CMS performed subsequent sample size analyses using the 2015 and 2016 benefit years EDGE data to assess precision for small, medium, and large issuers. The sample sizes were approximately in-line with the original proxy populations. For additional detail on how CMS determines an acceptable sample size for issuer populations see Section 4.3 – Sample Size.

4.2.3 No-HCC Assumptions

CMS will use the lowest error rate and variance across all HCC strata as the error rate and variance assumption for the No-HCC stratum. A 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 that the No-HCC population will make up the vast majority of the expected enrollee population (82% of the total population for the 2016 benefit year), 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 HHS-RADV process). Consequently, there is some risk that CMS may be understating the error rate, variance, and risk score assumptions for the No-HCC stratum.

CMS performed a sensitivity analysis with the No-HCC population establishing more conservative assumptions for the risk score, error rate, and variance. The resulting sampling precision remained within an acceptable range (<10 percent at a two (2)-sided 95 percent confidence level), even under the more conservative assumptions.

4.2.4 2017 Sampling Assumptions

The sampling assumptions used for the 2017 benefit year HHS-RADV are held constant from the 2016 benefit year and are expected to approximate the average issuer size and the issuer population distributions for the HCC versus no-HCC groups, and achieve the targeted precision levels.

4.3 Sample Size

45 C.F.R. § 153.350(a) requires that a statistically valid sample of enrollees from each issuer be validated every year. For the initial years of HHS-RADV, as well as the 2017 benefit year, the enrollee sample selected for the IVA will include 200 enrollees from each issuer to estimate a risk score error rate related to RA. The assumptions discussed above in Section 4.2 support the sample size of 200 enrollees per issuer. Note that a lower sample size may be calculated for issuers with a small number of enrollees by using a finite population correction factor (discussed in greater detail in Section 4.3.3 below).

The sample of 200 enrollees is selected from all state risk pool markets in which the issuer had enrollment in RA covered plans for the benefit year. However, as finalized in the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule, beginning with the 2017 benefit year HHS-RADV, the IVA sample will only include enrollees from state risk pool markets in which there was more than one (1) issuer.

4.3.1 Precision and Confidence Level

CMS utilizes an enrollee sample size to target a 10 percent relative sampling precision (or margin of error) at a two-sided 95 percent confidence level (CL). The use of a 10 percent targeted precision was selected based on a survey of guidance from the Office of Management and Budget (OMB), the Internal Revenue Service (IRS), and the CMS-developed Payment Error Rate Measurement (PERM) program.[9] This target will be re-evaluated in subsequent years based on actual results.

HHS selected a sample size of up to 200 enrollees to achieve the targeted precision threshold based on the assumptions documented above in Section 4.2.

Neyman Allocation

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 (i.e., more variable strata should be sampled more intensely).

To calculate the sample size for each stratum, consider the following notations:

Variable	Description
n	Overall sample size
H	Number of strata
N_h	Population size of the h^{th} stratum
S_h	Standard deviation of risk score error amount for the h^{th} stratum

The sample size for each stratum is calculated from:

$$n_h = n \times \frac{N_h S_h}{\sum_{h=1}^{H} N_h S_h}$$

On average, two-thirds of the total sample size will be allocated to the HCC Strata [Strata one (1) through nine (9)] using the Neyman optimal allocation method, with the remaining one-third assigned to the "No HCC" Strata ten (10). Based on population characteristics for some issuers, there could be instances in which the original HCC target sample size for a strata - determined using the Neyman optimal allocation method - is larger than the actual sample size allocated to that strata. This situation could occur if an issuer has a stratum with small number enrollees with highly variable risk scores. In these cases, the Neyman allocation weight for that stratum could be relatively high, leading to a Neyman allocation-calculated sample size that exceeds the total number of enrollees in that stratum. If this occurs, the actual sample size must be used in place of the target sample size for that stratum, but as a result, the total sample size will not meet the minimum number of enrollees required to achieve the target precision threshold referenced above. In these instances, an incremental factor equal to one (1) will be added to the total target HCC sample size and the Neyman allocation for stratum one (1) through nine (9) will be re-executed. This will allow for an increase in the target sample size of all the strata, making it possible to meet the minimum total sample size required, even if the actual sample size for

[9] For additional information on the sampling guidance surveyed by CMS for this purpose, see section 4.3.1 in the 2016 Benefit Year Protocols PPACA HHS-Operated Risk Adjustment Data Validation Version 14.00.00 (October 20, 2017), available at: https://www.regtap.info/reg_librarye.php?i=2104.

a particular strata is used instead of the target sample size. This process continues until the target sample size is reached or exceeded across Strata one (1) through nine (9), or until the number of iterations reaches 100. If a sample size equal to or larger than the original HCC target sample size is not generated after 100 iterations, then the selected sample will be used. This looping process is described in Section 4.5.3 (Step 8).

4.3.2 Alternate Sample Sizes

While a sample size of 200 is adequate, based on the assumptions presented above, a smaller sample size will be calculated for issuers with a small enrollee population. In such cases, a Finite Population Correction (FPC) will be used to adjust the sample size:[10]

$$FPC = \frac{N - n}{N}$$

An FPC is used when sampling without replacement from a finite population and the sample size, n, is significant in comparison with the population size, N, so that n/N > 0.05 (i.e., more than five [5] percent of the population is sampled). Consequently, any issuer with an enrollee population size less than 4,000 (as 200 / 4,000 = 0.05) will use an FPC to adjust the sample size, by multiplying the original sample size by its FPC factor. Note that the calculated sample size should be rounded up to the nearest whole number. As an example, assume an issuer has a population of 1,400 enrollees; the FPC would be calculated and applied to adjust the sample size down from 200 as follows:

$$\text{FPC} = \frac{1400 - 200}{1400} = 0.8571$$

This issuer's sample size will now be 172, rather than 200 (0.8571 * 200 = 171.43). If the application of an FPC results in a sample size smaller than 50 enrollees, that issuer should sample a minimum of 50 enrollees. In rare cases where an issuer has less than 50 enrollees in its population, all enrollees in the population will be reviewed.

4.3.3 SVA Subsample Sizes

In addition to the IVA sample size of 200, there will be multiple incremental samples used for the purposes of the SVA process. The SVA sample sizes will consist of an initial sample of 12 enrollees and expand if necessary to include 24, 50, 100, and beginning for 2017 benefit year HHS-RADV, to the full IVA sample of 200. Since pairwise testing will be performed on all SVA initial subsamples, comparing them to their corresponding enrollees in the IVA sample of 200 during the sample review portion of the HHS-RADV process (discussed in Section 5 below), the SVA subsamples must be large enough to validate testing results. In cases where pairwise means testing of the SVA subsample of 12 enrollees fails, CMS will increase the SVA subsample by 12 enrollees for a total of 24 enrollees.

If the pairwise means testing continues to fail, the SVA subsample may be expanded up to a total of 200 enrollees, so that the final SVA results which would replace the IVA results would be based on a sample large enough to extrapolate. A sample size of 200 for SVA testing is approximated by the precision analysis mentioned above. Issuers that have to apply an FPC for the IVA sample size will use the initial subsample size of 12 and an expanded SVA subsample size that may be equivalent to the IVA sample size (depending on the results of the pairwise means testing).

[10] The Finite Population Correction formula can be found in Section 2.6: *Cochran, William G., Sampling Techniques, third edition, John Wiley & Sons*, 1977.

4.4 Future Sample Size Refinement

CMS will assess summary-level data and RADV results from prior years to support refinement of sampling assumptions needed for future years. Changes to the stratification and/or size and allocation of the sample among each stratum may be refined, based on average issuer HCC failure rate distributions, once more data becomes available.

CMS will obtain snapshots of issuer populations throughout the first few RADV payment adjustment years and may refine the sampling assumptions and strategy by using a combination of the best available data and the initial years' assumptions. As HHS-RADV progresses, CMS will gain experience that may improve the reliability of the error estimates by more effectively estimating areas at high-risk for error. CMS expects to improve upon the sampling process as follows:

- Preliminary results that will be available from the prior year(s) HHS-RADV process will be used for expected error rates and variance assumptions;
- Actual risk score distributions from the prior or current year will be used in place of data from past years; and
- Actual issuer populations from the prior or current year will be used in place of assumed number of enrollees and issuers.

Based on these factors, CMS may adjust the sample size requirements for future 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 enrollee risk scores. CMS is also considering varying the sample sizes based on actual data submitted for RA for different issuer populations, i.e. "large," "medium," and "small." All issuers will fall into one (1) of these three (3) sizes based on their enrollee count, and sample sizes may be adjusted depending on the average issuer size. The sampling design also may consist of a minimum and maximum sample size per stratum for each average issuer (large, medium, and small) to follow when selecting the sample. Any changes made to the IVA design and sample size may affect the SVA subsample's design and size.

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

4.5 Review of Reports

The following sections outline the suite of reports used to determine the issuer's RADV population. In order to determine the RADV population, one (1) RA report (the RADVPS Report) and multiple RADV sampling reports are utilized. It is critical that issuers review their RA report and RADV sampling reports to verify and attest to the accuracy of the data, as well as to report any discrepancies to CMS (discussed in greater detail in Section 4.5.4 below). Additionally, Appendix B provides an overview of EDGE server RADV Reports resources.

4.5.1 RA Report - RADV Population Summary Statistics (RADVPS) Report

The RADVPS report is generated during the RA report run. Issuers are encouraged to regularly review their RADVPS Report prior to the EDGE server data submission deadline by executing local commands on their EDGE server to generate the report. If an issuer identifies data that was inaccurately submitted to their EDGE server prior to the EDGE server data submission deadline, then the issuer should update the EDGE server with the correct information.

The RADVPS Report contains population statistics for the issuer's total population separated into sub-categories, or "strata," based on enrollee age (infant, child, adult) and risk score (low,

medium, high). The RADVPS Report provides issuer level data, including total enrollees and plans, number of enrollees in each risk pool market (individual, small group, catastrophic), strata-level data (including number of enrollees in each of the specific stratum), and summary statistics for each of the specific stratum, including mean (average), minimum (min), and maximum (max) risk scores for enrollees in the stratum. Issuers should review this report to ensure that the data contained in it is accurate, as compared to their knowledge of their enrolled populations, and that the stratification is representative of their total population.

If an issue is identified in the RADVPS Report generated by the RA final report command, issuers must communicate that issue to CMS through the RA formal discrepancy reporting process (see Section 4.5.4 for additional detail). However, issues related to data incorrectly submitted by an issuer to their EDGE server is not considered a discrepancy on the RADVPS Report and should not be filed as a RA formal discrepancy.

It is essential that issuers review the RADVPS Report because the sample size will be applied to the entire population. For more detailed information about the RADVPS Report, see the ***Job Aid for Validation of RADVPS Reports (4/20/18),*** available in the REGTAP Library at the following link *https://www.regtap.info/reg_librarye.php?i=2039*

4.5.2 RADV Report - RADV Population Summary Statistics Final (RADVPSF) Report

The RADVPSF Report is a new RADV sampling report that will be made available beginning with the 2017 benefit year HHS-RADV process. The RADVPSF Report has the same data elements as the RADVPS Report (as listed above), but is generated by the RADV Report command after the RA transfer calculation and the Issuer Reference Table is populated with risk pool markets included in the RADV sampling logic (RADV population). The new report removes markets in which the issuer is the only issuer in that risk pool market within a state, limiting the report to risk pool markets that are included in the RADV population.

In the event a lone issuer is in a risk pool market in a state in a benefit year, then that risk pool market will be excluded from RA payments and charges, and also excluded from HHS-RADV for that benefit year. The RADVPSF report should be utilized when reviewing the RADV population as the RADVPS Report contains the total population.

4.5.3 RADV Report - RADV IVA Statistics (RADVIVAS) Report

CMS selects a sample of up to 200 enrollees from eligible RA issuers for HHS-RADV. The RADVIVAS Report contains a summary of the issuer's sample at the stratum level, using the same format and data elements as the RADVPS and RADVPSF Reports. For more detailed information about the RADVIVAS Report, see the ***Job Aid for Validation of RADVIVAS Reports (5/21/18),*** available in the REGTAP Library at the following link https://www.regtap.info/reg_librarye.php?i=2552

The RADVIVAS Report contains only the information on the sampled enrollees, whereas the RADVPS Report contains information on the issuer's entire population, and the RADVPSF report contains information on the issuer's population only in the risk pool markets included in RADV. Issuers are able to validate the IVA sample generated by CMS, based on the RADVPSF Report, by following the 10 steps outlined in the section below. With these steps, issuers can confirm that the HHS-RADV process has selected a statistically valid sample size of enrollees that is representative of the issuer's RADV population, including the expected number of enrollees assigned to each of the ten (10) stratum. The calculation steps are as follows:

Step 1: Calculate Risk Score for Each Enrollee

The issuer should calculate the risk score for each enrollee in their RADV population:

The enrollment period-level risk score from the risk score process will be weighted by member months to generate one (1) average risk score for each enrollee, across all the enrollee's plans, within the issuer's enrollee population. The formula below is used to calculate the weighted risk score.

$$\overline{rs} = \frac{\sum_i M_{mi} * RS_i}{\sum_i M_{mi}}$$

- $\overline{rs}$ is the weighted average risk score
- M_{mi} is the member month (months in the enrollment period)
- RS_i is the enrollee level risk score for that enrollment period

- The risk score used should include demographic factors, enrollment duration factors, HCC factors, and Cost-sharing Reduction (CSR) factors (if applicable). Note that the risk scores on the Risk Adjustment Risk Score Details (RARSD) Report cannot be used in this step, since they are calculated at the rating area level. This step requires the enrollee risk scores at the issuer level.

Step 2: Determine IVA Sample Size

The issuer can determine the IVA target sample size by using the total number of enrollees from the RADVPSF Report and applying the following criteria:

- *If the issuer population is zero (0) to 50 enrollees, the sample size will be all enrollees;*
- *If the issuer population is greater than or equal to 4,000, a sample size of 200 enrollees is used;*
- *If the issuer population is greater than 50 and less than 4,000, then the larger of 50 or the result of the FPC is used. The FPC formula is defined as:*

$$Sample\_Size = FPC * n = \left(\frac{N-n}{N}\right) * n$$

- N is the issuer's population size; and
- n is the default sample size (200).

Note: The calculated value should be rounded up to the next whole number. For example, 183.2 would be rounded to 184.

Step 3: Calculate the HCC Target Sample Size (Strata 1-9)

The HCC target sample size for strata one (1) through nine (9) is two-thirds of the total IVA sample size calculated in Step 2. The target sample size for strata one (1) through nine (9) can be calculated by using the following formula:

$$HCC\ Target\ Sample\ Size\ for\ Strata\ 1-9\ = Target\ IVA\ Sample\ Size * (\frac{2}{3})$$

Note: The calculated value should be rounded up to the next whole number. For example, 133.3 would be rounded to 134.

Step 4: Execute Neyman Formula for Strata one (1) through nine (9)

The issuer should execute the Neyman formula for strata one (1) through nine (9) using the HCC target sample size. Use the following Neyman formula to calculate how many enrollees should be assigned to each stratum from 1 to 9 (n_h):

$$n_h = (Target\ HCC\ Sample + i) * \frac{N_h S_h}{\sum_{h=1}^{H} N_h S_h}$$

The following are the parameter definitions:

- *i* is the +1 incremental value when re-executing the Neyman formula, e.g., 0, 1,2,3,4.
- n_h is the sample size (# of enrollees) of each individual stratum *h* that should be calculated.
- N_h is the issuer's population size (# of enrollees) in each individual stratum *h*.
- H is the total number of strata (1-9) excluding the No-HCC stratum.
- S_h represents the standard deviation of risk score error for the h^{th} stratum. The standard deviation of risk score error is the square root of the variance of risk score error (Estimated variance for initial years of HHS-RADV). This is the HCC + CSR and Demographic factor only risk score. See definition of this variable below.

Note: The calculated value should be rounded to the nearest whole number. For example, 133.3 will be rounded to 133 and 133.5 will be rounded to 134.

Step 5: Calculate the Standard Deviation of Risk Score Error

The standard deviation (S_h) of risk score error is calculated as:

$$S_h = \sqrt{Var} \times Inflation\ factor\ \times \overline{RS}$$

Where *Var* is the variance of net error (from the table shown below), *Inflation factor* is a 3x factor, and $\overline{RS}$ is the mean risk score for stratum *h*.

The variance of net error is shown in the following table. CMS derived the variance of error solely for purposes of developing samples and error estimates for HHS-RADV using data that included Medicare Advantage RADV error rates and MarketScan data used to calibrate the HHS-operated risk adjustment models.

Risk Stratum	Variance of Error
Low	0.095
Medium	0.201
High	0.654

While CMS does not anticipate the expected variance of net error to be uniform across all age groups, age-level data to determine variance will not be available for the initial years. Thus, the values above are merely an assumption for the initial years of HHS-RADV. Adult, Child, and Infant age groups will utilize the same variance of net error rates in the calculation of standard deviation of risk score error for their respective low, medium, and high-risk strata, while the lowest variance of net error is assumed for the No HCC stratum.

An example calculation of Issuer ABCDE's Adult Low Risk stratum standard deviation, with a mean risk score of 4.500 is as follows:

$$Sh_1 = \sqrt{9.5\%} \times 3 \times 4.500$$
$$Sh_1 \approx 4.161$$

An inflation factor of 3x, a conservative base standard deviation assumption, is used for risk score estimates during the program's initial years.

Step 6: Calculate the Number of IVA Sampled Enrollees to Assign to Each Stratum

The issuer should then determine the number of enrollees to include in each stratum based on the steps below:

- If population of the stratum is 1, then sample size = 1
- If population of the stratum is 2, then sample size = 2
- If population of the stratum is > 2, use Neyman to calculate stratum sample size and:
  - If Neyman output is < 2, then use 2
  - If Neyman output is < or = to the population, then use Neyman output
  - If Neyman output is > total population of the stratum, use the population of the stratum.

Step 7: Calculate Total Actual Sample Size for Strata one (1) through nine (9)

The issuer should sum the sample size for each stratum (one [1] through nine [9]) to confirm if a large enough sample size was selected for the HCC strata (e.g., sample size in Strata one [1] through nine [9] should be at least 2/3 x Target Sample Size).

Table four (4) below contains an example of the resulting sample size per stratum. Note that the issuer population is greater than 4,000, so the IVA sample size will be 200 enrollees. The HCC target sample size is two-thirds of the IVA target sample size, so the HCC target sample size is 134.

Table 4: Example of IVA Sample

Age	Risk Level	Stratum	Population (N)	Calculated # of IVA Enrollees
Adult	Low	1	1200	15
	Med	2	300	32
	High	3	100	60
Total Adult			**1,600**	**107**
	Low	4	200	5
Child	Med	5	20	4
	High	6	10	5
Total Child			**230**	**14**
	Low	7	90	5
Infant	Med	8	15	4
	High	9	5	4
Total Infant			**110**	**13**
No HCCs	Low (assumed)	10	9,560	66
Total IVA (1-9)			**1,940**	**134**
Total IVA (1-10)			**11,500**	**200**

Step 8: Compare Actual Sample Size to Original Target Sample Size for Strata 1-9

Decision Point: The issuer should determine if the actual sample selected is smaller, larger, or equal to the original HCC target sample size. If the original HCC target sample size is reached, skip Step nine (9) and go on to Step 10. If the actual HCC sample selected is

smaller than the original HCC target sample, follow the instructions in Step nine (9) to re-execute the Neyman Allocation until the original HCC target sample size is reached, or you have completed 100 iterations.

Step 9: Re-Execute Neyman Allocation for Strata 1-9 if Sample Selected is less than the Original Target for Strata one (1) through nine (9)

The issuer should add one (1) to the target HCC sample size and re-execute the Neyman allocation for stratum one (1) through nine (9) if the actual sample size selected is less than the original HCC target sample size.

If a sample size equal to or larger than the original HCC target sample size is not generated after 100 iterations, then the selected sample will be used.

Step 10: Calculate the Number of IVA Sample Enrollees to Assign to Stratum 10

The issuer should determine the number of enrollees to assign to stratum ten (10).
For stratum ten (10), the issuer should use the following formula to calculate how many enrollees should be assigned (n_{10}):

$$n_{10} = (Target\ Sample\ Size) - (Actual\ Sample\ Size\ for\ strata\ 1\ through\ 9)$$

$$n_{10} = (190) - (127)$$

$$n_{10} = 63$$

Note: If n_{10} > No-HCC population, then use the population.

4.5.4 RADV Sampling Reports

Once CMS transmits the HHS-RADV command to the EDGE servers to perform the HHS-RADV sampling calculations and the issuer runs the command, the sample reports are then generated and sent to CMS. CMS reviews the sample reports to determine if the sample is representative of the issuer's population by comparing the RADVIVAS Report to the RADVPSF Report. If the sample is approved by CMS, the final command to generate the HHS-RADV sampling reports is sent to the EDGE servers and the HHS-RADV Reports including the IVA sample are released to issuers via their EDGE servers and accessible to IVA Entities via the Audit Tool. Issuers should review their HHS-RADV sampling reports to ensure they are representative of the issuer's population in the risk pool markets included in HHS-RADV.

The HHS-RADV sampling reports consists of six (6) reports generated by the issuer's EDGE server:

- **RADV Population Summary Statistics Final (RADVPSF) Report**
  - Contains population statistics for an issuer's population included in RADV broken into sub-categories, known as "strata," which are based on enrollee age (infant, child, adult) and risk score (low, medium, high).
  - Contains only enrollees in a risk pool market where a risk adjustment transfer occurs, and excludes enrollees in a risk pool market if the issuer is the only issuer in that risk pool market.
- **RADV IVA Statistics (RADVIVAS) Report**
  - Contains the sample statistics calculated at the strata-level for the enrollees selected for the RADV IVA sample.
  - Similar in layout to the RADVPS and RADVPSF Reports, but limited to the enrollees selected for the IVA sample.
- **RADV Detailed Enrollee (RADVDE) Report**
  - Identifies the issuer's enrollees selected for the RADV IVA sample.
  - Contains enrollee-level data for each enrollee selected for the RADV IVA

sample, such as the sampled enrollee's risk score, demographic, and health status information.

- **RADV Enrollee Extract (RADVEE) Report**
  - Contains all active enrollment data that was submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Medical Claims Extract (RADVMCE) Report**
  - Contains all active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Supplemental Extract (RADVSE) Report**
  - Contains all active supplemental records for active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.

For further information about the RADV sampling reports, see the **Interface Control Document - Risk Adjustment and Reinsurance Addendum Version 05.00.19 (8/3/18)**, the **EDGE Server XML and XSD Contents Job Aid (8/3/18)**, the **Job Aid for Validation of RADVPS Reports (4/20/18)**, the **Job Aid for Validation of RADVPSF Report (5/21/18)**, and the **Job Aid for Validation of RADVIVAS Reports (5/21/18)** the available in the REGTAP Library.

4.5.5 Sampling Discrepancy Reporting

Once CMS has notified issuers that the RADVPS report and RADV sampling reports are available for review, the attestation and discrepancy reporting process begins. Issuers must review the reports and either attest to the accuracy of the reports or qualify that attestation by submitting a discrepancy. If issuers identify a discrepancy between the data they believe should be present and what is reflected in their RADVPS report or RADV sampling reports, they should qualify their attestation with a discrepancy.

More specifically, if an issuer identifies an issue with the RADVPS report or any of the RADV sampling reports, they may file a discrepancy with CMS using the appropriate discrepancy reporting process as outlined in the Table Five (5) below, which depicts the reports included in each report run (RA versus RADV) and the process for reporting discrepancies for each report. Both the RA Report discrepancies and RADV Sampling Discrepancies must be reported within fifteen (15) calendar days. Once the fifteen (15) calendar day discrepancy window has closed, the population statistics are not subject to further dispute or appeals. While these reporting windows may overlap, there are two (2) separate processes.

Table 5: HHS-RADV Reports and Discrepancy Reporting Process

Report Run	Report Name	Discrepancy Reporting Process
RA Report	RADVPS	If an issuer identifies an issue with the RADVPS report, they may file a discrepancy with CMS using the formal RA discrepancy reporting process. The discrepancy must be submitted using the separate EDGE Attestation and Discrepancy Reporting web form. Note: The formal EDGE discrepancy reporting period is 15 days and will generally open ahead of the RADV discrepancy reporting period.
RADV Sampling Reports	RADVPSF RADVIVAS RADVDE RADVEE RADVMCE RADVSE	If an issuer identifies an issue with any of the HHS-RADV sampling reports, they may file a discrepancy with CMS during the HHS-RADV discrepancy reporting window. The issuer may submit the discrepancy in the HHS-RADV Audit Tool. Note: The discrepancy reporting window is 15 days beginning the date the final RADV command is pushed to the EDGE servers.

Section 5

HHS Risk Adjustment Data Validation Protocols

IVA and SVA Test Procedures and Reporting Requirements for CMS Risk Adjustment Data Validation

5 IVA and SVA Test Procedures and Reporting Requirements

5.1 Purpose

Section five (5) provides the validation items, testing procedures, and reporting requirements to be performed by the IVA Entities and SVA Entity to validate D&E and health status information used in the RA process, as well as the issuer's enrollee-level risk score calculation. CMS has selected data elements required for IVA Entity and SVA Entity validation based on their impact on risk score calculations and RA payment transfer calculations.

IVA Entities will document the validation results of these data elements and submit the results to CMS using an eXtensible Markup Language (XML) file format with additional supporting documents including workpapers, mapping documents, screenshots, and medical records.

The following sections of this document, "*IVA Entity Audit Results Submission XML"* is referring to the XML file that will be submitted containing the IVA findings.

Some data elements from D&E Data Validation, such as "Premium Amount," are not used in the enrollee risk score calculation, but are used during RA payment transfer calculations, and are therefore subject to validation.

Table 6: Section 5 Sub-Section Table of Contents

Audit Phase (if applicable)	Description	Section Reference
N/A – General Guidance	HHS-RADV Documentation Requirements	Section 5.2
Phase 1	Create Mapping Documentation (Issuer)	Section 5.3
Phase 2	Review & Confirm Mapping	Section 5.4
Phase 3	Demographic and Enrollment Data Validation	Section 5.5
Phase 4	Health Status Data Validation	Section 5.6
Phase 5	Record Validation Results	Section 5.7

Section 5 can be broken into two (2) key subject-matter areas:

1. HHS-RADV Documentation Requirements

    - Documentation requirements including mapping documentation, source system documentation, workpapers, and medical records.

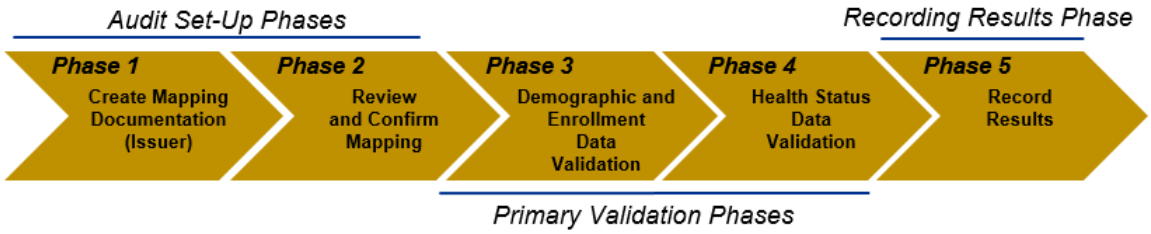
2. Five (5) Audit Execution Phases

The five (5) audit specific phases of HHS-RADV consist of:

- Two (2) prerequisite phases specific to mapping documentation creation, retrieval, and review;

- Two (2) primary validation phases of the audit process; and
- One (1) final phase of recording results. See Figure 2 below.

Figure 2: HHS-RADV IVA/SVA Audit Execution Phases



The initial step of the audit process requires issuers to create documentation, or gather existing documentation, that maps issuer source system data to EDGE server data submissions (Phase one [1]) – Section 5.3). Issuers are required to document mapping evidence for D&E data elements. Issuers and IVA Entities must then review and confirm the accuracy of the mapping evidence (Phase two [2] – Section 5.4). This mapping documentation will be used in the review and validation of D&E data elements (Phase three [3] – Section 5.5).

After gaining an understanding of issuer source systems and data submission methods, the D&E Data Validation (Phase three [3] – Section 5.5) begins. In this phase, D&E data elements for a subsample of enrollees from the IVA sample are validated against issuer source systems. In Phase three (3), issuers must also link the masked Unique Enrollee IDs from the EDGE server in the IVA sample to the actual issuer member IDs and enrollee first and last names. Next, in Health Status Data Validation (Phase four [4] – Section 5.6), medical records are matched to the enrollees in the IVA sample using the unique enrollee ID linked to member ID and member name in Phase three (3), and valid diagnosis codes are abstracted. In the final audit phase (Phase five [5] – Section 5.7), audit results are entered into the *IVA Entity Audit Results Submission XML*.

5.1.1 Audit Timing Considerations

CMS recognizes the rigorous documentation requirements of the audit process, specifically in relation to the time necessary to procure screenshot documentation and medical records from providers. While CMS does not require specific milestones to be met within the IVA execution window (apart from submission deadlines), general guidance regarding order of audit operations is detailed below:

- D&E Data Validation is NOT required to be completed prior to Heath Status Data Validation.

- If a medical record linked to a Non-EDGE claim (NEC) is provided as part of the IVA, the claim should be validated prior to review of the associated medical record utilizing a screenshot with mapping documentation. This will be discussed in Section

5.1.2 Issuer and IVA Entity Correspondence

During D&E Data Validation and Health Status Data Validation (Phases three [3] and four [4]), IVA Entities will review and validate documentation provided by the issuer in order to validate the accuracy of issuer-submitted EDGE server data.

Throughout the course of the validation process, IVA Entity reviewers may encounter documentation, processes, or source information which may be unclear or appear to reflect an error when compared to the values in the EDGE server.

If an error or issue is identified during the course of the validation process, issuers and IVA Entities are encouraged to communicate about the validity of the finding. The IVA Entity is encouraged to interact with the issuer when potential errors have been identified, and the issuer is encouraged to present evidence which mitigates the findings.

Additional documentation generated for these purposes must always be documented in workpapers and submitted along with the audit results. Refer to Section 5.2 for additional detail on screenshot and workpaper requirements.

5.2 HHS-RADV Documentation Requirements

Audit documentation is a critical component of a successful audit program. Clear and concise audit documentation allows the SVA Entity to effectively evaluate the practices performed and results determined by the IVA Entity, and therefore increases consistency in results.

During the IVA process, the IVA Entity will review the supporting audit documentation for the sampled enrollees to validate the issuer's EDGE server data, as well as document their own audit validation methods and findings. The four (4) key documentation types are listed below. These are defined and discussed in this section and will be referenced later in the applicable validation phases. The key documentation types are:

- Mapping Documentation
- Source System Documentation (Screenshots)
- Audit Workpapers
- Medical Record Documentation

5.2.1 Mapping Documentation

Issuers are required to provide IVA Entities with a set of documents that map the issuer's source system data to EDGE server data submissions. Often, data from the issuer's source systems is transformed to comply with EDGE server data submission business rules. This required mapping documentation allows both the IVA Entity and the SVA Entity to gain an understanding of the path of data from issuer source systems into the EDGE server.

CMS requires that mapping documentation be captured for D&E Data Elements and NEC. Mapping documentation created by issuers for IVA Entities must be identified and recorded in the *IVA Entity Audit Results Submission XML* and submitted during the IVA Data Submission process. The mapping documents must be clear and legible for the SVA Entity's comprehension or may result in a data element validation error.

CMS requirements for issuer source system mapping documentation and corresponding data validation activities are detailed within Section 5.3.

5.2.2 Source System Documentation (Screenshots)

IVA Entities must work with issuers to obtain evidence from issuer systems that include the D&E data for the selected enrollees in the issuer's sample, as well as for NEC data

validation. This evidence is expected to be in the form of screenshots of the actual data in the issuer's source system(s). In order to validate the required D&E data elements, screenshots from various source systems may be necessary, including membership or enrollment, premium billing, and claims adjudication systems.

Source documentation requirements are defined in Table Seven (7), below.

Table 7: Source Documentation

Source documentation is expected to:
• Capture all required HHS-RADV data elements. o *The 11 required D&E data elements are identified in Section 5.3.*
• Be in the form of screenshots of the actual data in the issuer source system(s). o *Any data elements that exist in an issuer's source system must be documented from that source system using the screenshot requirements as stated.*
• Be understandable in the context of an audit. o *The screenshot should provide sufficient information to allow a reviewer the ability to confirm the accuracy of the data being validated with no additional inquiry required.* o *Tick-marking screenshots is encouraged to achieve this requirement and is discussed further in Section 5.2.3.*
• Reflect the most recent enrollment file submission to the EDGE server for the 2017 benefit year.
• Be accompanied by workpapers in the event that a data element has been manipulated or differs from that which was submitted to EDGE. o *These workpapers should be based directly on supporting documentation provided by the issuer to substantiate the manipulation of the source data.* o *Refer to Section 5.2.3 for additional information regarding workpaper documentation.*
NOTE: Source documentation shall not be in the form of a data extract or report query.

The IVA Entity is not required to have physical or logical access to issuer systems and is not required to oversee the screenshot process in real time. However, all screenshots taken, whether by the issuer or IVA Entity, must be understandable in the context of an audit and meet all criteria as specified in Table Seven (7) above. Both IVA and SVA Entities will rely upon screenshot documentation to abstract data values and compare them to data submitted to the EDGE server.

5.2.2.1 Screenshot Automation

Though not required, CMS will allow issuers and IVA Entities to use an automated/scripted process for capturing screenshots to reduce the manual burden of capturing screenshots from source systems. CMS is permitting the automation of the screenshot generation process **only** and is **not permitting** other means of "extracting" source data for validation (e.g., screen scraping or data warehouse extracts).

For the purposes of HHS-RADV, an automated screenshot process is defined as "the implementation of a data capturing process which utilizes an automated tool to emulate a user's interaction with the source systems' screens."

The outputs of an automated screenshot process are screenshots saved with time and date stamps in a PDF document. If an automated process is utilized, the IVA Entity is responsible for evaluating the processes used for generating the screenshot.

Requirements of this evaluation are presented below:

- Issuer creates scripts using an automated tool
- Scripts are executed by the issuer or IVA Entity
- Script and script parameters are validated by the IVA Entity, along with script logs for successful/unsuccessful execution
- Screenshots captured should be stored in a system folder with system date and time a portable document format (PDF).

The IVA Entity will be responsible for understanding and validating script parameters, execution results, and log review.

5.2.3 Audit Workpapers

Issuers may provide workpapers to IVA Entities, and IVA Entities may submit workpapers to CMS and the SVA Entity. Workpapers provide a means to communicate HHS-RADV program related matters that would not otherwise be documented in the *IVA Entity Audit Results Submission XML*.

Workpapers will be drafted as required throughout Phase three (3) (D&E Data Validation) by the IVA Entity. Workpapers should document the IVA Entity's procedural steps taken to validate the issuer data using the screenshot documentation and any accompanying mapping documentation. IVA Entities will validate the workpapers with the issuer to ensure the procedures align with the issuer's systems and processes. IVA Entities will combine workpaper documentation with source system documentation (screenshots) to capture evidence of their validation process. Documentation of validation procedures in workpapers is important and should be prepared so that an experienced auditor, having no previous connection to the audit, can re-perform the validation.

Additionally, issuers can also use workpapers to outline any data inaccuracies that occurred during EDGE server submission and were reported as a RA discrepancy. IVA Entities can use these workpapers as a reference document when performing HHS-RADV procedures.

For workpaper guidelines and sample documentation to use during the workpaper documentation process, please refer to the **Workpaper Documentation Sample**, available in the Audit Tool file library.

5.2.3.1 Tick-Marking Source System Documentation

Audit workpapers assist auditors (including IVA Entities and, subsequently, the SVA Entity) in interpreting evidence and understanding the validation process performed. Workpapers should align with source system documentation to indicate the location and value of the data element observed in the screenshot, as well as describe any procedural steps taken to transform data from what is observed in the source system into a value submitted to EDGE.

Tick-marking, such as adding numeric indicators to a source system screenshot and then identifying each numeric value in a workpaper, is an effective method in supporting validation procedures and is strongly encouraged. A tick-marking example is included within the Audit Tool file library in conjunction with the workpaper example.

5.2.4 Medical Record Documentation

Collection and submission of medical record documentation is a key component of the HHS-RADV program. Issuers and IVA Entities are required to obtain medical record documentation for enrollees in the IVA sample.

For the purpose of HHS-RADV, medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers, observations, notes, therapies, assessment, clinical impression, diagnosis, tests, and services. ‘‘Medical record documentation’’ means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified time period. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services.

IVA Entities must review medical record documentation and submit diagnosis findings during the IVA results submission process for all enrollees. After signoff of submitted findings, by both the IVA Entity and issuer, CMS will notify both parties of the enrollees selected for SVA review. For these enrollees, the IVA Entity must upload the corresponding medical record documentation files listed in the IVA Entity Audit Results Submission (XML) to the Audit Tool.

5.3 Create Mapping Documentation (Issuer) – Phase 1

The initial step in the audit process is for the issuer to document which issuer source system data maps to EDGE server data submissions. The documentation provided from the issuers must indicate:

- Which screens in their source systems contain the information necessary to validate specific EDGE data elements;
- Navigational steps necessary to understand how EDGE server data was derived from source system data;
- Any internal code sets used for any relevant data elements.

Screen references and internal code sets should provide sufficient information to substantiate how data elements in the EDGE server are derived from source system data. Navigational steps (referenced above) should be captured in order to allow the IVA Entity and SVA Entity to connect these pieces of information, by providing a step-by-step understanding of how a source system data value is linked, transformed, manipulated, and then submitted to the EDGE server. To demonstrate this understanding, documentation must include:

- A detailed process narrative, which may include supporting documentation such as process flows, data mapping tables, screenshots, or other information that would allow a third party to understand the processes and to map the data without additional inquiry.
- Mapping documentation linking each data element (and their EDGE server acceptable values) to the corresponding element in the issuer’s source systems via screenshots. The EDGE server data elements that must be mapped to source systems/processes are listed in Table Eight (8) below.

The table below outlines the data elements required to be mapped (Column one [1]), the

corresponding XML element in the HHS-RADV sampling reports (Column two [2]), and the EDGE Sampling Report where that data element is located (Column three [3]).

Table 8: EDGE Enrollment Data Elements

Enrollment Data Elements (ICD)	XML Element Reference	EDGE Sampling Report Reference
Unique Enrollee Identification (UID)	insuredMemberIdentifier	RADVEE
Member ID	N/A	N/A - IVA Entity to Identify
Enrollee First Name	N/A	N/A - IVA Entity to Identify
Enrollee Last Name	N/A	N/A - IVA Entity to Identify
Enrollee Date of Birth (DOB)	insuredMemberBirthDate	RADVEE
Enrollee Gender	insuredMemberGenderCode	RADVEE
Plan ID, which includes: • HIOS ID • CSR Factor	insurancePlanIdentifier	RADVEE
Enrollment Start Date	coverageStartDate	RADVEE
Enrollment End Date	coverageEndDate	RADVEE
Premium Amount	insurancePlanPremiumAmount	RADVEE
Rating Area	ratingAreaIdentifier	RADVEE

CMS requires that five (5) specific mapping documents be created (at a minimum), containing the data elements referenced in Table Eight (8) above. IVA Entities may elect to submit additional "Other" mapping documents, outside of the five (5) required documents, to provide additional information on audit procedures. Note that enrollee demographic information and EDGE server UIDs must be submitted as a single document (Mapping Document one [1]), providing the IVA Entity and SVA the ability to map UIDs to the corresponding enrollee. Additional detail regarding this mapping document can be found in Section 5.3.1. The mapping documents are specified below:

- Mapping Document 1 – UID / Member ID / Name / DOB / Gender Mapping *(Required)*
    - Refer to Section 5.3.1 for additional detail
- Mapping Document 2 – Plan ID Mapping *(Required)*
- Mapping Document 3 – Rating Area Mapping *(Required)*
- Mapping Document 4 – Premium Mapping *(Required)*
- Mapping Document 5 – Enrollment Period Mapping *(Required)*
- Mapping Document 6 – Other Mapping *(Optional)*
    - Refer to Section 5.7.1 for additional detail

In the event the data does not exactly match an EDGE server field definition, the issuer

must document any interim steps or transformations performed to change the data (e.g., DOB 1/1/40 changed to DOB 1940-01-01). The issuer must also document the process of creating and linking UIDs between their EDGE server and their source data systems.

A separate mapping document must be submitted for each data element. A single document should not be submitted for all D&E data elements. Mapping documentation will be used in the analysis and validation of D&E data elements and is essential for both the IVA Entities and SVA Entity to complete audit activities.

5.3.1 Mapping EDGE Unique Enrollee ID to Source System Member ID & Demographic Information

An essential step in the mapping of data from source systems to EDGE server data is documenting a crosswalk between masked UIDs, and DOB, Gender, Member ID, First Name, and Last Name. **This is an essential step required for all enrollees in the complete IVA sample**. This is required to link EDGE server data to key information not found in the EDGE server (Source system Member ID, First Name, Last Name). This document is referred to as Mapping Document 1 in Section 5.3.

This crosswalk should provide an IVA Entity reviewer or SVA Entity reviewer the ability to identify the corresponding enrollee when provided with the EDGE UID. Screenshots are not required for the documentation of this mapping.

For example, a table populated by the issuer with values “EDGE Unique Enrollee ID” and “Enrollment Source System – Member ID”, “Enrollment Source System – First Name”, “Enrollment Source System – Last Name”, “EDGE Date of Birth”, and “EDGE Gender” would be an acceptable form of mapping for the D&E system.

5.3.2 Mapping of Supplemental Diagnosis

CMS recognizes that there are limited circumstances where relevant diagnoses may be missed or omitted during claim or encounter submission. In cases where diagnosis codes were missed or omitted during EDGE data submission, issuers have been provided specific business rules for submitting supplemental diagnosis codes for risk adjustment data submission. If supplemental diagnosis files are used to reflect enrollees’ diagnoses, the issuer must document how those additional diagnosis codes were identified, linked to submitted claims, and submitted to EDGE in compliance with the applicable business rules.

5.4 Review & Confirm Mapping – Phase 2

Once the issuer has provided documents mapping the source system elements to the EDGE server elements, the next step is for the IVA Entity to review and discuss with the issuer the contents of the issuer’s mapping documentation, so the IVA Entity can gain an understanding of the issuer’s environment, as well as the D&E, premium, and claims source systems for NEC if provided for the audit.

Workpapers must be drafted by the IVA Entity as required throughout D&E Data Validation and NEC Data Validation to supplement mapping documentation. Workpapers must combine issuer documentation (source system documentation and mapping documentation) with the IVA Entity’s procedural steps taken to validate the issuer data. The IVA Entity will review the workpapers with the issuer to ensure the procedures align with the issuer’s systems and processes. For additional information regarding workpaper

requirements, refer to Section 5.2.3.

5.5 Demographic and Enrollment Data Validation – Phase 3

In the D&E Data Validation process, source system documentation must be obtained to enable the validation of key D&E data elements by the IVA and SVA Entities for enrollees in the IVA sample. IVA Entities need to validate that the data submitted to the EDGE server matches D&E data stored within the issuer's source systems. The information that is gathered from the D&E data review is subsequently used to verify the identity of an enrollee during the Health Status Data Validation phase of the IVA process.

For the current benefit year HHS-RADV audit program, CMS will select a subsample of 50 randomly selected enrollees from the IVA sample selection for D&E validation. For enrollees to be eligible for CMS D&E validation selection, enrollees must be enrolled for 30 continuous days in a calendar month with the issuer. In the event the targeted D&E sample size of 50 enrollees cannot be achieved based on the CMS selection criteria, a smaller sample of enrollees may be selected by CMS. IVA Entities will need to perform the D&E process on only the enrollees in the selected D&E subsample.

However, the issuer and/or IVA Entity must provide a cross-walk between the EDGE server UID and the issuer's member ID, DOB, gender, and first and last names for **each enrollee in the complete IVA Sample,** in order for medical records to be linked to the correct sampled enrollee.

CMS will not use D&E errors identified during the HHS-RADV audit program in the risk score error calculation. Rather, CMS will use the findings from the D&E validation as a data quality control measure. CMS will conduct data analysis to determine if any issuers are outside of the norm related to each of the D&E data elements and conduct outreach as needed.

As set forth in the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule, CMS will use HHS-RADV as a method of discovering materially incorrect EDGE server data submissions and making adjustments pursuant to § 153.630(e), as described in guidance issued on September 2, 2015.[11] D&E errors discovered during HHS-RADV would be the basis for adjustments to the applicable benefit year transfer amount, rather than the subsequent benefit year risk score, as underlying errors in diagnoses contributing to risk scores are treated.

For example, in cases where there is a material impact on risk adjustment transfers for that particular market as a result of incorrect EDGE server premium data, discovered through HHS-RADV or otherwise, CMS would calculate the dollar value of differences in risk adjustment transfers, and, where the difference is detrimental to one (1) or more issuers in the state market risk pool, adjust the other issuers' risk adjustment transfer amount by that calculation, and increase the risk adjustment charge (or decrease the risk adjustment payment) to the issuer that made the data error, in order to balance the market.[12]

[11] This guidance is also included in the Evaluation of EDGE Data Submissions for the 2017 Benefit Year, released on November 3, 2017, available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-Submissions-2017.pdf.

[12] Calculation of the dollar value will include adjustment to the Statewide premium average and, to the extent possible, adjustment to the geographic cost factor.

5.5.1 Audit Steps

D&E data validation consists of two (2) primary steps:

1. Linking the enrollee in the IVA sample to the enrollee in the issuer's source system (required for the full IVA sample)
2. Validating enrollee data elements (required for D&E subsample only)

The D&E data validation process begins once the EDGE server RADV sample reports and the source documents are obtained for the sampled enrollees. The EDGE server Unique Enrollee ID used in the IVA sample reports will likely not be found in the issuer's source system screenshots, as it is an EDGE server specific data value.

Therefore, the issuer must map the UIDs for each enrollee in the complete IVA sample (RADVEE Report) to the actual enrollee in the issuer's source enrollment system. The UID mapping document must include the UID from the RADVEE Report and the Member ID, first name, last name, DOB, and gender for the matched enrollee from the issuer's source system. The UID mapping document will be needed by both the IVA Entity and SVA Entity to link submitted medical records to the proper enrollee in the IVA sample. The UID mapping document must be submitted as part of IVA Package One (1).

The steps that should be taken when performing D&E data validation for the enrollees in the IVA sample are detailed below:

1. Linking the Enrollee to the IVA Sample (required for the complete IVA sample)

Step	Description	Additional Details
1	IVA Entity confirms Unique Enrollee IDs from the RADVEE Report are mapped to correct enrollees from the issuer's source system.	Reviewer obtains the Unique Enrollee ID mapping document from the issuer and compares the date of birth and gender to the date of birth and gender for the same Unique Enrollee ID in the RADVEE Report to verify the enrollee mapping provided by the issuer.

It is important to note that, as stated in Section 5.3.1, the linking of source system data to the enrollee in the IVA sample is done by linking the masked UID from the EDGE server to the actual enrollee Member ID within the issuer's source system, and this is required for all enrollees in the IVA sample. Without this linkage, IVA Entities and the SVA Entity will not have the ability to verify the enrollee in the IVA sample or verify that the medical records are the linked to the correct enrollee.

2. Validating Enrollee D&E Data Elements (required for D&E subsample only)

Step	Description	Additional Details
1	IVA Entity gathers source system documentation **including screenshots** for the enrollees in the D&E subsample.	Reviewer gathers issuer mapping documentation and enrollment screenshots to perform D&E data review for the enrollees in the D&E subsample.

Step	Description	Additional Details
2	IVA Entity obtains EDGE server data element values and performs D&E data review.	The reviewer performs D&E data review for EDGE server data elements based on screenshot evidence. These data elements are: - DOB - Gender - Plan ID - Enrollment Start Date - Enrollment End Date - Premium Amount (for subscriber enrollees only) - Rating Area (for subscriber enrollees only) Reviewers identify the corresponding data element in the source system screenshot documentation and consult with the issuer to determine an accurate value (i.e. what should have been submitted to the EDGE server, based on the source system). Once identified, this value is compared to the RADVEE Report data value.
3	IVA Entity drafts workpaper documentation as needed.	In the event that the source system data does not match the EDGE server data, or requires data transformation, the reviewer will document the correct value or data transformation in an accompanying workpaper.
4	IVA Entity records results.	The reviewer records the results found from the issuer's source system for the enrollee in the *IVA Entity Audit Results Submission XML*.
5	IVA Entity repeats for the next enrollee in the D&E subsample.	The reviewer repeats the steps for the next enrollee in the D&E subsample.

5.5.1.1 Validating Data Elements – Additional Detail

The validation of issuer source system data and later documentation of data elements within the *IVA Entity Audit Results Submission XML* requires IVA Entities to document the data element value as seen in the source system and:

- substantiate how data submitted to the EDGE server correctly or incorrectly corresponds to the information within the issuer's source system.
- record results found from the issuer's source system in the IVA Entity Audit Results Submission XML.

The 2017 benefit year HHS-RADV Sampling D&E Subsample Data Elements Table Nine (9) below lists the business data elements associated with the D&E subsample Report. The data elements will be comma separated and quote wrapped. The first row of data in the file will be the headers.

Table 9: 2017 Benefit Year HHS-RADV Sampling D&E Subsample Data Elements

Element Name	Definition	Data Type	Acceptable Values
Enrollee ID	Unique identifier for the enrollee. This represents the MASKED identifier submitted by the issuer into EDGE	String	minLength=2; maxLength=80
Gender	Gender of enrollee	String	M=Male F=Female U=Unknown (only used for newborns)
Date of Birth	Date of Birth of enrollee	Date	YYYY-MM-DD
Plan ID	Unique 16-digit plan identifier for the insurance plan offered by the issuer that the enrollee is covered under the plan ID includes the CSR variant	String	Must be the assigned 16-character HIOS ID.
Enrollment Start Date	The date when the enrollment coverage for the enrollee became effective for the associated plan	Date	YYYY-MM-DD
Enrollment End Date	The date when the enrollment coverage for the enrollee is terminated for the associated plan.	Date	YYYY-MM-DD
Enrollment Month	The whole month which will be used to validate Premium Amount and Rating Area.	Date	YYYY-MM-DD (being the first calendar day of that month)
Subscriber Indicator	Contains an “S” when the enrollee is the plan subscriber, otherwise blank.	String	S = Subscriber “” = Not Subscriber

Data Element – Date of Birth

An enrollee’s DOB is used to determine the enrollee’s assignment to a risk adjustment model (infant, child, or adult) and to further assign the enrollee to a specific age band within the child or adult models. An error in an enrollee’s DOB may cause assignment to the wrong risk adjustment model and/or age band within a model, which may cause an enrollee risk score error.

The IVA Entity must validate the DOB of the enrollee in the D&E subsample against the DOB for the enrollee in the issuer’s source system. Screenshots of the enrollment system showing the enrollee’s DOB are required for this validation. Additionally, the issuer must provide the IVA Entity with the source system format used for DOB and provide any

mapping used to transform the data to the EDGE server submission format of year, month, date (YYYY-MM-DD). If the DOB in the issuer source system does not match the month, date, and year of birth for the enrollee in the RADVEE Report, the IVA Entity shall record the DOB from the issuer's source system in the *IVA Entity Audit Results Submission XML.*

Data Element – Gender

IVA Entities must validate the gender of the enrollee in the D&E subsample against the issuer's source system. Screenshots of the enrollment system showing the enrollee's gender are required for this validation. Additionally, the issuer must provide the IVA Entity with the source system format used for enrollee gender and provide any mapping used to transform the data to the EDGE server submission format of M=male and F=female. If the gender in the issuer source system does not match the gender identified for the enrollee in the RADVEE Report, the IVA Entity shall record the gender from the issuer's source system in the *IVA Entity Audit Results Submission XML.*

Data Element – Plan ID

The 16-digit Plan ID was created solely for the purpose of EDGE server data submission and is not expected to exist in issuer source systems. Therefore, it is necessary for the issuer to provide the IVA Entity with a mapping document explaining how the enrollee's policy/plan/product ID is transformed to the 16-digit Plan ID used for EDGE server data submission.

For each enrollee in the D&E subsample, IVA Entities must validate that the 16-digit Plan ID in the RADVEE Report is the appropriate Plan ID based on a comparison of the issuer-provided Plan ID mapping document and screenshots from the issuer's source system showing the policy/plan/product in which the enrollee is enrolled. If an enrollee in the D&E subsample is enrolled in multiple plans during the benefit year, only the Plan ID and enrollment period identified in the D&E subsample is required to be validated. CMS will provide the specific Plan ID and enrollment start and end dates to be validated.

IVA Entities must also validate that the CSR factor in the 16-digit Plan ID in the RADVEE Report is the appropriate CSR factor for the specified enrollee based on review of screenshot data from the issuer's source system where CSR information is stored.

If the IVA Entity determines that an enrollee is enrolled in a plan that does not match the Plan ID indicated on the D&E subsample report, the issue must be documented in a separate workpaper for the enrollee. Plan ID mapping must be captured in the workpaper's narrative, including specific explanations of all provided source system screenshots to enable the SVA Entity to clearly understand the mapping allocation.

Data Element – Rating Area (required for subscriber enrollees only)

The Market Rules and Rate Review Final Rule (45 C.F.R. Part 147) provides that each state will have a set number of geographic rating areas that all issuers in the state must uniformly use as part of their rate setting. Information about each state's market rating areas in the individual and small group markets, and methodology for dividing the state into rating areas, has been made available to issuers for the 2017 benefit year by CMS[13]

Issuers must provide the IVA Entity an address, zip code, and/or county information for

[13] https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-market-reforms/state-gra.html

Rating Area validation. Issuers should provide the IVA Entity with documentation that maps the state rating areas to the counties and zip codes in those rating areas. IVA Entities will only need to validate the Rating Area for enrollees who appear in the D&E subsample and who are identified in the RADVEE Report as a subscriber. It is not necessary to validate the rating area for non-subscribers/dependents in the D&E subsample.

Rating area is only required to be validated for a subscriber's Plan ID in the D&E subsample and only for the single month provided. If the subscriber enrollee is enrolled in multiple plans during the benefit year, only one (1) random month for one (1) of the Plan IDs will be selected by CMS for validation. CMS will provide the specific enrollment period and month of rating area to be validated along with the D&E subsample.

To validate the rating area for a subscriber enrollee in the D&E subsample, you must first determine if the enrollee is in an individual or small group plan. For individual plans, the rating area is based on the subscriber's address. For small group plans, the rating area is based on the employer's business address.

To validate rating area for **individual plans**, the IVA Entity must verify that the rating area assigned to the subscriber enrollee maps to the subscriber enrollee's home address zip code or county code, based on how the rating area is assigned in that state.

To validate rating area for **small group plans**, the IVA Entity must verify that the rating area assigned to the subscriber enrollee map to the employer's business address zip code or county code, based on how the rating area is assigned in that state.

Data Element – Premium Amount (required for subscriber enrollees only)

The premium amount submitted to the EDGE server and reported on a subscriber enrollee's enrollment record for their enrollment period is defined as the total monthly rated premium charged for a subscriber's policy, including the Advanced Premium Tax Credit (APTC) amount, if applicable. As such, the premium amount may include more than the amount billed directly to a subscriber.

IVA Entities need to validate the "Premium Amount" for only the enrollees who appear in the D&E subsample who are identified in the RADVEE Report as a subscriber. It is not necessary to validate the premium amount for non-subscriber/dependents in the D&E subsample.

Additionally, IVA Entities will only need to validate one (1) month's premium for a subscriber enrollee. If the subscriber enrollee is enrolled in multiple plans during the benefit year, only one (1) random month will be selected by CMS and validated. CMS will provide the specific enrollment period and month of premium to be validated along with the D&E subsample.

To determine if a D&E subsample enrollee is a subscriber, see the Subscriber Indicator (XML tag subscriberIndicator) data element in the Enrollment Period Category of the RADVEE Report. If the value in the data field is an "s," then the enrollee is identified as a subscriber. If the XML data element is "null", then the enrollee is not the subscriber.

The issuer must explain to the IVA Entity, in mapping documents, how the premium amount submitted to the EDGE server was derived. If there are multiple members under one (1) subscriber's policy, the premium is equal to the sum of all individual rates for all rated members on a policy and not the rate associated with the subscriber. Normally, these rates are only derived during policy initiation or renewal and are not carried forward to

premium billing systems, which normally have the full premium less any APTC. The sum of the billed premium and APTC must be aggregated and submitted under the subscriber to the EDGE server. This aggregated premium amount will then be validated.

To validate the premium amount in the RADVEE Report, the IVA Entity must obtain screenshots of the premium billing system and screen shots of the APTC values if APTC information is not captured in the premium billing system screenshots. The IVA Entity must then use this information to perform the validation of the policy premium amount submitted and document their work and methodology in a workpaper.

Clarification of APTC Validation

As stated above, CMS requires the IVA Entity to validate the premium amount that is reported to the EDGE server, which should be inclusive of the APTC amount (if applicable). However, CMS is not requiring the IVA Entity to validate the amount of the APTC for a sampled enrollee, but only to report it if it is included in the premium amount submitted to the EDGE server in cases where the sampled enrollee is a subscriber. If the sampled enrollee is not a subscriber, then IVA Entities may leave the APTC amount ('aptcAmount') on the IVA Entity Audit Results Submission (XML) blank (i.e. no data entered).

If the sampled enrollee is a subscriber, but there is no APTC on the policy, a value of '0' is to be entered and no further documentation is required. 'OMITTED' is not an acceptable value.

If the sampled enrollee is a subscriber and the policy has an APTC amount, the issuers should capture in mapping documentation how APTC amounts are recorded in the source system. IVA Entities should reference the issuer provided mapping documentation to determine how premium amounts are calculated in the issuer's source system. Screenshots that capture the premium amount as evidence should capture all data required to define the APTC.

In cases where the issuer's system captures premium not inclusive of APTC, the issuer should record the premium not inclusive of APTC in the 'policyPremiumAmount' tag and record the APTC amount in the 'aptcAmount' tag of the IVA Entity Audit Results submission (XML). In cases where the issuer's system captures premium inclusive of APTC, the IVA Entity should record the full premium about in the 'policyPremiumAmount' tag, record '0' for the APTC amount in the 'aptcAmount' tag, and document the APTC amount in workpapers, in addition to capturing any calculations performed to arrive at the APTC amount for the sampled subscriber enrollee.

Examples:

1. For subscriber enrollees selected in the D&E subsample, if the premium amount in the issuer's source system is not inclusive of the APTC amount, the APTC amount, if applicable, should be recorded in the APTC amount ('aptcAmount') on the IVA Entity Audit Results Submission (XML).

   For example, the premium amount in the issuer's source system is not inclusive of APTC. The issuer reported a total premium of $1,400 to EDGE and $400 of the premium amount is APTC. The IVA Entity would record '1000' for the premium amount ('policyPremiumAmount' tag) and '400' for the APTC amount ('aptcAmount' tag) in the IVA Entity Audit Results Submission (XML).

2. The subscriber's premium amount is reflected in the issuer's source system and is inclusive of the APTC amount. The IVA Entity should record the value '0' for the APTC amount ('aptcAmount' tag) and record the actual premium amount (inclusive of APTC) to be validated against the issuer's EDGE server in the 'policyPremiumAmount' tag of the IVA Entity Audit Results Submission (XML).

   For example, assuming the premium amount in the issuer's source system is inclusive of APTC, the issuer reported $1,400 total premium on their EDGE server and $400 of the premium amount is APTC. The IVA Entity would record '1400' for the premium amount ('policyPremiumAmount' tag) and '0' for the APTC amount ('aptcAmount' tag) in the IVA Entity Audit Results Submission (XML).

   In this case, it is important to note that IVA Entities must separately document the APTC amount for each sampled subscriber enrollee, if applicable, in workpapers in addition to capturing any calculations performed to arrive at the APTC amount for the sampled subscriber enrollee.

Validating Premium Amount for Subscriber Enrollees in Small Group Plans

The issuer will need to provide the IVA Entity with the necessary mapping of the enrollee's premium to the group premium in their source system. If the issuer uses composite premiums or average enrollee premium amounts, then that methodology must be explained in mapping documents as well. The issuer must make clear if it is the composite premium/average enrollee premium or the individual enrollee's portion of the small group plan's premium that is submitted to the EDGE server. The issuer must also provide the necessary screenshots to determine how the premium submitted to the EDGE server for the subscriber enrollee in the D&E subsample was derived from the premium billed to the group.

Premium Validation – Non-Subscriber Enrollees

Validation of premium amount is not required when a non-subscriber/dependent is the sampled enrollee.

Data Element – Enrollment Start and End Dates

The issuer must explain how enrollment start and end dates are determined in their source system. Findings must be recorded in the *IVA Entity Audit Results Submission XML* in the format YYYY-MM-DD using the month, day, and year as it appears in the issuer's source system. If no enrollment end date is present, or the end date is beyond December 31st (20XX-12-31) of the benefit year, the issuer must demonstrate in the mapping documentation whether the enrollee is still enrolled or if the end date is in a subsequent benefit year.

Examples:

1. If the enrollee's Enrollment Start Date, as indicated in the issuer's source system screenshot, contains an Enrollment Start Date prior to the start of the 2017 benefit year audit, the IVA Entity must record the month, day, and year from the issuer's source system screenshot.

2. The Enrollment End Date value is 'Blank' or no data is captured in the issuer's source system, as observed in the source system screenshots. If the issuer confirmed in the

mapping document that a 'Blank' value indicates that the enrollee is enrolled through the current benefit year the IVA entity must capture the 'enrollmentEndDateSourceSystem' as the last day of the current benefit year. For benefit year 2017, the date captured would be: 2017-12-31.

3. The Enrollment End Date value is captured in the issuer's source system, as observed in the source system screenshots, and is past the last day of the benefit year being audited (post 12/31/2017 for the 2017 benefit year) then the value should be recorded in the IVA Entity Audit Results Submission (XML) in the format YYYY-MM-DD using the month, date, and year (as seen in the issuer's source system).

5.5.1.2 Key Considerations of Enrollment Data Validation

Validation of D&E Information for Enrollees with System Generated Enrollment Periods

For the purposes of D&E review specific to enrollees with system-generated enrollment records associated with cross-year claims, IVA Entities should validate the 2016 benefit year enrollment period which led to the creation of the 2017 benefit year system-generated enrollment period.

For these enrollees, the IVA Entity or issuer should substantiate the latest enrollment information from the prior year via screenshots and workpapers and document that the enrollee was appropriately enrolled prior to creation of the system-generated enrollment period. Issuers should provide IVA Entities with the applicable 2016 benefit year plan enrollment screenshots to confirm that the system-generated enrollment period was appropriately created for the individual. IVA Entity workpapers should indicate how the source system enrollment period corresponds to the system-generated enrollment record. IVA Entities should submit this documentation as part of their IVA Entity Audit Results Submission (XML) and Package 1 Submission for CMS and SVA review. Note that Premium Amount and Rating Area are only required to be validated for Subscriber enrollees.

Newborn Verifications with No Source System Support

Newborns may not have complete data within the issuer's source system. Some states require issuers to cover a newborn under the mother's enrollment for a specific period of time. Additionally, some hospital claims for childbirth include both the mother's record and the newborn infant's record on the same claim. In these situations, it is acceptable for an issuer to not have created a separate enrollment for the newborn in their systems, but rather handled all claims related to the newborn under the mother's policy. Note that in order for a risk score to be assigned to the newborn for purposes of the RA program, the newborn must have its own enrollment record, must appear separately from the mother's in the issuer's EDGE server data submission, and the newborn's claims must have been unbundled from the mother's claim.

IVA Entities should only evaluate medical record documentation for enrollees in the IVA Sample. In the event the newborn information was not separated and unbundled from the mother, in accordance with the ESBR, the newborn information should not be evaluated as part of the mother's health status. Detailed information related to unbundling of newborn and mother data is captured in the ESBR Version 8.0, which can be found in the REGTAP Library by using the following link:
https://www.regtap.info/reg_librarye.php?i=1390

The IVA Entity must confirm that the guidance contained in ESBR Version 8.0 was followed appropriately for handling newborn coverage. The issuer must provide evidence of newborn coverage through workpaper documentation, if there are no screenshots.

Changes to Enrollment Records Following RA Data Submission

In certain circumstances, it is possible that enrollee information is updated following final data submission for RA (e.g., gender changes from Male to Female). In the event issuers can adequately support these situations with documentation from source systems, IVA Entity reviewers will document the post-submission updated enrollment data value as stored in the issuer's source system, along with workpaper documentation providing a clear explanation of the steps taken to validate the issuer's information.

Documentation of Enrollment Periods

For enrollees in the D&E subsample, CMS will provide the Plan ID and enrollment period that is required to be validated. If an enrollee has multiple enrollment periods, only the enrollment period identified by CMS needs to be validated.

5.6 Health Status Data Validation – Phase 4

Health Status Data Validation will be performed on all enrollees in the IVA Sample in order to substantiate diagnoses in accordance with the International Classification of Diseases (ICD) Clinical Modification (CM) Tenth edition coding guidelines, hereafter referred to as ICD-10-CM.

Figure 3: Health Status Data Validation

Figure 3 illustrates the IVA and SVA Entity health status data validation process.

The issuer or IVA Entity will link medical records for the enrollee with at least one (1) claim per medical record, and the issuer will provide the medical records to the IVA Entity to evaluate. The linked claim for each medical record must be a claim on the RADVMCE report, or a RA eligible paid/positively adjudicated NEC submitted via the NEC section of the *IVA Entity Audit Results Submission XML.* If this criteria is met, the medical record is permissible for review for the purposes of the 2017 benefit year HHS-RADV audit program. All diagnoses within the benefit year from a permissible medical record may be abstracted, independent of the enrollee's plan enrollment.

Note: At a minimum, medical records are needed to substantiate each HCC reported in the RADVDE Report for the enrollees in the IVA Sample. If there are medical records associated with a RA eligible paid/positively adjudicated NECs, then those records should be provided as well.

For the 2017 benefit year, CMS will allow medical records to be submitted that do not have an associated EDGE server claim, but for which the issuer did bear a financial risk. The IVA

Entity should ensure that all required EDGE server data elements for these NECs are documented in the *IVA Entity Audit Results Submission XML* and that evidence of the source systems, including adjudication, is provided with the results.

Additionally, screenshot documentation of NECs must be provided along with the medical record for the purposes of Health Status Validation. Refer to the NECs section (Section 5.6.4) for guidance regarding the screenshot documentation requirements for claims data.

5.6.1 Medical Record and Chart Retrieval

The Health Status Validation phase begins when the IVA or SVA Entity obtains medical records. Issuers and contracted IVA Entities should attempt to retrieve medical records and documentation sufficient to provide evidence of HCCs from providers. This request for medical records from providers should begin as soon as the IVA sample is released to each issuer and IVA Entity.

Failure to retrieve a medical record will impact audit results in the event an HCC is unable to be substantiated. A legitimate medical record may both validate an existing diagnosis and provide evidence of an unreported RA eligible diagnosis or new HCC for the enrollee.

A HHS-RADV Provider Medical Record Request Memo, on CMS letterhead, will be provided via the Audit Tool for issuers and/or IVA Entities to send to relevant providers. The memo will identify the purpose of the request and underscore the necessity that providers deliver the requested documentation. This memo shall not be altered in any way and shall not be used by the issuer or IVA Entity for any purpose other than retrieval of documentation to support HHS-RADV.

It is the issuer's responsibility to assist its IVA Entity in the retrieval of medical records and documentation sufficient to provide evidence of HCCs from providers; CMS cannot provide assistance. Issuers and IVA Entities can leverage the HHS-RADV Provider Medical Record Request Memo when engaging with providers to obtain medical record documentation. Please note this memo is only to be used to support and accompany the issuer's medical record request letter related to HHS-RADV. It is the issuer's responsibility to ensure all medical record requests contain the necessary information for the provider to fulfill the request, including the sampled patients' names, information about the date(s) of service being audited, and the corresponding address for medical record submission, so that providers can provide the relevant medical record documentation. **Medical records are not to be sent directly to CMS.** The HHS-RADV Provider Medical Record Request Memo can be accessed in the HHS-RADV Audit Tool by selecting the "Library" tab and then clicking the "Guidance" section and should not be altered by anyone.

The timely and thorough retrieval of medical records from providers is a key component of the Health Status Data Validation procedures. Without access to the relevant medical records, the ability of IVA Entities to accurately validate submitted EDGE server data will be hindered. An HCC failure will be recorded during the diagnosis abstraction process in the event that a specific medical record, reflecting the only source of a diagnosis mapping to an HCC, is unavailable for the IVA Entity to review.

5.6.2 Medical Record Review and Diagnosis Abstraction – Overview

After obtaining the medical records and claims documentation, the IVA Entities and SVA Entity will compare data from the medical records to validated elements and the EDGE server report.

Enrollee medical record review consists of the following steps:

- Medical record intake
- Validation of acceptable medical record dates of service
- Validation of acceptable medical record signatures
- Diagnosis Abstraction

Medical record intake ensures that the medical record can be affirmatively linked to a sampled enrollee. Medical record intake can be completed by the Primary Reviewer, Senior Reviewer, or by certified medical coders.

Medical record review and diagnosis abstraction involves linking the medical record to one of the enrollee's claims identified in the EDGE server RADVMCE Report or as documented in the source system evidence.

The medical record is then reviewed to identify any ICD-10-CM diagnoses and ensure it meets CMS requirements for acceptable dates of service, facility type, bill type, service code, service type, provider credentials, and signature (see Appendix A for additional information on ICD-10-CM Official Guidelines for Coding and Reporting). CMS is not requiring IVA Entities to document or submit specific signature and credentialing data, but IVA Entities are required to validate the information identified on the medical record in accordance with coding guidelines. This is in order to verify that the medical record meets CMS requirements to validate the issuer-submitted data for enrollee risk scores. Certified medical coders must verify that the medical record originates from the provider of the medical service(s) and that the medical record reflects acceptable providers and services. This step requires a Senior Coder to review the medical record if discrepancies are found by the Primary Coder.

IVA Entity Senior Coders shall also perform IRR on a sample of records for all Primary Coders and record the results of any revalidation. This process is detailed in Section 6.

5.6.3 Medical Record Intake

The purpose of medical record intake is to ensure that submitted medical records are for the appropriate sampled enrollee and that the dates of service align with an issuer adjudicated and paid RA eligible claim. Medical records that cannot be linked to a sampled enrollee, or to an RA eligible paid claim, should be determined non-eligible.

Medical record intake can be completed by the Primary or Senior Reviewer, or by certified medical coders. Medical record intake is not required to be completed by certified medical coders. If discrepancies are found by the Primary Reviewer, medical record intake does require a Senior Reviewer to review the medical record to confirm the discrepancies. The roles of these individuals involved in the Health Status Validation – medical record intake process are as follows:

- **Primary Reviewer:** The Primary Reviewer verifies that the enrollee name, DOB, and gender documented on the medical record matches the enrollee data on the UID mapping document provided by the issuer and confirmed by the IVA Entity. If there is a discrepancy, the issuer or IVA Entity may engage providers to verify that the correct medical record was provided or to obtain the correct record if the provider supplied an incorrect record. If no provider errors are identified and discrepancies persist between the medical record and the enrollee, the Primary

Reviewer will flag the medical record as an error. After review, files marked as errors will be sent to a Senior Reviewer.

- **Senior Reviewer:** The Senior Reviewer revalidates the steps for medical records that did not link to enrollee data on the UID mapping document provided by the issuer and confirmed by the IVA Entity. If the Senior Reviewer is unable to link the medical record to an enrollee in the IVA Sample, the Senior Reviewer will reject the record.

Table 10: Medical Record Intake Testing

Step	Description	Additional Details
1	Gather medical record documentation.	Primary Reviewer gathers enrollee medical record documentation from the issuer to identify linking data element values on the medical record (First Name, Last Name, DOB, Gender).
2 (a-c)	Primary Reviewer – Compare medical record data to the Unique Enrollee ID mapping document.	The Primary Reviewer compares the demographic data from the medical record to the UID mapping document provided by the issuer and confirmed by the IVA Entity to determine, using professional judgment, that the fields recorded reasonably match.
		a. If there is agreement or the Primary Reviewer determines, using professional judgment, that the fields reasonably match then the Primary Reviewer records the results as final in the *IVA Entity Audit Results Submission XML*. No additional review is necessary.
		b. If there are differences, the Primary Reviewer marks the inconsistent findings and submits the record to the Senior Reviewer for confirmation.
		c. Chart Request Feedback Loop For enrollee medical records for which inconsistent findings are initially identified, the IVA Entity reviewer should confirm with the issuer that the appropriate medical record requested was provided. This step may be performed either by the Primary Reviewer, prior to Senior Reviewer review, or by the Senior Reviewer once the files marked as containing errors are allocated for senior review. If performed by the Senior Reviewer, this process step would relocate within the table.
		The Senior Reviewer compares the results from the medical record to the UID mapping document provided by the issuer and confirmed by the IVA Entity to ensure that all fields recorded reasonably match.

Step	Description	Additional Details
3 (a-b)	Senior Reviewer – Compare medical record data to the Unique Enrollee ID mapping document.	a. If there is agreement and the Senior Reviewer determines, using professional judgment, that the fields reasonably match, then the medical record should be passed along for diagnosis abstraction.
		b. If there is a difference and if the *Chart Request Feedback Loop* has been completed, the Senior Reviewer should reject the medical record.

5.6.3.1 Key Considerations of Medical Record Intake

Evaluating Match Between Medical Record and Demographics and Enrollment Data

In this process, the enrollee's first name, last name, DOB, and gender should reasonably match between the medical record and the UID mapping document provided by the issuer and confirmed by the IVA Entity. Reasonability of match is based upon the IVA Entity reviewer's professional judgment. For example, one (1) source may show the name as Michael Smith, whereas the second source may show Mike Smith – this is an example of a discrepancy that would be acceptable. In the event that the enrollee name, DOB, and gender cannot be corroborated between the UID mapping document and the data on the medical record, the IVA Entity must perform necessary due diligence to contact issuers or providers and determine if the correct medical record was provided.

If the Primary Reviewer is unable to reasonably conclude that the medical record is for the corresponding sampled enrollee, the reviewer will forward to the Senior Intake Reviewer to determine if the inconsistent finding is final.

5.6.4 Documentation of Claims Not Accepted in EDGE

CMS will allow issuers to submit medical records for which no claim was accepted into the EDGE server. If issuers wish to have medical records reviewed with no associated EDGE server claim, they must allow the IVA Entity to view and document these claims within the source system and record their results in the *IVA Entity Audit Results Submission XML.*

Additionally, a screenshot from the issuer's claims adjudication system must be submitted along with the medical record for the SVA Entity to review. The screenshot must include the claim source, dates of service claimed, the service code, and bill type (if applicable), as well as a paid/positive adjudication status. These claims are referred to as NECs.

IVA Entity reviewers must document all claims data elements within the issuer source system via a screenshot. However, these values will not be compared to EDGE server values (as no EDGE server values for these additional claims will exist).

Cross-Year Claims

For 2017 benefit year HHS-RADV, CMS has updated the RADVMCE Report claim logic to be inclusive of "cross-year claims" or claims with dates of service spanning across two (2) benefit years. "Cross-year claims" should not be submitted as NECs.

5.6.5 Acceptable Date of Medical Record or Claim

The medical record date of service (DOS) defines when an enrollee received medical treatment from a physician, permitted provider, medical facility, or telehealth visit (as described in Section 5.2.4 Medical Record Documentation). For medical records to be permissible for HHS-RADV, the criteria listed below must be confirmed by IVA Entities. If the below criteria are met, then those medical records are permissible for review for the 2017 benefit year HHS-RADV audit.

1. All authenticated medical records from inpatient hospital, outpatient, and professional sources must match the demographic data for the sampled enrollee on the UID mapping document.

2. The medical record must be linked to either one (1) EDGE server accepted RA eligible claim from the RADVMCE Report or an RA eligible paid/positively adjudicated NEC for the specified sampled enrollee.

If a medical record meets these two (2) requirements, the record is deemed to be permissible for abstraction as part of the HHS-RADV process and all diagnoses may be abstracted within the benefit year according to ICD-10-CM guidelines, including other DOS and associated diagnosis codes found on the medical record.

For inpatient records, when linking the medical record to a claim, the dates of service or admission and discharge dates on a medical record should align to the statement covers from/through dates on the claim. The statement covers through date and the discharge date MUST fall within the benefit year being audited. For example, if an enrollee is admitted to a hospital in December 2017 and is discharged in January 2018, the services performed that occurred in both December 2017 and January 2018 are considered in the 2018 benefit year for calculation of enrollee risk scores and therefore are not eligible for the 2017 benefit year HHS-RADV.

For outpatient and physician/professional services, the “from” and “through” dates should be identical due to the services being performed on a single day. However, there are exceptions where the provider may bill for multiple encounters together. For example, an outpatient physical therapy treatment “from” and “through” dates may not be performed on a single day, but instead span over a prescribed period of time. The IVA Entity must use professional judgment to determine if the outpatient physical therapy treatment is permissible for review for the benefit year being audited. If the IVA Entity determines, based on its professional judgment, that the service or treatment is eligible for review for the benefit year being audited, the IVA Entity must explain this determination in workpapers accompanying the medical record.

The medical record intake portion of the Health Status Validation process may be performed by Primary Reviewers or Senior Reviewers. Detailed steps for reviewing acceptable dates in a Medical Record are defined in Table Eleven (11) below:

Table 11: Acceptable Date of Medical Record Testing

Step	Description	Additional Details
1 (a-b)	Primary Reviewer – Record medical record dates of service	The Primary Reviewer identifies that the "statement covers from" (for inpatient claims, this is the admission date) and "statement covers through" (for inpatient claims, this is the discharge date) from the medical record links to a claim in the RADVMCE Report or a RA eligible, paid/positively adjudicated NEC, if applicable.
		a. The Primary Reviewer determines if the "statement covers from" (admission date) "and through" (discharge date) from the medical records are linked to a claim in the RADVMCE Report and documents the associated RADVMCE claim number in the *IVA Entity Audit Results Submission XML*.
		b. The Primary Reviewer reviews the NEC (if applicable) to determine if valid RA services were provided within the "statement covers from/through" dates on the claim.
2(a-b)	Primary Reviewer – Compare medical record dates of service to linked claim on the RADVMCE Report or to a RA eligible, paid/positively adjudicated NEC to identify inconsistent findings	The Primary Reviewer compares the results of the medical record to the RADVMCE Report or a RA eligible, paid/positively adjudicated NEC to ensure that all fields recorded match using professional judgment.
		a. If there is agreement, document results in the IVA Entity Audit Results Submission XML, and no additional review is necessary.
		b. If there is a difference, the Primary Reviewer marks the enrollee file as an inconsistent finding and forwards the record to the Senior Reviewer to review.
3	Senior Reviewer – Record medical record dates of service	The Senior Reviewer identifies that the "statement covers from" (for inpatient claims, this is the admission date) and "statement covers through" (for inpatient claims, this is the discharge date) from the medical record links to a claim on the RADVMCE Report or a RA eligible, paid/positively adjudicated NEC, if applicable.
4 (a-b)	Senior Reviewer – Compare medical record dates of service to linked	The Senior Reviewer compares the results of the medical record to the EDGE server RADVMCE Report or the NEC to ensure that all fields recorded match, using professional judgment.

Step	Description	Additional Details
	claim on the RADVMCE report to identify final inconsistent findings	a. If there is agreement, document results in the *IVA Entity Audit Results Submission XML,* and no additional review is necessary.
		b. If there is a difference, the Senior Reviewer should use professional judgment to determine if the difference is a result of a claims submission error from the provider and the IVA entity may need to reach out to the issuer for clarification. However, a claim with dates prior to the medical record dates of service should be carefully scrutinized before consideration. If the reviewer is able to reasonably determine that a date discrepancy exists only as a result of a billing error, then the Senior Reviewer *IVA Entity Audit Results Submission XML* should record the correct date, but should NOT note a final inconsistent finding. If the reviewer is not able to reasonably determine that a date discrepancy exists only as a result of a billing error, then the Senior Reviewer will reject the record. This may result in the medical record not being coded.

5.6.5.1 Key Considerations for Professional Judgment in Evaluating Dates of Service

If a single date of service between a medical record and claim do not agree, the Senior Reviewer, using his or her professional judgment, may determine that the discrepancy is a result of a provider billing error; this applies to inpatient, outpatient, or professional claims. The intent is to not fail a medical record for not aligning to claim dates due to provider billing errors.

For example, if the Senior Reviewer determines that all facts regarding the services rendered are consistent between the medical record and the claim from the RADVMCE Report or the NEC, if applicable (procedures, diagnoses, individual, etc.), but the single date of service does not directly align, the reviewer may use professional judgment to not indicate an error if this may be the result of a provider billing error.

For the purposes of HHS-RADV, a provider attestation is not required in these circumstances, but the IVA Entity and its reviewers must perform necessary due diligence before making such a determination. The IVA Entity must also explain this determination in workpapers.

5.6.6 Documentation of Capitated Encounter Data

Issuer capitated encounter data may need to be used during the IVA process for medical records linked to RA eligible, paid/positively adjudicated NECs. In Phase 2 – Review and Confirm Mapping (Section 5.4), the IVA Entity must document the path of capitated

encounter data to the EDGE server. The issuer must provide a clear description of how the issuer determined if claims/encounter data submitted was covered by a capitated arrangement. Capitated encounter data may require the documentation of additional workpapers to demonstrate the mapping between EDGE server claims data elements and the encounter data in the issuer system(s). These workpapers should document how the EDGE data was populated for the encounter and how the encounter was allowable within RA criteria.

The issuer must provide documentation as to how the issuer converted encounter data into EDGE claims and if any of the validated fields were derived. This documentation should be documented in a workpaper and identified within the *IVA Entity Audit Results Submission XML.*

Note: Claim dollar values are not validated and, therefore, derived claim paid values are not subject to validation in HHS-RADV.

5.6.7 Acceptable Medical Record Source

The IVA Entity will utilize a medical coder with proper certification to perform Health Status Validations (see Section 1.3 for personnel qualifications). All validations and coding procedures performed by contracted medical coders on behalf of the IVA Entity are to be performed in accordance with best practices and regulatory standards as determined by his/her certifying agency.

IVA Entities and the SVA Entity determine if the claim and the associated medical record are from an acceptable source by reviewing the claim form type to determine if it is an institutional (for example, a hospital inpatient or outpatient facility) or professional (for example, an individual physician or group practice) claim.

For institutional claims, IVA Entities and the SVA Entity review the bill type code to determine if the claim is allowable. For professional claims, IVA Entities and the SVA Entity note that the claim is a professional claim and no additional review is necessary. See Table 10 and 11 for the allowable and non-allowable bill type codes for RA data submission. Note that issuers should follow the EDGE Server Business Rules when submitting bill type codes to their respective the EDGE servers (See ***EDGE Server Business Rules (ESBR) Version 8.0***).

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Table 12: Allowable Bill Type Codes for Institutional Claims

Stay Type	Description	Bill Type Code	Allowable?
Inpatient	Inpatient admit through discharge	111	Yes
Inpatient	Inpatient replacement of prior claim	117	Yes
Outpatient	Hospital outpatient admit through discharge	131	Yes
Outpatient	Hospital outpatient replacement of prior claim	137	Yes
Outpatient	Rural health clinic admit through discharge	711	Yes
Outpatient	Rural health replacement of prior claim	717	Yes
Outpatient	Community mental health center admit through discharge	761	Yes
Outpatient	Community mental health replacement of prior claim	767	Yes
Outpatient	Federally qualified health center admit through discharge	771	Yes
Outpatient	Federally qualified health center replacement of prior claim	777	Yes
Outpatient	Critical access hospital admit through discharge	851	Yes
Outpatient	Critical access hospital replacement of prior claim	857	Yes

Table 13: Not Allowable Bill Type Codes for Institutional Claims

Stay Type	Description	Bill Type Code	Allowable?
Inpatient	Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria)	4XX	No
Inpatient	Medical Assistance Facilities/Critical Access Hospitals	85X	No
Inpatient	Skilled Nursing Facilities	21X	No
Inpatient	Hospital Swing Bed Components	18X	No
Inpatient	Intermediate Care Facilities	15X or 16X	No
Inpatient	Hospice	81X or 82X	No
Outpatient	Rehabilitation Hospitals	74X or 75X	No
Outpatient	Ambulatory Surgical Centers	83X	No
Outpatient	Home Health Care	33X	No
Outpatient	Renal Dialysis Facilities	72X	No
Outpatient	Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria)	3XX	No

Note for HHS-RADV and Mental Health or Behavioral Health Records: As set forth in 45 C.F.R. § 153.630(b)(6), as amended by the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule, a qualified provider that is licensed to diagnose mental illness by the State and that is prohibited from furnishing a complete medical record by applicable State privacy laws concerning any enrollee's treatment for one or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable Federal and State privacy laws, should contain: (1) the enrollee's name; (2) sex; (3) DOB; (4) current status of all mental or behavioral health diagnoses; **and** (5) dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable State privacy laws. Psychotherapy notes are not required for RADV.[14]

Table 14: Allowable Facility Type Testing

Step	Description	Additional Details
1 (a-b)	Primary Coder – Identify linked claim type and identify errors	The Primary Coder identifies if institutional or professional type from the medical record and claim.
		a. If the type is institutional, the Primary Coder reviews the bill type code from the claim to determine if the claim is allowable per the institutional claims table (Table 12 and 13), and records their findings.
		b. If the type is professional, the Primary Coder does not need to consult the table and will record that the MR is from a Valid RA Source.
2 (a)	Primary Coder – Record results and documen	The Primary Coder, based on the review performed, determines if the MR is from a valid RA source, and records the findings.
		a. If the Primary Coder finds the MR is not from a valid RA source, then the record is flagged for review by the Senior Coder for a final determination.
3 (a-b)	Senior Coder – Identify linked claim type and identify errors	The Senior Coder identifies if institutional or professional type from the medical record.
		a. If the type is institutional, the Senior Coder reviews the bill type code from the claim to determine if the claim is allowable per the institutional claims table.
		b. If the type is professional, the Senior Coder does not need to consult the table and will record that the MR is from a Valid RA Source in the *IVA Entity Audit Results Submission XML*.
4 (a)	Senior Coder – Record results and document errors	*a.* The Senior Coder, based on the review performed, determines if the claim is from a valid RA source, and records the result in the *IVA Entity Audit Results Submission XML* The results from the Senior Coder's review are considered the final determination.

[14] "Psychotherapy notes" is defined as notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. The term excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. See 45 C.F.R. § 164.501.

5.6.7.1 Key Considerations for Validating Medical Records without Bill Types or Service Codes

In the instance where the medical record does not contain the specific information or detail necessary to link a medical record to an acceptable claim (e.g. a Service Code/Bill Type not in a medical record, but on a claim form), RADVMCE Report data may be utilized to satisfy the validation step. Obtaining additional claim documentation or billing documentation is not required for Health Status Validations. IVA Entities may utilize the RADVMCE Report to identify the associated information (e.g., a service code) for the claim linked to the medical record under review.

In this case, the IVA Entity should reference the RADVMCE Report and, using professional judgment, review the medical record in conjunction with the information contained on the RADVMCE Report to determine if the validation can be confirmed. Alternatively, for NECs not identified in the RADVMCE Report, a claim data file may be used for evaluation when the information being validated is not present in the medical record. For Health Status Validations, procedure steps referencing the “claim” may be replaced with the RADVMCE Report reference.

5.6.8 Recommended Documents for Medical Record Abstraction Submission

CMS recommends that the following documents be abstracted from medical records and submitted into the Audit Tool during the IVA Submission Process. These documents, if submitted separately from, or in lieu of, a medical record must be able to independently substantiate the diagnoses found on the RADVMCE Report or non-EDGE claims. CMS recommends providing the complete medical record of an inpatient stay which should follow the guidance within this section. It is important to note that list below includes examples of acceptable sources from which reviewers can capture diagnosis codes, and is not an exhaustive list of documents:

- Progress Notes
- History & Physical
- Discharge Summary
- Consultation Reports
- Operative / Procedure Notes

NOTE: The following documents **cannot,** on their own, be used to substantiate a diagnosis. However, they may be used in conjunction with other medical documentations to help substantiate a diagnosis:

- Pathology Reports
- Physician Orders
- Medication List
- Radiology (can be useful to target the code, i.e. type of fracture)
- Medication Administration Record (MAR)

Diagnosis codes will **not** be captured from the following sources of documentation and therefore should be **excluded from submission**:

- Nurse notes
- Flow sheets
- Photos (including photos of wounds or infants)

- Labs
- Discharge instructions

5.6.9 Acceptable Service Code Validation (Outpatient and Professional Medical Records Only)

The service code is validated from the medical record to ensure that the service code is acceptable per the risk adjustment business rules. The service code qualifier, found on the RADVMCE Report, identifies if the code is Current Procedural Code/Healthcare Common Procedure Coding System (CPT/HCPCS).

For hospital outpatient bill types and physician/professional services, the service code displays the code that was used for the procedure performed during the visit for the enrollee. Medical records may not contain the CPT/HCPCS, in which case the IVA Entity must gain an understanding of how those codes were obtained, such as evidence of a claim submission. IVA coders must determine if the medical record confirms that a valid RA service was performed.

Note that the purpose of Service Code Validation is to determine if the Service Code assigned is RA Acceptable. No other validation of the service code is required to be performed (i.e. if the correct management level code was appropriately assigned).

Table 15: Acceptable Service Code Validation Steps

Step	Description	Additional Details
1	Primary Coder – Identify service	The Primary Coder identifies the service code on the medical record.
2	Primary Coder – Compare service code data to EDGE server data	The Primary Coder compares the service code from the medical record to the service code on the associated claim in the RADVMCE report, or to the NEC if applicable.
3 (a)	Primary Coder – Identify errors and document errors	The Primary Coder determines if the service provided per the analysis of the medical record is a valid RA service and record the findings in the IVA Entity Audit Results Submission XML. a. If the Primary Coder finds a discrepancy between the service documented in the MR and the service code in the RADVMCE report or the NEC, then the record is flagged for review by the Senior Coder for a final determination.
4	Senior Coder – Identify service code data.	The Senior Coder identifies the service code on the medical file.
5	Senior Coder – Compare service code data to the EDGE server.	The Senior Coder compares the service code from the medical record to the service code on the associated claim in the RADVMCE report, or to the NEC if applicable.
6 (a-b)	Senior Coder – Identify errors and document final errors.	The Senior Coder determines if the service provided per the analysis of the medical record or claim is a valid RA service and documents the findings in the *IVA Entity Audit Results Submission XML*.
		a. The results from the Senior Coder's review are considered the final determination.

Step	Description	Additional Details
		b. If the Senior Coder is unable to validate the service is RA eligible than the MR is rejected.

5.6.10 Acceptable Medical Record Signature

When gathering medical records from providers to substantiate an HCC, issuers and IVA Entities must be aware of the various provider types and physician sources that are acceptable for the HHS-RADV testing.

A provider is defined as a physician, or any qualified healthcare practitioner, who is legally accountable for establishing the patient's diagnosis in a State.

All medical records must have an acceptable provider signature and credentials displayed on the document. Electronic signatures dated greater than 180 calendar days from the encounter date must include a valid attestation in order for medical record review to continue.

If the medical record is signed, but the provider's name and credentials are not present, coders are unable to determine whether the beneficiary was evaluated by an acceptable provider. This type of medical record documentation is considered incomplete and may result in a risk adjustment error. However, if the signature is present and the provider's credentials are not identified on a medical record, a directory or signature log containing the issuer's contracted healthcare providers listing the name and credentials of the provider would be acceptable to validate the credentials.

For the purposes of HHS-RADV, we define a signature log as a log that identifies the author associated with initials. The signature log might be included on the actual page where the initials are used or might be a separate document. Reviewers should consider all submitted signature logs regardless of the date they were created.

In the course of a face-to-face or telehealth visit, medical record documentation is required to be generated, documented, and authenticated by a permitted provider. The method used to authenticate must be a handwritten or electronic signature. Stamped signatures are not acceptable.

The criteria for an allowable medical record or attestation that is signed by a provider are discussed in the table below. CMS will not provide an attestation template. Issuers are responsible for providing the attestations, if used.

Table 16: Allowable Provider Signature Types

Type	Allowable
Handwritten signature, including credentials	Full Name: Mary C. Smith, MD
Electronic signature, including credentials	Requires authentication by the responsible provider (For example, but not limited to, "Approved by", "Signed by", "Electronically signed by", "Accepted by")
Signed attestation	Attestation on provider letter head or attestation furnished by the issuer.

*See section "Medical Record Attestations" for additional detail.

Table 17: Unallowable Signature Types

Type	Unallowable unless…
Typed name	Authenticated by the provider as prescribed in the above table
Non-physician or non-physician extender (for example, medical student)	Co-signed by acceptable physician as prescribed in the above table
Provider of services' signature without credentials	Name is linked to provider credentials or is on provider's stationery as prescribed in the above table

5.6.10.1 Key Considerations for Medical Record Attestations

CMS will also accept attestations to authenticate medical documentation that was not authenticated at the time of service. Specifically, if a signature is missing, the IVA Entity may consider evidence in an attestation statement to determine the identity of the author of a medical record entry.

Issuers and IVA Entities should establish a process to resolve conflicts if a medical record does not contain a valid signature and/or credentials. Part of the resolution should include issuers and/or IVA Entities requesting an attestation from the provider affirming the medical documentation that was not authenticated properly at the time of service. Signature attestations allow diagnoses to be abstracted and coded from medical records that do not contain acceptable signatures or credentials.

IVA Entities should still abstract diagnoses from the medical record with signature or credential issues while attestations are being sought. However, if an attestation cannot be obtained to validate the medical record, the medical record and abstracted diagnoses remain invalid, and therefore should not be submitted via the *IVA Entity Audit Results Submission XML* for use in the enrollee's risk score calculation.

The issuer or IVA Entity should include a medical record signature attestation, grouped under the medical record ID it corresponds to, in the *IVA Entity Audit Results Submission XML.*

CMS will allow for the attestation document to be submitted as a separate file or consolidated with the medical record PDF. At a minimum, the attestation statement must contain the signature and date. DO NOT include the issuer name.

Coders will not consider attestation statements where there is no associated medical record entry or from someone other than the author of the medical record entry in question. Even in cases where two (2) individuals are in the same group, one (1) provider may not sign for the other in medical record entries or attestation statements.

Note: Table 18 "Provider Situations for Medical Record Attestations" summarizes acceptable signature requirements and alternatives.

Table 18: Provider Situations for Medical Record Attestations

Item	Signature Description	Signature Requirement Met	Signature Attestation May Apply
1	Full signature and credentials included	X	
2	First initial and last name, credentials included	X	
3	Initials over a typed or printed name	X	
4	Unsigned handwritten note, the only entry on the page		X
5	Unsigned handwritten note where other entries on the same page in the same handwriting are signed	X	
6	“Signature on File”		X
7	Electronic Medical Record with notation “Auto Authenticated”		X

If the proper credential(s) are missing, an attestation is needed to fulfill the signature requirement.

5.6.10.2 Key Considerations for Telehealth

Valid Telehealth Services

For the purposes of RA data submission, and subsequent data validation under HHS-RADV, any service provided through telehealth that is reimbursable under the state law of the issuer’s state of licensure that otherwise meets RA data submission standards may be submitted. As such, IVA Entities should also apply these verification steps when encountering telehealth services during the IVA for HHS-RADV.

Step	Description
1	Confirm that the applicable state insurance law regarding telehealth services requires or permits issuer reimbursement for telehealth services. The applicable state insurance law would be the law of the state of licensure of the issuer.
2	Confirm that the provider is a valid telehealth provider under state insurance law in the state of licensure of the issuer. Telehealth rules typically specify those providers that are allowed, such as physicians, certain categories of nurses, and certain mental health professionals. A telehealth provider should also meet any applicable licensing requirements in the state in which he or she practices and the state in which the patient is located.
3	Verify the diagnosis and procedure code(s) for which the telehealth service was rendered and follow all applicable coding guidelines.

5.6.11 Diagnosis Abstraction Coding

CMS seeks to promote consistency across the HHS-RADV process. As such, the SVA Entity, in accordance with industry standards, utilizes the following: American Hospital Association's (AHA) Coding Clinic in combination with the ICD-10-CM Official Guidelines for Coding & Reporting for diagnosis abstraction and the companion document ICD-10-CM

Official Guidelines for Coding & Reporting that is provided by CMS and National Center for Health Statistics (NCHS).

It is important to note that although reimbursement methods may vary by state, diagnosis coding should be assigned based on ICD-10-CM Official Coding Guidelines for Coding and Reporting. As such, CMS requires that medical record abstraction coding be conducted by certified medical coders, certified after examination by a nationally recognized accrediting agency for medical coding.

In accordance with the ICD-10-CM Official Guidelines for Coding & Reporting, in order to be coded as a diagnosis, a condition must be clinically evaluated at the time of the encounter or affect patient care or management of the patient, and it must be properly documented. The AHA Coding Clinic may be used in combination with the ICD-10-CM Official Guidelines for Coding & Reporting and the ICD-10-CM Coding guidance document.

Considerations Related to Chronic Conditions

For the purposes of HHS-RADV, the following guidance from the ICD-10-CM Official Guidelines for Coding and Reporting should be used for abstracting chronic conditions from medical records.

The ICD-10-CM Official Guidelines for Coding and Reporting specific to outpatient services provides guidance to code, “all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. History codes may be used as secondary codes if the historical condition or family history have an impact on the current care of influences treatment. Chronic diseases treated on an ongoing basis may be coded and reported as many times as the patient receives treatment and care for the condition(s).”

The following is an excerpt from the 2017 ICD-10-CM Official Guidelines for Coding and Reporting. The information documented below should be utilized when abstracting diagnoses related to outpatient services:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

G. ICD-10-CM code for the diagnosis, condition, problem, or other reason for encounter/visit

List first the ICD-10-CM code for the diagnosis, condition, problem, or other reason for encounter/visit shown in the medical record to be chiefly responsible for the services provided. List additional codes that describe any coexisting conditions. In some cases, the first-listed diagnosis may be a symptom when a diagnosis has not been established (confirmed) by the physician. (ICD-10-CM, 2017)

J. Code all documented conditions that coexist

Code all documented conditions that coexist at the time of the encounter/ visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (categories Z80-Z87) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment

(ICD-10-CM, 2017).[15]

In addition, although neoplasms are not on the listing of HCCs that may be considered chronic for HHS-RADV in Appendix C, the following is an excerpt from the 2017 ICD-10-CM Official Guidelines for Coding and Reporting that should be utilized when abstracting diagnoses related to neoplasms:

Section I. Conventions, General Coding Guidelines and Chapter Specific Guidelines

C. Chapter-Specific Coding Guidelines 2. Chapter 2 Neoplasms (C00-D49)

m. Current malignancy versus personal history of malignancy: When a primary malignancy has been excised but further treatment such as additional surgery for the malignancy, radiation therapy or chemotherapy is directed to that site, the primary malignancy code should be used until treatment is completed.

When a primary malignancy that has been previously excised or eradicated from its site, there is no further treatment (of the malignancy) directed to that site, and there is no evidence of any existing primary malignancy, a code from category Z85, Personal history of malignant neoplasm, should be used to indicate the former site of the malignancy.[16]

Coding Chronic Conditions

As previously stated, the ICD-10-CM Official Coding Guidelines for Coding and Reporting and the Protocols must be followed when considering the applicability of the underlying diagnoses for chronic conditions. For purposes of HHS-RADV, CMS considers a chronic condition as lasting for a year or more and requiring ongoing medical attention. CMS also utilized the Chronic Condition Indicator developed by the Agency for Healthcare Research and Quality (AHRQ) to develop a list of HCCs in the HHS-RA models that CMS considers to be chronic conditions. See Appendix C for a listing of HCCs that may be considered chronic for HHS-RADV. A chronic condition from this list may be coded for an enrollee based on a face-to-face visit documented in the medical record. The chronic conditions must be documented in a way that it is reasonable to determine that a physician is managing the patient and treating the chronic condition for **the benefit year that is being audited**.

Coders should utilize these Protocols and ICD-10-CM coding guidelines when determining chronicity of a diagnosis.

Below are some recommended steps to follow:

Step 1: Is the condition chronic or acute? If chronic, proceed to Step 2. Reference Appendix C for a listing of HCCs that **may be** considered chronic for the purposes of HHS- RADV.

Step 2: If chronic, is the condition still present?

Step 3: If unsure, is there documentation of current medication treatment or other management of the condition? Examples of this would include: a current problem

[15] 2017 ICD-10-CM Official Guidelines for Coding and Reporting FY2017 (October 1, 2016 – September 30, 2017)
[16] 2017 ICD-10-CM Official Guidelines for Coding and Reporting FY2017 (October 1, 2016 – September 30, 2017)

list or past medical history, encounter/progress notes, medical management list or medication lists. Chronic conditions affect the medical decision making of providers when considering treatment options for other presenting problems. This includes considering current treatments and /or medications being taken for those chronic conditions, and the risk/benefit analysis of medical decision making for the treatment options of any other comorbidities.

Step 4: Do the current provider encounter notes contradict or further specify the condition?

Step 5: If the condition is chronic and there is no documentation that contradicts or shows the condition is resolved, then the condition can be abstracted. A chronic condition is assumed to be present if it is documented in any portion of the medical record.

Problem lists (active, ongoing, current, etc.) must reside within an encounter note, as a part of the medical record and not a standalone listing, for the date of service of a face-to-face visit. CMS recognizes that problem lists may be utilized differently based on the provider and method of capturing (electronic health records or paper charts) and encourages the use of ICD-10-CM Coding Guidelines for final guidance.

Past Medical History (PMH) may also be utilized differently, as some providers use these lists to document all current and past diagnoses, while other providers attempt to use them for PMH or resolved conditions only. A diagnosis listed in PMH must be supported as either a life-long permanent condition or have additional supporting documentation elements within the same date of service (since each date of service stands on its own), such as medication which is documented for the diagnosis or used only to treat the diagnosis in question. Such diagnoses considered to be current should be coded as a part of the enrollee's risk profile.

"History of" statements documented in the encounter in the format of Chief Complaint (CC) or History of Present Illness (HPI) such as *"Ms._____is here today for her history of x"* should not be handled in the same manner as PMH lists. Such statements found within a MR under the CC or HPI section establish the reason for the visit by including those histories of items as a part of the review in the encounter.

A few examples are provided, but are not meant to be exhaustive.

Example 1: An internist's medical record has been submitted for medical record review for a 30-year-old female with a history of Lupus. The medical record problem list has Lupus recorded in the medical record. The problem list is dated 02/12/2017 and has been incorporated into the encounter note signed by the eligible provider. In this case, Lupus can be abstracted from the medical record even though no claims indicating the treatment of Lupus have been submitted to the issuer's EDGE server as Lupus is a life-long, permanent condition.

Example 2: A hospital outpatient medical record is being reviewed by an IVA Entity. The patient was receiving treatment for breast cancer on 4/20/2017. The service provided was administration of chemotherapy and a diagnosis code of adenocarcinoma of the left breast (C50.912) was present. During the visit, a diagnosis of diabetes was also recorded as a co-morbidity. The medical record denotes an eligible provider signature for the visit. In this case, diabetes and adenocarcinoma can be submitted because the service provided was chemotherapy, with a diabetes comorbidity and glyburide is listed under current medications.

Example 3: A hospital outpatient medical record is being reviewed by an IVA Entity. The service provided was a colonoscopy and a diagnosis code of colon polyps (K63.5) was present. The past medical history includes a 2011 diagnosis of breast cancer and a double mastectomy. The medical record denotes an eligible provider signature for the visit. In this case, colon polyps (K63.5) can be submitted and because there is no additional evidence to show breast cancer is still present or under treatment, Z85.3 (personal history of malignancy neoplasm of breast) would be assigned in accordance with the ICD-10-CM Official Coding Guidelines for Coding and Reporting as referenced above.

Example 4: A medical record has been submitted for a 62-year-old male for a cardiology visit to check the patient's status of congestive heart failure (CHF). The medical record shows a note about past medical history of diabetes (E11.9) and documentation of current medication for diabetes with current disease management. In this case, diabetes and CHF should be coded.

Example 5: Chief Complaint: An enrollee has a face-to-face visit with an eligible provider for a follow-up of the enrollee's diabetes, who also has a history of CHF and chronic obstructive pulmonary disease (COPD). The CHF and COPD are being noted as a part of the medical decision-making in the opening statement. Daily medications include Lasix and Combivent. These are chronic conditions that are also a part of the medical decision-making of the diabetic visit and should be coded.

Example 6: From the ICD-10-CM Official Guidelines for Coding and Reporting, Chapter 17: Congenital malformations, deformations, and chromosomal abnormalities (Q00-Q99): "…Codes from Chapter 17 may be used throughout the life of the patient. If a congenital malformation or deformity has been corrected, a personal history code should be used to identify the history of the malformation or deformity." Example – Twelve-year-old patient is in for a physical exam. Physician documents transposition of the great arteries. Surgical history lists status post repair of the transposition of the great arteries as an infant. Code assignment Q20.3 (transposition of great vessels) would not be assigned. Code Z87.74 (personal history of [corrected] congenital malformations of heart and circulatory system) would be assigned.

Example 7: Diabetes with Chronic Complication is listed as a Chronic Condition HCC in Appendix C, as stated in the AHA Coding Clinic 2Q 2016, *"The sub term 'with' in the Index should be interpreted as a link between diabetes and any of those conditions indented under the word 'with'. The physician documentation does not need to provide a link between the diagnoses."* Example - A medical record was submitted with a patient who has a PMH of diabetes mellitus (DM) and neuropathy. Given that ICD-10-CM presumes a causal relationship between diabetes and neuropathy (unless the physician states otherwise), DM with neuropathy should be coded (E11.40).

Example 8: Immunodeficiencies- The AHA Coding Clinic 3Q 2015 states the following:

"Do not assign a code for immunocompromised state caused by drug treatment or an underlying disease process, such as AIDS, cancer, etc. When a patient is taking immunosuppressant medication as prescribed, the intent is to suppress the immune system. Assign code Z79.899, Other long-term (current) drug therapy, to show the long-term use of immunosuppressants. The ICD-10-CM does not provide a specific code to identify these drugs. Immunosuppressants are commonly used to treat autoimmune diseases, such as Lupus, Crohn's disease, myasthenia gravis, rheumatoid arthritis, etc. and they are also used to prevent organ rejection in transplant patients."

Example 9: A medical record was submitted for physician office visit where the patient has a PMH of lymphoma and a history of a bone marrow transplant. The patient is currently on immunosuppressive medication and the physician documents the patient as 'immunocompromised'. Code assignments of Z85.72 (history of lymphoma), Z94.81 (Bone marrow transplant status) and Z79.899 (other long-term [current] drug therapy) should be captured. Code assignment D89.9 (Disorder involving the immune mechanism, unspecified) would not be assigned based on the AHA Coding Clinic guidance as the immunosuppressive drug treatment is for the underlying disease/transplant.

5.6.12 Abstraction Coding

The final step in the Health Status Data Validation process is to review the medical records and abstract substantiated diagnoses. The previous test steps ensure that the medical record is signed appropriately and that an acceptable type of physician or non-physician provider has performed the diagnosis.

In this step, the coder reviews a medical record to abstract diagnosis codes which are used to validate the enrollee's HCCs.

ICD-10-CM diagnosis codes are used to describe the clinical reason for a patient's treatment. ICD-10-CM codes do not describe the service performed, only the patient's medical condition. Coders will first code all medical records for the applicable enrollee per the applicable ICD-10-CM code set. Once the ICD-10-CM codes are abstracted from all the enrollee's medical records, the codes need to be mapped to HHS-HCCs using the 2017 Benefit Year HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software to allow for error identification versus EDGE server data. As a reference, the HHS DIY Software instructions, and Technical Details, which includes the ICD-10 to HHS-HCC mappings, can be found on the CCIIO homepage.[17]

Enrollee HCCs validated by the IVA Entity are then compared to enrollee level EDGE server detail report data found in the RADVDE Report. The RADVDE Report contains all diagnoses and HCCs for each enrollee in the IVA sample. The Primary Coder will indicate the following:

- Supported HCCs
- Newly identified HCCs
- Unsupported HCCs

Newly identified HCCs are characterized as HCCs that are identified by the Primary Coder that are not on the RADVDE Report. Unsupported HCCs are characterized as HCCs that are on the RADVDE report, but are not identified on medical documentation after review by the Primary Coder. The below table outlines the steps for diagnosis validation. Note that IVA Entities have the option to choose whether to escalate the single medical record that contains a newly identified HCC or escalate all medical records for an enrollee to Senior Coders for re-review.

Please note, CMS cannot provide specific coding guidance beyond what has been released in these Protocols. CMS encourages the utilization of the ICD-10-CM Official Guidelines for Coding and Reporting, the AHA Coding Clinic, and the HHS-RADV 2017

[17] 2017 Benefit Year DIY Software Instructions https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-Instructions-2017.pdf and 2017 Benefit Year DIY Software Technical Details https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Details-2017.xlsx

benefit year Protocols, along with professional judgment to make final determinations when abstracting diagnoses. Historical best practice utilizes inpatient guidelines for an inpatient record and outpatient guidelines for an outpatient record.

For the current HHS-RADV benefit year, CMS is only requiring final IVA Entity diagnoses be recorded in the *IVA Entity Audit Results Submission XML*. If an enrollee's medical records are reviewed by both a Primary and Senior Coder, only the final diagnoses are required to be submitted to CMS. The RADV XML Data Elements Job Aid located in the Audit Tool library provides further detail on the technical requirements for submission.

Table 19: Diagnosis Validation

Step	Description	Additional Details
1	Primary Coder – Abstract diagnoses.	The Primary Coder identifies the ICD-10-CM diagnoses from the medical record, for all of the enrollee's medical records, and records the diagnoses in the *IVA Entity Audit Results Submission XML**.
2	Primary Coder – Map diagnoses to HCCs.	The Primary Coder maps the identified ICD-10-CM diagnoses from the medical records to their assigned HCCs.
3	Primary Coder – Collate enrollee HCCs across medical records.	The Primary Coder collates HCCs for each enrollee and removes duplicate HCCs identified. IVA Entities should use these identified HCCs as the basis of comparison to EDGE HCCs, as outlined in Step 4 (a-c).
4 (a-c)	Primary Coder – Compare IVA abstracted HCCs to EDGE server HCCs and identify errors and document results.	The Primary Coder compares the HCCs determined from MR abstraction to the enrollee's HCCs identified in the EDGE server RADVDE report.
		a. The Primary Coder identifies supported HCCs (HCCs in the RADVDE Report which are supported by HCCs assigned to diagnoses abstracted from the medical record). A supported HCC is considered an agreement.
		b. The Primary Coder identifies newly identified HCCs (HCCs assigned to diagnoses following MR abstraction, but which are not present in the EDGE server RADVDE Report). Newly identified HCCs are considered a New Finding.
		c. The Primary Coder identifies unsupported HCCs (HCCs which are present in the EDGE server RADVDE Report but were not assigned to abstracted diagnoses identified during the review of the enrollee's medical records). Unsupported HCCs are considered an error.
5 (a-c)	Primary Coder – Determine requirement of Senior Coder review.	The Primary Coder determines next steps based on the results in Step 4.
		a. If there is agreement between the HCCs identified by the Primary Coder and the EDGE server RADVDE Report, no additional review of the enrollee's medical records is necessary.
		b. If a newly identified HCC is found, the IVA Entity has the option to have the Primary Coder escalate either the individual medical record that contains the newly identified HCC or all medical records for the enrollee to Senior Coders for re-review.

Step	Description	Additional Details
		c. If, after all medical records have been reviewed for the enrollee, and an HCC found on the RADVDE Report has not been substantiated, then all the medical records for the enrollee must be escalated to Senior Coders for re-review. ***Note**: If the Primary Coder abstracts all supported diagnoses that are assigned HCCs, and there is no difference between the RADVDE report and the Primary Coder's findings, then the Primary Coder may record the final medical record diagnoses in the *IVA Entity Audit Results Submission XML.*
6	Senior Coder – Abstract diagnoses	For those enrollees for which an unsupported or newly identified HCC were noted: The Senior Coder identifies the ICD-10-CM diagnoses for all of the enrollee's medical records, and record all final diagnoses in the *IVA Entity Audit Results Submission XML.* **Note:** Only final medical record diagnoses, regardless of Primary or Senior Coder review, are required to be recorded in the *IVA Entity Audit Results Submission XML*.
7	Senior Coder – Map diagnoses to HCCs	The Senior Coder maps the identified ICD-10-CM diagnoses from the medical records to their assigned HCCs.
8	Senior Coder – Collate enrollee HCCs across medical records	The Senior Coder collates HCCs for each enrollee, removes duplicate HCCs identified. IVA Entities should use these identified HCCs as the basis of comparison to EDGE HCCs.
9 (a-d)	Senior Coder – Compare IVA abstracted HCCs to EDGE server HCCs and identify final errors	The Senior Coder compares the HCCs to the EDGE server RADVDE Report.
		a. The Senior Coder identifies supported HCCs (HCCs in the RADVDE Report that are supported by HCCs assigned to diagnoses abstracted from the medical record). A supported HCC is considered an agreement.
		b. The Senior Coder identifies newly identified HCCs (HCCs that are determined as valid based on identified diagnosis codes, but which are not present in the EDGE server RADVDE Report). Newly identified HCCs are considered a New Finding.
		c. The Senior Coder identifies unsupported HCCs (HCCs that are present in the EDGE server RADVDE Report, but were not identified during the review of the enrollee's medical records).

Step	Description	Additional Details
		Note: Only final diagnoses, regardless of Primary or Senior Coder review, are required to be submitted via the *IVA Entity Audit Results Submission XML.* No additional indicators regarding errors identified, new HCCs, or unsupported HCCs are required. CMS and the SVA will utilize diagnoses to determine enrollee HCCs and compare to EDGE server HCCs from the RADVDE Report.

For all health status and diagnosis validations performed over sampled enrollees, Primary Coders and Senior Coders are required to work in tandem to identify, validate, and review errors, and to complete IRR (Section 6). While a Senior Coder may act as a Primary Coder, the results of this Senior Coder's review must be reviewed by another Senior Coder so that all errors are always given a second review by a Senior Coder. Additionally, any Senior Coder who acts as the Primary Coder will be subject to IRR testing to ensure that they are meeting IRR consistency measure requirements, as required for all Primary Coders.

Senior Coders may identify additional findings when reviewing sample enrollee records identified as containing errors by the Primary Coder. In these instances, the newly identified findings (identified in addition to the initial Primary Coder errors) do not require additional review and are accepted.

5.6.12.1 Key Considerations for Medical Record Abstraction

Blind Coding

Blind Coding occurs when Primary and Senior Coders conduct the medical record review and diagnosis abstraction without prior knowledge of an enrollee's diagnoses or HCC(s). CMS believes that the practice of blind coding provides a greater potential to identify new diagnoses not previously submitted to the EDGE server, potentially identifying new HCCs for an enrollee, than coding with prior knowledge of the enrollee's previously identified HCCs. While blind coding has the potential to yield new HCCs, it does place a greater burden on the IVA Entity and, potentially, a greater cost to the issuer. Therefore, CMS believes the issuer may decide whether the IVA Entity must conduct the medical record review using a blind coding approach.

New HCC Findings with Positive Risk Score Impact

To more effectively assist CMS in assessing an issuer's outlier status related to validation of diagnoses and their assigned HCCs used in enrollees' risk scores, IVA Entities are encouraged to prioritize the validation of diagnoses attributable to HCCs submitted to EDGE and used in RA risk score calculations. Beginning in 2017 benefit year HHS-RADV, under the HCC Failure Rate Methodology for Error Estimation, the addition of a new diagnosis from medical record documentation that maps to an HCC not previously identified on the RADVDE Report (a non-EDGE HCC) may benefit issuers' failure rate calculation within an HCC group and thus, the issuer's determination of outlier status. If an IVA Entity discovers a diagnosis code during the IVA that was not previously reported to the EDGE server and the diagnosis code maps to a new HCC, the comparison of HCCs identified by the IVA Entity to EDGE server RADVDE Report HCCs will result in a new HCC finding. While discovery of a new HCC during the audit process is technically an "error," the newly found HCC will lower the HCC Group Failure Rate which could potentially impact the issuer's outlier status.

However, the impact of newly identified HCCs is not a significant factor in the calculation of an issuer's HHS-RADV final Error Rate and would not correlate to the magnitude of the newly added HCC's risk score factor. Please refer to Section 7 for additional details regarding the HCC Failure Rate Methodology. IVA Entities are encouraged to prioritize the validation of diagnoses that map to HCCs identified on the RADVDE Report rather than searching for newly identified diagnoses. However, it is at the discretion of the issuer and IVA Entity to determine practices and policies related to validation of non-EDGE HCCs and targeting of HCCs identified in the RADVDE Report to validate.

Addressing HCC Errors and Additional Medical Record Chart Requests

When the diagnoses that are abstracted during the IVA process are compared to corresponding HCCs on the RADVDE Report, errors may be identified indicating that additional records need to be retrieved in order to fully validate all RADVDE Report HCCs.

In these situations, issuers may use additional medical records to substantiate these HCCs as needed during the IVA process. In the event the comparison to the EDGE server RADVDE Report HCCs reveals HCCs not substantiated, the issuer or IVA Entity is able to pull additional medical records to substantiate these HCCs, as long as the records are associated with a paid/positively adjudicated claim on the RADVMCE Report, or an RA eligible claim, or a paid/positively adjudicated NEC from the issuer's source system or 2017 benefit year HHS-RADV.

Additional medical records provided in these situations are still subject to all validation requirements in the HHS-RADV process, including medical record intake, abstraction, and collation of results for comparison to the enrollee's HCCs listed in the RADVDE Report. Furthermore, these additional medical records must be accounted for during the submission of the audit findings and will not be allowed after January 11, 2019 (in accordance with the 2017 RADV Timeline).

SOAP Notes Acceptability

For the purposes of HHS-RADV, Subjective, Objective, Assessment, and Plan (SOAP) notes are acceptable as a stand-alone medical record. However, SOAP notes are permissible as a stand-alone record **only** if they meet all criteria of an acceptable medical record for RA, as defined in the HHS Notice of Benefit and Payment Parameters for 2015 Final Rule.

Death Summaries

Death summaries are allowable forms of medical record documentation for HHS-RADV. A death summary is, as the term states, a summation and may not include every diagnosis during a hospital stay or adequately support patient diagnoses. Often times, death summaries contain a 'listing' of diagnoses without addressing or evaluating the diagnosis(es), which is a requirement to substantiate a diagnosis for RADV.

A death summary submitted for HHS-RADV should be sufficient to support the diagnoses submitted to the EDGE server if it is intended to be utilized as a stand-alone medical record document to substantiate an HCC. If a submitted death summary does not support the diagnoses submitted to the EDGE server, then the medical record detailing the entire stay is needed in order to properly code for the inpatient stay.

5.7 Record Validation Results – Phase 5

At the conclusion of the Demographics and Enrollment Data Validation and the Health Status Data Validation processes, results will be documented in the *IVA Entity Audit Results Submission XML*. Supporting documentation and workpapers generated during D&E Data Validation and NEC Data Validation must be submitted in the Package 1 submission along with the *IVA Entity Audit Results Submission XML* at the conclusion of the IVA. All mapping documentation utilized during these processes will also be submitted as part of Package 1.

Medical record documentation utilized during the Health Status Data Validation process is part of Package 2 submission process and will not be submitted with Package 1 submission. After IVA results submission and Package 1 submission, CMS will identify specific enrollees for whom medical records are to be submitted for the SVA. If CMS determines that the precision is low after SVA review, CMS may request Package 3 submission of the additional medical records that were not submitted during Package 2 submission. If CMS requests the submission of Package 3, IVA Entities and issuers will have seven (7) calendar days to complete the submission of medical records, inclusive of Issuer SO sign off.

5.7.1 Key Considerations for Recording Validation Results

Diagnosis Validation Submission

IVA Entities are required to follow all audit steps as indicated in 5.6.12 Abstraction Coding but only final Coder diagnosis are required to be submitted in the *IVA Entity Audit Results Submission XML.* CMS is not requiring that both Primary Coder and Senior Coder diagnosis codes be submitted in the *IVA Entity Audit Results Submission XML.* Instead IVA Entities are to determine the final diagnosis codes and submit those final diagnosis codes under the Senior Coder Diagnosis Codes section of the *IVA Entity Audit Results Submission XML.*

File Naming and Submission Considerations

All files submitted during the IVA submission process must be uniquely named. The Audit Tool does not distinguish case sensitivity in the file name. For example, “RADV123.pdf” and “radv123.pdf” would be recognized as the same file name. CMS recommends that files possess a comprehensible link to each IVA submission package (for example, a HIOS ID in the file name for all files submitted for a single HIOS ID), but this is not required. Specific situational guidance will be provided at a later date within the HHS-RADV Audit Tool related to audit findings and supporting document submission format.

Medical Record Documentation Submission

Issuers and IVA Entities should submit only the medical records needed to substantiate each diagnosis and assigned HCC reported in the RADVDE Report for the enrollees in the IVA Sample. Issuers and IVA Entities should not submit duplicate medical records for an enrollee multiple times in the *IVA Entity Audit Results Submission XML.* Only unique medical records for an enrollee should be captured in the *IVA Entity Audit Results Submission XML.* Refer to the HHS-RADV IVA Submission Process User Manual located in the Audit Tool File Library for information regarding acceptable file sizes. Failure to retrieve medical records may impact audit results due to lack of evidence necessary substantiate submitted diagnoses.

Documenting Strata 1-9 Enrollees without Medical Records

If an issuer is unable to obtain any medical records for an enrollee in the IVA sample that was expected to have one (1) or more HCCs based on their EDGE server data, issuers or IVA Entities may provide a mapping document to CMS to document their inability to obtain any medical records for the specified enrollees. This document is not a requirement and is optional for submission.

The mapping document would identify Strata 1-9 enrollees impacted and provide supporting rationale for why the medical records were not or could not be obtained, and were therefore not included in the *IVA Entity Audit Results Submission XML*. Enrollees in Stratum 10 do not have EDGE HCCs and therefore should not be included in this document.

If the mapping document is utilized it should contain the following elements:

Components of the "Strata 1-9 Enrollees Without Medical Records" Document
Unique Enrollee ID of Strata 1-9 enrollees for whom no medical records were obtained
Written confirmation that, for the enrollees identified, no medical records were submitted despite being in the IVA Sample with diagnoses and HCCs on the EDGE server.
Explanation of why the enrollee's medical record was not reviewed. Example: "Unable to obtain record from provider."

If the issuer decides to submit a mapping document, the IVA Entity should record the document under the 'mappingDocumentItem' tag and utilize the 'fileType' of 'Other Map' in the *IVA Entity Audit Results Submission XML*. If issuers and IVA Entities utilize this mapping document, CMS encourages the use of a descriptive file name (e.g. *EnrolleesWithMissingMRs.pdf*) for the title of this document.

Section 6

HHS Risk Adjustment Data Validation Protocols

Inter-Rater Reliability

6 Inter-Rater Reliability

6.1 Purpose

Section six (6) provides a detailed overview of the Inter-Rater Reliability (IRR) process steps, sampling approach, and reporting requirements for IRR determinations on the Health Status Data Validation, as described in Section 5.6. The purpose of IRR is to determine the accuracy of the abstraction diagnoses by Primary Coders when compared to Senior Coders. IRR measures the consistency between coders by comparing the mapped HCCs assigned to the diagnoses found on medical records, using the ICD-10-CM coding guidelines and HHS-RADV Protocols. Medical records reviewed by the Primary Coder and sampled for IRR are then re-reviewed by a Senior Coder. The comparison of HCCs assigned to diagnoses found between the Primary Coder and the Senior Coder are then used to determine the Primary Coder's IRR consistency measure. Effective starting with the 2017 benefit year HHS-RADV, CMS requires that IVA Entities achieve a consistency measure of at least 95% for all Primary Coder review outcomes, increased from the 85% utilized during the pilot 2015 and the 2016 benefit years of HHS-RADV.

The IRR process is a quality control measure to check the consistency and agreement in the application of medical coding requirements. IRR determinations provide assurance to CMS and issuers that certified medical coders are consistent in their performance of the Health Status Data Validation process. IRR results are calculated and submitted for an IVA Entity and are not specific to a HIOS ID. IRR results are submitted independent from issuer IVA findings.

Changes to the methodology for submission and documentation of the IRR Process are documented in Section 6.2.

6.2 IRR Submission and Documentation

This section contains guidance for IVA Entities related to consistency measurement requirements for IRR, along with submission and documentation procedural changes effective starting with the 2017 benefit year HHS-RADV.

Based on IRR feedback provided by IVA Entities from the HHS-RADV pilot years and with the intent of reducing burden on IVA Entities and their operational processes, CMS has modified the recommended approach for IRR Sampling and Evaluation. Specifically, the sampling methodology has been updated to use medical records as the basis for sampling, as opposed to HCCs (used in the 2015 and 2016 benefit years of HHS-RADV). This will be subsequently referenced as the "CMS recommended IRR methodology" and is defined in Sections 6.3 and 6.4.

Additionally, CMS will permit IVA Entities to use their own standard practices for executing IRR, in lieu of the CMS recommended IRR methodology, as long as the following requirements are satisfied by the IVA Entity's existing process:

- the IVA Entity's procedural process for IRR is documented and included with the IRR submission;
- the IVA Entity calculates the consistency measure for all Primary Coders;
- the IVA Entity requires a consistency measure of 95% for all Primary Coders;
- the IVA Entity requires Senior Coder review of a sample of Medical Records, re-

performing the IRR for any Primary Coder with a consistency measure of less than 95%, until the 95% consistency threshold is met;
- the IVA Entity uses a continuous monitoring process to ensure that the Primary Coders who achieve the consistency measure of 95% maintain this level throughout the entirety of the review;
- the IVA Entity calculates the consistency measure using the appropriate secondary review process, in accordance with all experience requirements for Senior Coders; and
- the IVA Entity maintains evidence that IRR reviews are being executed and evaluated in accordance with these guidelines.

IVA Entities who elect to use the CMS recommended IRR methodology, documented in Sections 6.3 and 6.4, will not be required to submit a summarization of their IRR procedural processes to CMS during IRR submission.

Independent of the IRR methodology used, IVA Entities will be required to submit Primary Coder results to CMS, including final consistency measures, at the conclusion of the IVA process. CMS will require that the IVA Entity indicate the IRR methodology used ('CMS recommended' or 'Other'), along with a written summarization of the IVA Entity's IRR process if the 'Other' option is chosen. This written summarization must be included with the IRR submission to the Audit Tool. IVA Entities will be required to attest to the methods used as well as to the consistency measures communicated for Primary Coders in their results to CMS, independent of the IRR methodology utilized ('CMS recommended' or 'Other'). All IVA Entities must also attest that Primary Coders who are unable to meet IRR consistency measure requirements had all medical records re-reviewed by a Senior Coder.

For details on the CMS recommended IRR process, please refer to Sections 6.3 and 6.4, below.

6.3 IRR Process Steps

Figure 4 depicts the five main steps of the CMS recommended IRR methodology. The steps are linear with a feedback loop based on the calculated consistency measure for the Primary Coder.

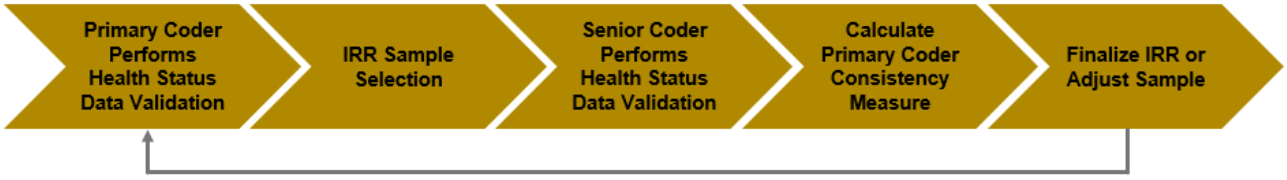


Figure 4: CMS Recommended IRR Methodology – IRR Process Steps

The five (5) main steps of the CMS recommended IRR process are described below.

Table 20: CMS Recommended IRR Process Steps

Step	Description	Additional Details
1	Primary Coder Performs Health Status Data Validation	Primary Coders perform Health Status Data Validations, and the number of medical records evaluated by each Primary Coder is monitored. The IRR sample selection process is initiated once twenty-five (25) medical records have been evaluated by the Primary Coder.
2	IRR Sample Selection	Once twenty-five (25) medical records have been evaluated by the Primary Coder, the initial sample of twenty-five (25) medical records are evaluated by the Senior Coder.
3	Senior Coder Performs Health Status Data Validation	The Senior Coder performs Health Status Data Validations, including diagnosis coding and abstraction for each medical record in the sample. Once Senior Coders complete the Health Status Data Validation for all twenty-five (25) sampled medical records, the consistency measure for the Primary Coder is calculated, as seen in Step Four (4).

4	Calculate Primary Coder Consistency Measure	Following Primary Coder and Senior Coder review, HCCs are assigned to abstracted ICD-10-CM diagnoses to enable calculation of the Primary Coder consistency measure. The Primary Coder consistency measure (CM_{PC}) for the sample of twenty-five (25) medical records is calculated using the following formula: $$CM_{PC} = \frac{Count\ of\ Primary\ Coder\ and\ Senior\ Coder\ HCC\ Matches}{Count\ of\ Unique\ HCCs\ (Primary\ Coder\ \&\ Senior\ Coder)}$$ The numerator term 'Count of Primary Coder and Senior Coder HCC Matches' indicates the instances of HCC agreement between the Primary and Senior Coders as they perform medical record abstraction. An HCC match is counted when both coders record diagnoses that result in identical HCCs for the same enrollee. Please note that each Primary Coder and Senior Coder HCC match for a unique HCC will be counted as a single match for each enrollee. The denominator term 'Count of Unique HCCs (Primary Coder & Senior Coder)' indicates the total universe of unique enrollee HCCs identified by both Primary and Senior Coders as they perform medial record abstraction. This value is calculated by totaling the number of unique enrollee HCCs identified within the 25 medical record sample by both the Primary Coder and Senior Coder. Please note that the same HCC for a single enrollee should not be counted more than once; however, the same HCC identified for different enrollees should be considered unique for each enrollee for the purposes of calculating the denominator. For example, if one (1) enrollee has twenty-five (25) medical records and HCC 8 is identified on all medical records, HCC 8 would be counted once in the denominator value of the calculated consistency measure. Assuming the Senior Coder also identified only HCC 8 on the medical records, both terms 'Count of Primary Coder and Senior Coder HCC Matches' and 'Count of Unique HCCs (Primary & Senior Coder)' would be one (1). That is, HCC 8 would be counted once in the numerator and once in the denominator. Alternatively, if one (1) enrollee has ten (10) medical records and a second enrollee has fifteen (15) medical records and HCC 8 was identified on both enrollee's medical records, HCC 8 would be counted once in both the numerator and denominator for each enrollee, assuming no other HCCs were identified. That is, HCC 8 would be counted twice in both the numerator and the denominator (if recorded by the primary and senior coder) The Count of Primary Coder and Senior Coder HCC Matches is calculated across all twenty-five (25) medical records, along with the count of unique HCCs identified by both the Primary Coder and Senior Coder(s). The calculated Primary Coder consistency measure is used to determine if the IRR threshold of 95% is met or if an additional sample of medical records is needed.

5 (a-b)	Finalize IRR or Adjust Sample	The last step in the IRR process is to either finalize IRR results or adjust the sample size. a) If the Primary Coder's calculated consistency measure meets or exceeds the required 95%, the Primary Coder has completed the requirements for IRR evaluation. b) If the Primary Coder's calculated consistency measure fails to meet the required 95%, the Primary Coder has not completed the requirements for IRR evaluation, and the IVA is required to re-perform the IRR assessment of the Primary Coder, re-performing steps 1 – 5. This process must be re-performed until the acceptable consistency measure is achieved or until no additional medical records reviewed by the Primary Coder remain.

6.4 IRR Sampling Methodology and Sample Selection

This section outlines the approach and the process for the IRR sample selection by the IVA Entity. IVA Entities are not required to have all medical records reviewed by a Senior Coder and can use the sampling approach below to meet the IRR requirement.

6.4.1 Required Consistency Measure

The required consistency measure is the accuracy rate by which Senior Coder HCC results match the HCC results of a Primary Coder. The Primary Coder is required to achieve an accuracy rate of 95% (without rounding) for benefit year 2017 HHS-RADV and beyond. If the consistency measure determined for the Primary Coder falls below these required targets either additional medical records must be sampled until the required accuracy rate is met, or, if the required sample size exceeds the remaining un-sampled records in the population, all medical records must be reviewed by a Senior Coder (i.e., a complete re-review).

6.4.2 Sample Population

All medical records reviewed by Primary Coders are subject to sampling (or complete re-review), without restriction. CMS believes that the sample size of 25 medical records is sufficient such that medical records without diagnoses abstracted will not substantially impact the calculation of the consistency measure for the Primary Coder.

IVA Entities are not required to obtain all medical records prior to initiating the IRR process, nor are they required to complete all medical record reviews before performing IRR. The IRR process for a Primary Coder may be initiated once the sample size requirement of 25 medical records is met. If the Primary Coder does not complete reviews of the necessary 25 medical records required to initiate the IRR sampling process, all medical records reviewed by the Primary Coder must be reviewed by a Senior Coder.

6.4.3 Sample Selection and Review

Senior Coders responsible for IRR review of Primary Coder sampled medical records are not required to be blind to Primary Coder findings; that is, Senior Coders are permitted to review Primary Coder findings for the medical record under review, including abstracted diagnoses and HCCs assigned to these diagnoses prior to or during their review. Senior Coders are permitted to review results of Primary Coder Health Status Data Validation steps prior to re-review as part of the IRR process.

6.5 IRR Scenarios

This section outlines example scenarios for calculating the consistency measure for the Primary Coder and the steps associated with finalization or additional evaluation.

Scenario 1 – Primary Coder First Iteration – Pass

Step	Description	Scenario 1
1	Primary Coder Performs Health Status Data Validation	The Primary Coder performs Health Status Data Validations and is selected for IRR evaluation following the review of twenty-five (25) medical records.
2	IRR Sample Selection	Twenty-five (25) completed medical records are selected and allocated to Senior Coders for review.
3	Senior Coder Performs Health Status Data Validation	The twenty-five (25) medical records are allocated to Senior Coders for review. Senior Coders performs Health Status Data Validations and records diagnoses abstracted for each of the evaluated medical records.

Step	Description	Scenario 1
4	Calculate Primary Coder Consistency Measure	After completing the review of the twenty-five (25) medical records, the abstracted diagnoses are mapped to HCCs and the Primary Coder findings are used with the Senior Coder findings to calculate the Primary Coder's consistency measure. Within the twenty-five (25) medical records, the Primary Coder identified diagnoses mapping to four (4) HCCs, which were also found by Senior Coders for the same enrollees. The Senior Coder found no other diagnoses assigned to additional HCCs. The Primary Coder consistency measure (CM_{PC}) for the sample of twenty-five (25) medical records is calculated using the following formula: $$CM_{PC} = \frac{Count\ of\ Primary\ Coder\ and\ Senior\ Coder\ HCC\ Matches}{Count\ of\ Unique\ HCCs\ (Primary\ Coder\ \&\ Senior\ Coder)}$$ $$CM_{PC} = \frac{4}{4} = 100\%$$ **NOTE:** Senior Coder results are captured as final for all medical records reviewed if deviations are identified, even when the calculated consistency measure meets the required 95%. See Scenario Two (2) for additional detail.
5	Finalize IRR or Adjust Sample	The Primary Coder's calculated consistency measure meets the required 95%. The Primary Coder has completed the requirements for IRR evaluation.

Scenario 2 – Primary Coder First Iteration – Fail; Second Iteration – Pass

Step	Description	Scenario 2
1	Primary Coder Performs Health Status Data Validation	The Primary Coder performs Health Status Data Validations and is selected for IRR evaluation following the review of twenty-five (25) medical records.
2	IRR Sample Selection	Twenty-five (25) completed medical records are selected and allocated to Senior Coders for review.
3	Senior Coder Performs Health Status Data Validation	The twenty-five (25) medical records are allocated to Senior Coders for review. Senior Coders performs Health Status Data Validations and records diagnoses abstracted for each of the evaluated medical records.
4	Calculate Primary Coder Consistency Measure	After completing the review of the twenty-five (25) medical records, the abstracted diagnoses are mapped to HCCs and the Primary Coder findings are used with the Senior Coder findings to calculate the Primary Coder's consistency measure. Within the twenty-five (25) medical records, the Primary Coder identified diagnoses mapping to seven (7) HCCs. Four (4) of the seven (7) HCCs were also assigned to diagnoses abstracted by the Senior Coder for the same enrollees, and three (3) HCCs were unsubstantiated. Additionally, the Senior Coder found additional diagnoses which were assigned to two (2) HCCs not found by the

Step	Description	Scenario 2
		Primary Coder. The Primary Coder consistency measure (CM_{PC}) for the sample of twenty-five (25) medical records is calculated using the following formula: $$CM_{PC} = \frac{Count\ of\ Primary\ Coder\ and\ Senior\ Coder\ HCC\ Matches}{Count\ of\ Unique\ HCCs\ (Primary\ Coder\ \&\ Senior\ Coder)}$$ $$CM_{PC} = \frac{4}{9} = 44.44\%$$ Senior Coder results are captured as final for all medical records reviewed with deviations identified.
5	Finalize IRR or Adjust Sample	The Primary Coder's calculated consistency measure does not meet the required 95%. The Primary Coder is required to re-perform the IRR assessment, re-performing steps 1 – 5.
1-5	IRR Iteration 2 – Sample Selection, Execution, and Finalization	The Primary Coder continues to review medical records until twenty-five (25) additional medical records have been reviewed. The second iteration of the IRR process initiates, and Steps One (1) through Four (4) are performed. Following the completion of Primary Coder and Senior Coder review for the second iteration of IRR, the Primary Coder consistency measure is calculated. Within the second set of twenty-five (25) medical records, the Primary Coder identified diagnoses mapping to nineteen (19) HCCs which were also assigned to diagnoses abstracted by the Senior Coder for the same enrollee. The Senior Coder also identified a diagnosis which mapped to one (1) additional HCC which was not found by the Primary Coder. The Primary Coder consistency measure (CM_{PC}) for the sample of twenty-five (25) medical records is calculated using the following formula: $$CM_{PC} = \frac{Count\ of\ Primary\ Coder\ and\ Senior\ Coder\ HCC\ Matches}{Count\ of\ Unique\ HCCs\ (Primary\ Coder\ \&\ Senior\ Coder)}$$ $$CM_{PC} = \frac{19}{20} = 95\%$$ Senior Coder results are captured as final for all medical records reviewed with deviations identified. The Primary Coder's calculated consistency measure meets the required 95%. The Primary Coder has completed the requirements for IRR evaluation. Had the Primary Coder not achieved the required consistency measure of 95%, the process would restart and a third iteration of IRR would be executed.

Section 7

HHS Risk Adjustment Data Validation Protocols

Error Estimation

7 Error Estimation

7.1 Overview

The objectives of the Error Estimation processes are to verify the accuracy of the IVA results, calculate failure rates, determine if risk score adjustments are required, and project corresponding adjustments to risk scores in the issuer's population. Without viewing the actual IVA results, the SVA Entity validates a random subsample of the issuer's health status (HCC) data for all IVA submissions. The SVA Entity re-performs the validation steps executed by the IVA Entity on a sample of enrollees validated by the IVA Entity to verify the accuracy of the IVA results. The initial SVA sample must be sufficiently large enough to determine the statistical significance of any differences between the IVA and SVA results by pairwise means testing.[18] At the conclusion of the SVA review, CMS identifies the issuers that are statistical outliers in their health status submission inaccuracies and applies an adjustment to those issuers' risk scores.

If the pairwise means test results conclude that there is not sufficient evidence of disagreement between the SVA and IVA findings of the issuer's errors, meaning the difference in enrollee risk score results between the IVA and SVA is not statistically significant, then the IVA results are used for the calculation of HCC inaccuracies or HCC failure rates and any adjustment to an issuer's RA covered plan average risk scores. For the 2017 benefit year HHS-RADV, CMS will use the demographic data from the EDGE server reports for risk score calculations used in the pairwise test rather than the demographic results of the IVA or SVA D&E Data Validation. Therefore, any pairwise differences will be the result of health status variance between the IVA and SVA.

If pairwise means test results show disagreement, meaning there is a statistically significant difference between the IVA and SVA, then the SVA confirmed HCC failure rates are used for the calculation of an issuer's HCC failure rates and, if necessary, an adjustment for each of the issuer's RA covered plan average risk scores.

Details regarding the Pairwise Analysis Process and the Error Estimation process are provided in the following sections.

7.2 Pairwise Test and IVA Sample Adjustment

CMS will conduct a pairwise means test to either accept or replace the IVA's result based on the results of the SVA.

7.2.1 Pairwise Test between SVA and IVA

During the pairwise test, the SVA Entity will compare the SVA results to the IVA results to determine if the results are statistically significant in their difference. The pairwise test will be conducted on the initial SVA subsample and if the difference in results are found to be statistically significant, then the SVA subsample will be expanded incrementally from 12 to 24, then to 50, then to 100 with the pairwise test re-performed after the SVA review at each incremental sample size. The SVA sample may potentially be expanded to the full IVA sample of 200 as a result of low precision when using 100 enrollees.[19] CMS will prioritize enrollees with medical records in the initial subsample groups.

[18]Pairwise Means Test: A statistical means test, which is a hypothesis-testing procedure to determine if two (2) population means are different when there is a one-to-one (1:1) correspondence between the values in the two (2) samples.

[19] In the event the SVA subsample is expanded to the full IVA sample, we will still refer to the SVA sampled enrollees as the SVA subsample to distinguish the SVA sample from the IVA sample.

If the results from the initial pairwise test (or the pairwise test from any of the incremental SVA subsample expansions) are found to be statistically similar to IVA findings, then the IVA results will be used (i.e., the IVA confirmed HCCs and HCC failure rates will be used in the calculation of HCC Group Failure Rates and any applicable adjustments).

If there is a significant difference between the IVA results and the result of the expanded SVA sample, the SVA Entity will estimate the error based on the SVA results (i.e. the SVA confirmed HCCs and HCC failure rates will be used in the calculation of HCC Group Failure Rates and any applicable adjustments). To illustrate the pairwise statistical test, consider the following notations where *i* stands for sampled enrollee *i*:

$\tilde{x}_i$	is the ith IVA risk score observation in the SVA subsample of **n** observations
$\tilde{y}_i$	is the ith SVA risk score observation in the SVA subsample of **n** observations
d_i	is the difference between $\tilde{y}_i$ and $\tilde{x}_i$ within the SVA subsample $$d_i = \tilde{y}_i - \tilde{x}_i$$
S_d	is standard deviation of d_i
$\bar{d}$	is the mean of d_i in all n observations within the SVA subsample $$\bar{d} \pm t_{1-\alpha,\gamma}\left(\frac{S_d}{\sqrt{n}}\right)$$
N	is the number of enrollee records. N=200 because there are 200 IVA records

From the N IVA records (N=200), CMS will select a small subsample of n SVA records (n=12). For each SVA selected record, CMS will calculate the difference, $d_i = \tilde{y}_i - \tilde{x}_i$. CMS will then conduct a pairwise means test to determine whether the mean difference, $\bar{d}$ is statistically different than zero (0) at a 95% confidence level (two-sided). Specifically, CMS will test if zero (0) is contained within the bound, $\bar{d} \pm t_{1-\alpha,\gamma}\left(\frac{S_d}{\sqrt{n}}\right)$ where $t_{1-\alpha,\gamma}$ is the critical t-value associated with a two-sided 95% confidence level.[20] If zero (0) is contained, CMS will conclude that there is no statistically significant difference between the IVA and SVA results for the sampled enrollees and accept the results of the IVA review.

However, if zero (0) is not contained within this bound (i.e., the difference is statistically significant), CMS will incrementally expand the SVA subsample from 12 up to 100 and at each expansion, reviewing the enrollee files and conducting an alternate pairwise means test using the larger SVA subsample.[21] This difference may be positive or negative depending on the direction and magnitude of each difference found between the IVA and SVA results. If the alternate statistical test shows no statistically significant difference, CMS will accept the results of the IVA review. If the alternate statistical test shows that there is a statistically significant difference between the IVA and SVA results, after expanding the SVA subsample to 100, CMS will conduct a precision analysis for evaluating the SVA findings to determine if selecting a larger subset of the 200 total IVA sampled enrollees can be justified.

For purposes of reviewing sample size for the SVA subsample when an issuer has insufficient

[20] The critical t-value $1-\propto = 1.96$, when the sample is large enough, approaching infinity. α represents the significance level and γ represents the degrees of freedom of the critical t-value associated with a two-sided 95 percent confidence level. CMS assumes that α = 0.05 for 95% confidence and $\gamma = n-1$.

[21] SVA subsample expands incrementally to 12, 24, 50, and 100, with a precision analysis conducted after pairwise failure at 100 to determine whether the SVA reviewed 100 enrollees are acceptable for error estimation, or whether the SVA will need to expand to review the full 200 enrollees and utilize the SVA results for the full 200 enrollees for error estimation.

agreement in the pairwise means test using an SVA subsample of 100, CMS will determine standard errors and confidence intervals around the error rate using a bootstrap procedure to assess precision. This approach is used to determine standard errors and confidence intervals when the underlying distribution is unknown, when sample sizes may be too small, and/or when no formula may exist for the complex calculation. If a subsample of 100 is determined to result in an error rate with acceptable precision, CMS will use the SVA subsample of 100 for the issuer's final HHS-RADV error rate, rather than expanding to the full IVA sample of 200.[22]

CMS uses a nonparametric bootstrap technique for estimating properties of the error estimate because the approach requires no assumptions to be made about the parent distribution. Due to the complexity of the Error Estimation method, the mathematical derivation of standard errors and confidence intervals cannot otherwise be derived as a formula.

The bootstrap resampling technique will allow CMS to derive precision metrics such as standard error and confidence intervals for the point estimate of the Error Rate of each issuer when the IVA failed pairwise at SVA 100 review. If the confidence interval or standard error of the Error Rate for any of these issuers is large enough to lose confidence in the quality of results (e.g. using CMS established precision targets of 10% and in comparison to other issuers with 200 samples), then CMS will conclude that the precision for the estimated error rate is poor and the SVA will expand and use the full SVA reviewed sample of 200 enrollees. However, if these metrics (standard error or confidence interval) fall in a similar range compared to other issuers, then the SVA subsample will not be expanded to 200.

CMS will implement the bootstrap procedure on each issuer's sample of enrollees to determine the standard error and confidence interval for an issuer's Error Rate estimate:

1. For issuer i, draw N enrollees from the list of all sampled enrollees with replacement (i.e., select a random enrollee from the sample and return the enrollee back into the sample prior to the next enrollee being selected), where N is the number of IVA or SVA sampled enrollees.

2. Calculate the issuer's Error Rate using the method, described above, by assuming the resampled enrollees create a bootstrap sample. The estimated Error Rate for issuer i and the bootstrap sample is recorded as $\widehat{ErrorRate}_{i,1}$.

3. Repeat Step 1 and 2 at minimum 1,000 times[23]. Each time, a new Error Rate is estimated based on a resampled data set. At the end of resampling experiment, a set of Error Rate estimates are collected as

   $$\widehat{ErrorRate}_{i,1}, \ldots \widehat{ErrorRate}_{i,B}$$

   where B is the times the resampling experiment repeats.

4. Calculate the sample standard deviation of all the B re-sampled Error Rates. This standard deviation is an approximation of the bootstrapped standard error (SE) of the Error Rate estimate for issuer i.

5. Obtain the 2.5^{th,} and 97.5th centiles of all the B re-sampled Error Rates. This is the bootstrapped two (2)-sided 95% confidence interval boundary for the Error Rate estimate for issuer i.

[22] Bootstrap Resampling: A non-parametric resampling procedure used to estimate the sampling distribution based on independent observations.

[23] Statistical standards note that 1000 iterations of bootstrap resampling adequately captures the range of variability produced as a results of random sampling.

The standard error is one way to indicate how precise the estimate of an issuer's error rate is. If an issuer's standard error is large enough to lose confidence in the quality of results, the issuer will be assessed as poor precision. The precision test and the calculated precision values are used to resolve the following scenarios:

- If the SVA100 findings were utilized in the calculation of an issuer's Error Rate and the findings of the bootstrap procedure indicates poor precision, CMS will increase the SVA sample size to 200 enrollees (i.e. full IVA Sample). In the event the sample increases to 200 enrollees in this way, these SVA200 findings will be used as final and the Error Estimation calculation will be re-run.
- If the SVA100 findings were utilized in the calculation of an issuer's Error Rate and the findings of the bootstrap procedure indicates acceptable precision, CMS will not increase the SVA sample. The findings of the SVA100 will be used as final in the Error Estimation calculation.

The error estimation results are finalized once all HIOS ID SVA sample expansions are exhausted, including increases to SVA200 for issuers for which low precision was determined.

Please note that CMS intends to use bootstrap resampling techniques to measure the precision of the finalized Error Rate estimates and inform future sampling methods.

7.3 Error Estimation

Under § 153.350(c), HHS may adjust risk adjustment payments and charges to all issuers of risk adjustment covered plans based on adjustments to the average actuarial risk of a risk adjustment plan due to errors discovered during risk adjustment data validation.[24] Under the original HHS-RADV error estimation approach, all issuers of risk adjustment covered plans would have received an adjustment to payment transfers in the subsequent benefit year based on risk adjustment data validation audit results and using the audit-confirmed, issuer-specific risk score error rate. However, as recognized in the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule, CMS believes that some variation and error should be expected in the compilation of data for risk scores.

To avoid adjusting all issuers' RA payments for expected variation and error, CMS finalized an approach in the HHS Notice of Benefit and Payment Parameters for 2019 Final Rule of using failure rates specific to HCC groups and subsequently adjusting the issuer's risk score when the issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate, or total failure rate, for that group of HCCs for all issuers that submitted initial validation audits. This approach is described in more detail below. CMS believes that determining outlier failure rates based on HCC groups yields a more equitable measure to evaluate statistically different HCC failure rates impacting an issuer's error rate than an approach based on an overall failure rate. Further, this approach should streamline the HHS-RADV process, improve issuers' ability to predict risk adjustment transfers, and promote confidence and stability in the budget-neutral payment transfer methodology while ensuring the integrity and quality of data provided by issuers.

The major changes that stem from adoption of this new approach are the HCC Group level analysis, no adjustment to issuers' risk scores whose HCC failure rates are within a confidence interval, and a partial risk score adjustment for all HCCs in an HCC Group where the issuer has outlier failure rates (as opposed to losing the full value of the coefficient for a missing HCC under the prior method).

CMS will estimate adjusted risk scores based on the weighted mean failure rate of the sampled enrollees' validated HCCs. HCC failures may be the result of any findings that cause a change to the health status components of an enrollee's risk score; this may include findings due to:

[24] Consistent with 45 C.F.R. §153.630(e), HHS also may adjust payments and charges for issuers that do not comply with HHS-RADV requirements and standards.

- invalid documentation (as described in Section 5.6);
- missing or insufficient medical record documentation; or
- incorrect diagnosis coding.

For error rate estimation, HCC failure rates are defined as the probability that an issuer's HCC for a sampled enrollee reflected on the EDGE server and in RA calculations is found to be inaccurate or unsubstantiated in the IVA and/or SVA review. The percent of the risk score that is incorrect due to audit findings (that is, due to HCCs that could not be validated through audit), is considered to be the issuer's risk score error rate. Because the EDGE server frequency of a unique HCC for a given issuer's enrollees IVA sample will be relatively small, HCCs are categorized into groups for evaluation. The HCC groups are determined by ordering HCCs from lowest to highest failure rates and weighting each HCC by its total frequency in the EDGE server for all IVA/SVA validated sample enrollees across all issuers. CMS will perform statistical analysis to determine if any issuers' Group Failure Rate is outside of the norm within an HCC Group related to the sample of issuers.

For the 2017 benefit year, CMS will apply HHS-HCC hierarchies to all submitted diagnoses on the IVA Entity Audit Results Submission XML to determine final IVA HCCs for each audited enrollee. The HHS-HCC hierarchy is similarly applied to SVA results to determine final SVA HCCs for an enrollee. HCCs for an enrollee are determined only after the hierarchies are applied to diagnoses documented, and HCC failure rates are calculated using only these final HCCs.

> Example: An issuer's EDGE data reflects multiple diagnoses linking to both CC 9 and CC 10 for a particular enrollee. When HHS-HCC hierarchies are imposed, HCC 9 is determined to be the final HCC for the enrollee. The HCC failure rate would be impacted by the IVA Entity's ability to validate HCC 9. If the IVA Entity abstracted a diagnosis that mapped to HCC 10 only, and identified no diagnoses linked to HCC 9, two outcomes occur: 1) The HCC 9 failure rate increases as the IVA Entity did not substantiate the HCC determined as final for the enrollee; and 2) HCC 10 failure rate would decrease as the IVA Entity identified that HCC 10 was the final determined HCC for the enrollee. Note that HCC 9 and HCC 10 may be assigned to different HCC Failure Rate Groups.

Upon completion of the IVA and SVA audits, CMS will derive an issuer-level adjustment factor for identified outliers. This adjustment will generally be applied to average plan-level risk scores for risk adjustment benefit year calculations subsequent to the benefit year being audited for each plan offered by the issuer. The one (1) exception to this general rule is for issuers who exit the market during or at the end of the benefit year being audited; in which case, these adjustments will be applied to the risk scores for RA benefit year calculations for the issuer's final benefit year in the state market risk pool. CMS plans to provide each issuer with enrollee-level audit results as well as their error rate.

The next four (4) sections further explain and illustrate the Error Estimation process. Section 7.3.1 describes how sampled enrollees' EDGE server data and IVA sample results will be used to Group HCCs into categories. Section 7.3.2 describes how the comparison of sampled enrollees' EDGE server data to IVA results (or SVA results when pairwise test concludes that significant differences exist) will be used to identify issuers who are statistically different from their peers. Section 7.3.3 describes how the sample results are projected to an issuer level adjusted risk score. Finally, Section 7.3.4 shows an example illustrating the pairwise and Error Estimation process. Note that error rates calculated in the 2017 benefit year HHS-RADV will generally be used to adjust 2018 benefit year RA risk scores and RA transfers.[25]

[25] CMS will adjust 2017 benefit year risk scores and recalculate transfers if an issuer exiting the market in 2018 is found to have a non-zero Error Rate in 2017 benefit year HHS-RADV.

7.3.1 Categorize HCCs into Groups

Since the IVA samples are stratified random samples based on enrollee risk score and age model, the underlying unique HCCs or an issuer's distribution of HCCs are not considered during the sample selection. At the issuer level, the sample size of each unique HCC would be too small to provide a sufficient amount of data for statistical analysis, especially for rare diseases. Therefore, to increase the HCC sample size for an issuer, CMS will categorize all HCCs into one (1) of three (3) Groups based upon the magnitude of their failure rates (FR^h) and EDGE server frequencies ($Freq\_EDGE^h$) across all issuers - creating a hierarchical order of "Low", "Medium," and "High" groups of failure rates with approximately equal number of HCC frequencies across all HHS-RADV issuers' sampled enrollees in each Group.

To illustrate the categorization of HCCs into Groups, consider the following notations:

Term	Definition
h	Is the h_{th} HCC code
$Freq\_EDGE^h$	Is the frequency of an HCC *h* occurring on EDGE, which is the number of sampled enrollees recording HCC *h* in EDGE across all issuers
$Freq\_IVA^h$	Is the frequency of an HCC *h* occurring in IVA results (or SVA results when pairwise test concludes that significant differences exist), which is the number of sampled enrollees with HCC *h* in IVA results across all issuers
FR^h	Is the failure rate of HCC *h* across all issuers

The HCC failure rate (FR^h) is the probability of all issuers coding an HCC incorrectly and is defined as one (1) minus the ratio of HCC frequencies in issuer audit results (IVA or SVA) to the EDGE server: $(FR^h = 1 - \frac{Freq\_IVA^h}{Freq\_EDGE^h})$. The HCCs are ordered by their failure rates and assigned to their Groups through the following process:

1. Add the HCC with the lowest failure rate into Group One (1); update the size of Group One (1) as $Freq\_EDGE^{h1}$
2. Add the next HCC from the ordered list into Group One (1); update the group size as $Freq\_EDGE^{h1} + Freq\_EDGE^{h2}$
3. Repeat until the group size (the cumulative sum of frequencies) reaches approximately 33.3% of the total frequencies of HCCs recorded on EDGE ($\sum Freq\_EDGE^h$).
    a) Note: if an HCC crosses the 33.3% boundary, it will be assigned to the group where the inclusion of the frequencies of the HCC best allows the Group's total frequencies to approximate 33.3% (Group One [1] or Group Two [2], depending on the preponderance of the HCCs).
4. Select the HCCs for Group Two (2) by repeating Steps 1 – 3 using the remaining HCCs in the ordered list, until the size of Group One (1) plus Group Two (2) reaches 66.7% of the total frequencies of HCCs recorded on the EDGE server ($\sum Freq\_EDGE^h$).
    a) Note: if an HCC crosses the 66.7% boundary it will be assigned to Group Three (3).
5. The remaining HCCs are placed in Group Three (3).

At the conclusion of this step, each HCC is assigned to only one (1) of three (3) Groups with an approximately equal number of observed HCCs. Note that the categorization process creates groups based on all sampled enrollees on the EDGE server, across all issuers.

7.3.2 Calculation of Adjustments based on Group Failure Rates

CMS will apply risk score adjustments to sampled enrollees only when one (1) or more of an issuer's Group Failure Rates statistically differs from the weighted mean of the Group Failure Rate across all issuers. An issuer's Group Failure Rate is the probability of an issuer coding HCCs incorrectly across all HCCs in the same Group. CMS approximates that an issuer's Group Failure Rate follows a normal distribution and uses the weighted mean as the measure of central tendency and the standard deviation as the measure for dispersion. The standard deviation is used to identify the two (2)-sided decision boundary, 1.96 standard deviations on each side of the weighted mean failure rate for each Group. When an issuer's Group Failure Rate falls outside this boundary, an adjustment is applied to all HCCs from the same Group in its sample.

To illustrate the calculation of adjustments based on Group Failure Rates, consider the following notations, where *i* stands for issuer *i* and *G* represents the *Gth* Group:

Term	Definition
i	The ith issuer
G	The Gth (1-3) HCC group
$Freq\_EDGE_i^G$	The frequency of HCCs recorded on EDGE in Group G in the IVA sample of issuer i
$Freq\_IVA_i^G$	The frequency of HCCs found by the IVA in Group G of the IVA sample of issuer i
GFR_i^G	The issuer i's Group Failure Rate for the HCC Group G
$\mu(GFR^G)$	The mean of GFR_i^G of all issuers for the HCC Group G
$Sd(GFR^G)$	The sampled standard deviation of GFR_i^G of all issuers for the HCC Group G
$Sigma\_cutoff$	The parameter used to set the threshold for outlier detection as the number of standard deviations away from the mean
$LB^G and\ UB^G$	The lower and upper thresholds to classify issuers as outliers and not outliers for Group G
$Freq\_SVA_i^G$	The number of HCCs in Group G in the IVA sample of issuer i adjusted from the SVA review
$Group\ Adjustment_i^G$	The calculated adjustment factor to adjust issuer *i*'s EDGE risk scores for all sampled HCCs in Group *G*

CMS will determine each issuer's frequency of HCCs in Group G that occurred across all sampled enrollees from the EDGE server ($Freq\_EDGE_i^G$) and the IVA ($Freq\_IVA_i^G$), then compute their Group Failure Rate for the HCC Group G as:

$$GFR_i^G = 1 - \frac{Freq\_IVA_i^G}{Freq\_EDGE_i^G}$$

Based on the result of the Pairwise Test described above (Sections 7.2.1), issuers who fail the pairwise test require a modified Group Failure Rate per HCC Group that takes into consideration the SVA results. The new GFR_i^G equation becomes:

$$GFR_i^G = 1 - \frac{Freq\_SVA_i^G}{Freq\_EDGE_i^G}$$

The Group Failure Rate for the HCC Group G is used to determine the decision boundary for each HCC Group. Decision boundaries, constructed from the mean and standard deviation, provide the range of values between which a parameter is expected to lie. The Sigma cutoff sets the threshold for the decision boundary and CMS selects to set the cutoff at 1.96.

$$LB^G = \mu(GFR^G) - Sigma\_cutoff * Sd(GFR^G)$$
$$UB^G = \mu(GFR^G) + Sigma\_cutoff * Sd(GFR^G)$$

CMS will establish the decision boundary by computing 1.96 standard deviations on each side of the mean Group Failure Rate for each HCC Group. By using the sample mean and standard deviation statistics, CMS assumes that the observed issuer failure rates within each HCC Group approximately follow a normal distribution. When calculating the mean and standard deviation of all issuers' Group Failure Rate, CMS also assumes issuers are not equal and are weighted by their Group EDGE HCC frequency to ensure an equitable contribution, thus making $w_i = Freq\_EDGE_i^G$.

$$\mu(GFR^G) = \frac{\sum_i (w_i * GFR_i^G)}{\sum_i w_i}$$

$$Sd(GFR^G) = \sqrt{\frac{\sum_i \left(w_i * \left(GFR_i^G - \mu(GFR^G)\right)^2\right)}{\sum_i w_i}}$$

Each issuer's Group Failure Rate for HCC Group G is compared against Group G's corresponding lower and upper boundaries. If an issuer's Group Failure Rate falls outside of these boundaries, then an adjustment is calculated as the difference between the issuer's Group Failure Rate and Group G's weighted mean. The adjustment to the mean provides an explicit correction back to the central tendency from the sample of issuers.

$$Group\ Adjustment_i^G = \begin{cases} GFR_i^G - \mu(GFR^G) & if\ GFR_i^G > UB^G\ \ OR\ GFR_i^G < LB^G \\ 0 & if\ GFR_i^G \leq UB^G\ \ AND\ GFR_i^G \geq LB^G \end{cases}$$

At the conclusion of this step, each issuer with a Group Failure Rate outside of the upper and lower boundaries is assigned up to three (3) adjustment factors, one (1) for each Group for which the issuer's Group Failure Rate is outside of the upper and lower boundaries. These Group adjustment factors will be weighted and used to compute the enrollee-level adjusted risk score.

7.3.3 Calculation of Error Rates to Adjust Issuer Plan Risk Scores

An enrollee-level adjustment to sample risk score will only be computed when the following conditions are satisfied simultaneously:

1. An issuer has at least one (1) HCC Group Failure Rate that falls outside of its corresponding two (2)-sided 1.96 standard deviation decision boundary (described in Section 7.3.2).

2. A sampled enrollee has an HCC recorded on EDGE that falls in an outlier HCC Group for which the issuer incurs a non-zero adjustment (i.e., a non-zero Group from Condition One [1]).

CMS will calculate the enrollee-level adjusted risk scores for the sample based on the adjustment factors calculated in Section 7.3.2 for the three HCC Groups. CMS will then estimate the issuer level Error Rates using the deviation from adjusted sample risk scores to original risk scores. The issuer's Error Rate is first calculated at the stratum level and then combined to a single value by weighing in the stratum size in the issuer's population and sample.

To clarify the description in the 2019 Payment Notice (83 FR 1693) that the adjusted risk score will not include enrollees without HCCs, we note the following:

- All enrollees (Strata 1-10) contribute to the calculation of the overall issuer error rate
- All enrollee HCCs identified by the IVA or SVA as applicable (including for Stratum 10 enrollees) will be used in determining HCC failures rates for the issuer in the HCC Groups (Low, Medium, High)
- Newly identified HCCs by the IVA (or SVA as applicable) will not contribute to enrollee risk score adjustments for enrollees, but will be used to calculate national and issuer-specific HCC failure rates
- Adjustment of enrollees' risk scores is performed only for sampled enrollees with EDGE HCCs (Strata 1-9), when the EDGE HCCs for these enrollees are in an HCC Group for which the issuer is an outlier

To illustrate the calculation of error rates to adjust issuer plan risk scores, consider the following notations:

Term	Definition
i	The ith issuer
e	The eth enrollee
G	The Gth HCC group
$RS_{i,e}^{hcc,G}$	The risk score component of a single HCC for the enrollee
$Enrollee\ Adjustment_{i,e}$	The calculated adjustment factor to adjust Enrollee e of issuer i's sample risk score
$EdgeRS_{i,e}$	The sampled Enrollee e of issuer i's risk score recorded on EDGE
$AdjRS_{i,e}$	The sampled Enrollee e of issuer i's adjusted risk score
$ErrorRate_i$	The final Error Rate for Issuer i based on the sampled enrollees
w_e	The stratum weight used to compute the Error Rate

CMS will first use the HCC Group level adjustment factor calculated in Section 7.3.2 to determine the enrollee level adjustment factor for all samples. The enrollee adjustment factor will be calculated as the weighted average of all HCCs' associated Group level adjustment factor(s) $(Group\ Adjustment_i^G)$, where the weight is assigned as the risk score component contributed by the single HCC along $(RS_{i,e}^{hcc,G})$.

$$Enrollee\ Adjustment_{i,e} = \frac{\sum_{hcc}\left(RS_{i,e}^{hcc,G} * Group\ Adjustment_i^G\right)}{\sum_{hcc}\left(RS_{i,e}^{hcc,G}\right)}$$

Next, for sampled enrollees, the adjustment factor is applied to the enrollee's EDGE server risk score to obtain their adjusted risk score $(AdjRS_{i,e})$.

$$AdjRS_{i,e} = EdgeRS_{i,e} * \left(1 - Enrollee\ Adjustment_{i,e}\right)$$

Then the issuer's Error Rate is estimated from all its samples using the total stratum weighted risk scores on EDGE and the adjusted risk scores. The stratum weight is the ratio of the stratum size in the population to the number of sample enrollees from the stratum.

$$ErrorRate_i = 1 - \frac{\sum_e \left(w_e * AdjRS_{i,e}\right)}{\sum_e \left(w_e * EdgeRS_{i,e}\right)}$$

$$\text{, where } w_e = \frac{stratum\ size\ in\ population}{number\ of\ sample\ enrollees\ of\ the\ stratum}$$

The risk score component of a single HCC $\left(RS_{i,e}^{hcc,G}\right)$ is calculated based on the logic defined in the applicable HHS Risk Adjustment Model table. The risk score calculation for the enrollee adjustment calculation only considers the risk factors related to HCCs and ignores any other risk factors purely triggered by demographic information like sex. However, CMS uses the actual sample stratum, plan metal levels, and age of sampled enrollees to calculate the risk score. Note that the aforementioned assumptions only apply to how the single component risk scores are computed to determine weights to compute enrollee level adjustment factors and not how the enrollee EDGE risk scores are computed.

7.3.4 Illustration of the Pairwise and Error Estimation Processes

To illustrate the pairwise process described above, assume that a sample of 200 enrollees is selected for IVA review for a particular issuer. From this sample, a subsample of 12 enrollees is selected for SVA review. Assume the issuer's average recorded population (EDGE Server) risk score is 1.60.

(1) Step One (1): The Pairwise process will determine if the IVA results should be replaced based on the SVA review or accepted.

1. CMS performs a pairwise means test to compare the difference between the IVA risk scores and SVA risk scores for the subsample of twelve (12) enrollees. (See Section 7.2.1.)

2. Assume the average recorded IVA risk score is 1.50 (post-validation) and the average recorded SVA risk score is 1.25 in the SVA sample of 12 enrollees;

d = 1.25 - 1.50 = -0.25

For this example, assume the statistical test fails (i.e., there is a statistically significant difference between the IVA and SVA subsample of twelve [12] risk scores).

3. The SVA will incrementally review the remaining 88 enrollees to increase the SVA subsample to 100 enrollees. CMS performs the pairwise means test again where the average recorded IVA risk score is 1.65, and average recorded SVA risk score is 1.42 in the SVA sample of 100 enrollees; (See Section 7.2.2).

d = 1.42 – 1.65 = -0.23

4. For this example, assume the statistical test fails again (i.e., there is a statistically significant difference between the IVA and SVA sample of 100).

5. For the example, assume that the SVA conducts a precision analysis on the SVA sample of 100 enrollees and determines the precision to be high. This process is detailed in Step Six (6).

(2) Step Two (2): CMS will replace the IVA inconsistent HCCs with the SVA validated HCCs for all 100 enrollees in the IVA sub-sample reviewed by the SVA. Then CMS will use the SVA validated HCCs and HCC failure rates to calculate HCC Group Failure Rates and any applicable adjustment. Note that the one-for-one replacement will replace the HCC failure rates calculated based on IVA findings with the HCC failure rates calculated based on SVA findings for the 100 sampled enrollees.

(3) Step Three (3): CMS will categorize each HCC into one (1) of three (3) groups using the failure rates and EDGE HCC frequencies across all issuers. Since there are over one hundred (100) HCCs, for simplicity in this example we will assume from the RADV sample of issuers that ten (10) HCCs were recorded on the EDGE servers across all issuers. (See Section 7.3.1).

1. CMS determines the frequencies for the EDGE HCCs and the IVA HCCs respectively, then calculates their HCC failure rates (FR^h). Note, the below IVA HCC frequencies are inclusive of the SVA validated HCCs that replaced the IVA HCCs that failed their pairwise test.

HCC	$Freq\_EDGE^h$	$Freq\_IVA^h$	FR^h
30	200	180	10%
115	700	607	13%
138	1,200	1,020	15%
248	1,700	1,428	16%
1	2,200	1,833	17%
125	2,700	2,237	17%
130	3,000	2,300	23%
12	2,500	1,700	32%
37	2,000	1,100	45%
57	1,500	500	67%
Total	**17,700**	**12,905**	**27%**

2. The HCCs are placed in ascending order, and two (2) boundaries are selected such that the size of the first two (2) Groups approximate 33.3% each, for a combined total of 66.7% of the total EDGE frequency.

   a. The two (2) boundaries to cut the list of ten (10) HCCs into three (3) Groups are 5,900 (17,700 * 33.3%), and 11,800 (17,700 * 66.7%) respectively.

   b. HCC 1 and HCC 12 are crossing the boundary line so they will be categorized in the higher Group in order to create balanced 33.3% EDGE frequency Groups. See the table below, along with Image 7.3.4.1 for a visual of the categorization.

HCC	$Freq\_EDGE^h$	$Freq\_IVA^h$	FR^h	$Freq\_EDGE^h$ Cumulative Probability	Boundary	Group
30	200	180	10%	1%		G1
115	700	607	13%	5%		G1
138	1,200	1,020	15%	12%		G1
248	1,700	1,428	16%	21%	33.3%	G1
1	2,200	1,833	17%	34%		G2
125	2,700	2,237	17%	49%		G2
130	3,000	2,300	23%	66%	66.7%	G2
12	2,500	1,700	32%	80%		G3
37	2,000	1,100	45%	92%		G3
57	1,500	500	67%	100%	100%	G3
Total	**17,700**	**12,905**	**27%**			

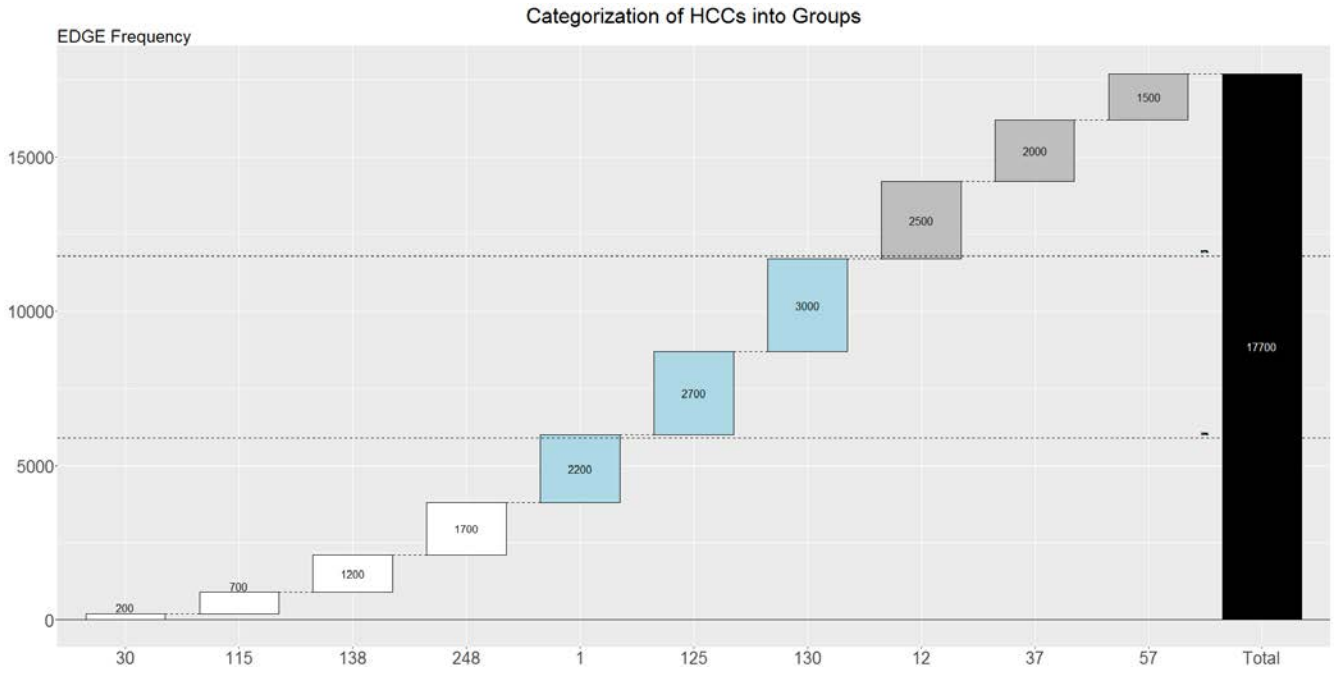


Image 7.3.4.1: In the image above (Image 7.3.4.1), the x-axis is the sorted list of HCCs in an increasing order of their failure rates. The bar height (and the text in each box) represents Freq_EDGE of each HCC. The bar on the right shows the total Freq_EDGE is 17,700. The two (2) boundaries to cut the list of 10 HCCs into three (3) groups are $(17{,}700 * 0.333)$, and $(17{,}700 * 0.667)$ respectively, which are shown as the two horizontal dashed lines. The two (2) horizontal lines cut all ten (10) boxes (one for each HCC) into three (3) groups. If a box is crossing a boundary line (e.g., HCC 1 and HCC 12), such box will be added to the Group to achieve equitable boundary cutoffs of 33.3% EDGE frequency allocation. The final grouping result is shown as three (3) colors in the chart.

(4) Step Four (4): CMS will evaluate each issuer's Group Failure Rate and assess if it statistically differs from the weighted mean of the sampled issuer's Group Failure Rates (See Section 7.3.2).

1. CMS will first determine the frequency of HCCs in each Group and calculate the Group Failure Rate across each issuer.

HCC Group	Issuer	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}
G1	10001	133	104	21.8%
	10002	96	87	9.4%
	⋮	⋮	⋮	⋮
G2	10001	171	128	25.1%
	10002	111	86	22.5%
	⋮	⋮	⋮	⋮
G3	10001	131	96	26.7%
	10002	96	79	17.7%
	⋮	⋮	⋮	⋮

2. For each Group, the weighted mean and standard deviations for the Group Failure Rates are calculated using column GFR^{G} by each HCC Group. They will be used to create a 1.96 standard deviation decision boundary. Since the entire universe of participating issuers are necessary to compute the Group Failure Rate for each HCC Group, for simplicity, we assume here the weighted mean Group Failure Rates for G1, G2, and G3 are 11.8%, 17.1%, and 25.9% respectively in the table below; and the weighted standard deviations are 3.0%, 3.4%, and 4%, respectively).

   Note: *The Group Failure Rate values of 11.8%, 17.1%, and 25.9% referenced in this step, and used in the following steps, do not correspond to data in Step 2 (e.g. Image 7.3.4.1 and the assoicated data table).*

HCC Group	Issuer	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}	μ(GFR^{G})	Sd(GFR^{G})	Sigma_cutoff	UB^{G}	LB^{G}
G1	10001	133	104	21.8%	11.8%	3.0%	1.96	17.7%	5.9%
	10002	96	87	9.4%					
	⋮	⋮	⋮	⋮					
G2	10001	171	128	25.1%	17.1%	3.4%	1.96	23.8%	10.4%
	10002	111	86	22.5%					
	⋮	⋮	⋮	⋮					
G3	10001	131	96	26.7%	25.9%	4.0%	1.96	33.7%	18.1%
	10002	96	79	17.7%					
	⋮	⋮	⋮	⋮					

3. Each issuer's Group Failure Rate for HCCs is compared against the corresponding Group's lower and upper decision boundaries. If the issuer Group Failure Rate falls outside of the decision boundary, then an issuer's Group adjustment is calculated.

   a. The Group adjustment is the difference between the issuer's Group Failure Rate and the Group mean.

   b. For Issuer 10001, the Group G1 and G2 failure rates fell outside of the upper boundary introducing positive adjustment factors. Issuer 10002's Group G3 failure rate fell outside the lower boundary introducing a negative adjustment factor. Note that the sign of the adjustment corresponds to the opposite impact on the risk score in samples in the next step (i.e., a positive

adjustment will reduce the risk score, while a negative adjustment will increase the risk score). In the examples below, the issuer's adjustments and error rate would result in a negative impact to the issuer's risk score, despite being positive numbers.

HCC Group	Issuer	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}	μ(GFR^{G})	Sd(GFR^{G})	sigma_ cutoff	UB^{G}	LB^{G}	Group Adjustment^{G}
G1	10001	133	104	21.8%	11.8%	3.0%	1.96	17.7%	5.9%	10%
	10002	96	87	9.4%						0
	⋮	⋮	⋮	⋮						...
G2	10001	171	128	25.1%	17.1%	3.4%	1.96	23.8%	10.4%	8%
	10002	111	86	22.5%						0
	⋮	⋮	⋮	⋮						...
G3	10001	131	96	26.7%	25.9%	4.0%	1.96	33.7%	18.1%	0
	10002	96	79	17.7%						-8.2%
	⋮	⋮	⋮	⋮						...

(5) Step Five (5): CMS will use the issuer's Group adjustment to correct enrollee-level risk scores and project a finalized risk score to the population (See Section 7.3.3). Note, Issuer 10001's Group adjustment factors for G1, G2, and G3 are 10%, 8%, and 0% respectively (derived in Step Four [4]), and assume the issuer enrollees have the following profile:

Issuer	Enrollee	Stratum Size in Population	Sample Enrollees from the Stratum	Stratum Level	HCCs	Maturity	Severity	$EdgeRS_{i,e}$
10001	10001-1	352	67	Infant-Medium	125,130,138,248	PREMATURE MULTIPLES	5	175.329
10001	10001-2	1418	37	Adult-High	1,12,30,37,57,115			19.012
10001	⋮			⋮	⋮	⋮	⋮	⋮

1. CMS will calculate the adjustment amount factor that will be applied to each enrollee in a sample using the three (3) adjustment factors calculated at HCC Group level.

   a. Calculate the adjustment factor for Enrollee 10001-1. See table below for reference. Enrollee 10001-1 is under the Silver metal plan and is age zero (0).

      i. This enrollee has four (4) HCCs recorded on the EDGE server. For EDGE HCCs [125,130,138,248]. Compute the risk score for a single HCC using the logic defined in HHS Risk Adjustment Model table. For an infant enrollee in the sample, the computation of the single HCC risk score takes into consideration the enrollee's actual maturity and severity levels.

      ii. Assume the four (4) HCC codes [138,248,125,130] were categorized in HCC Groups G1, G1, G2, and G2 respectively (the result of Step Three [3]). They are associated with the Group level adjustment factors of 10%, 10%, 8% and 8% (the result of Step Four [4]).

      iii. Compute the enrollee adjustment score as the weighted average of group level adjustment factors, weighting by the risk score of the HCCs. The four HCC codes have HCC risk scores of 6.402, 175.329, 41.549, and 41.549 with group level adjustment factors of 10%, 10%, 8%, and 8% respectively.

This results in a weighted adjustment score of 9.4% (i.e., $\frac{6.402*10\% + 175.329*10\% + 41.549*8\% + 41.549*8\%}{6.402 + 175.329 + 41.549 + 41.549}$).

b. Calculate the adjustment factor for Enrollee 10001-2. See table below for reference. Enrollee 10001-2 is under the Silver metal plan.

   i. This enrollee has six (6) HCCs recorded on the EDGE server. For EDGE HCCs [1, 12, 30, 37, 57, 115], compute the risk score of a single HCC using the logic defined in HHS Risk Adjustment Model table.

   ii. Assume the six (6) HCCs [30,115,1,12,37,57] were categorized in HCC groups G1, G1, G2, G3, G3, and G3 respectively (the result of Step Three {3}). They are associated with the Group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0% (the result of Step Four [4]).

   iii. Compute the enrollee adjustment score as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. The six HCC codes have HCC risk scores of 2.16, 5.29, 5.302, 3.117, 2.077, and 1.066 with group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0%% respectively. This results in a weighted adjustment score of 6.1%

   (i.e., $\frac{2.16*10\% + 5.29*10\% + 5.302*8\% + 3.117*0\% + 2.077*0\% + 1.066*0\%}{2.16 + 5.29 + 5.302 + 3.117 + 2.077 + 1.066}$).

Enrollee	Stratum Level	Age Last	HCC Failure Group	HCC	Severity	Maturity	$RS_{i,e}^{hcc,G}$	$Group\ Adjustment_i^G$	$Enrollee\ Adjustment_{i,e}$
10001-1	Infant-Medium	0	G1	138	4	AGE1	6.402	10.0%	9.4%
				248		PREMATURE MULTIPLES	175.329		
			G2	125	5	AGE1	41.549	8.0%	
				130	5	AGE1	41.549		
10001-2	Adult-High	N/A	G1	30			2.16	10.0%	6.1%
				115			5.29		
			G2	1			5.302	8.0%	
			G3	12			3.117	0%	
				37			2.077		
				57			1.066		

c. Use the enrollees' adjustment factors to correct (adjust) the EDGE risk score for samples.

   i. Apply the enrollee level adjustment factor to the EDGE Risk Score of the sampled enrollee. Enrollees 10001-1 and 10001-2 have 9.4% and 6.1% adjustment factors applied to their EDGE Risk Scores, respectively.

Issuer	Enrollee	EDGE HCCs	$EdgeRS_{i,e}$	$Enrollee\ Adjustment_{i,e}$	$AdjRS_{i,e}$
10001	10001-1	125,130,138,248	175.329	9.4%	158.85
10001	10001-2	1,12,30,37,57,115	19.012	6.1%	17.85

d. Calculate the issuer's Error Rate. Since there are one hundred enrollees, for simplicity, we assume here the stratum weighted summation of the EDGE risk score is 20,751 and the stratum weighted summation of adjusted risk score is 20,538.

i. Compute the Error Rate of Issuer 10001 using the EDGE risk score and adjusted risk score for all enrollees in the sample.

ii. Compute the stratum weight as the ratio of stratum size in population to the number of sample enrollees from the stratum.

iii. Finally, we calculate the issuer level error rate for Issuer 10001 of 1.03%

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	w_e	$w_e * EdgeRS_{i,e}$	$w_e * AdjRS_{i,e}$	$\sum w_e * EdgeRS_{i,e}$	$\sum w_e * AdjRS_{i,e}$	Error Rate
10001	10001-1	Infant-Medium	175.329	158.85	5.25	920	834	20751	20538	1.03%
10001	10001-2	Adult-High	19.012	17.85	38.32	729	684			
10001	⋮	⋮	⋮	⋮	⋮	⋮	⋮			

(6) Step Six (6): For IVA samples that indicate a statistically significant difference between IVA and SVA100 results following a pairwise means test, CMS will use bootstrap resampling to determine the standard errors and confidence intervals for the issuers' Error Rate calculated in Step Five (5). The bootstrap procedure is used to determine if expansion to SVA200 is required.

1. Draw a sample with replacement of enrollees equal to the number of IVA sampled enrollees from issuer 10001. For this example, as the result of the SVA review, there are 100 enrollees in the IVA sample. Repeat drawing a sample of enrollees (100) with replacement at minimum 1,000 times and determine the error rate for each sample.

    a. The error rates are determined by repeating the above mentioned steps using the enrollee details corresponding to the bootstrap sample (i.e., 1-1000).

Bootstrap Sample / Enrollee	1	2	...	1,000
1	10001-27	10001-12	...	10001-32
2	10001-1	10001-92	...	10001-67
⋮	⋮	⋮	⋮	⋮
100	10001-43	10001-85	...	10001-67
Error Rate:	0.96%	1.17%	...	1.09%

2. Compute the bootstrapped standard error by calculating the sample standard deviation across the 1,000 resampled error rates (i.e., the 1,000 error rates from the above table). This results in a standard error of 0.12%.

3. Determine the bootstrapped confidence intervals by identifying the 2.5th and 97.5th centiles of the 1,000 resampled Error Rates (i.e., the 1,000 error rates from the above table). This results in a confidence interval of [0.83%, 1.23%].

4. At the conclusion of this process, CMS reviews the confidence interval to determine if the error rate is statistically accurate and reliable, in order to determine whether the full review of SVA200 is required, or if the SVA100 can be used for calculating the error rate and subsequent payment adjustments. If the result concludes that the precision of the error rate estimate is too low for SVA100, CMS will expand the issuers' sample to SVA200. The entire error estimation process would be re-performed (starting with Step One [1]) to include these new samples since the overall HCC failure distribution changes after some issuers revise their samples.

Issuer	Error Rate	Standard Error	Confidence Interval	
			Lower	Upper
10001	1.03%	0.12%	0.83%	1.23%

At the conclusion of the HHS-RADV process, including the Discrepancy Reporting and Administrative Appeals process as described in Section 9, the issuer's error rate will be used to calculate the issuer's adjusted risk score during the RA payment transfer process, using the formula below:

$$(1 - (error\ rate)) * (plan\ liability\ risk\ score) = Adjusted\ Risk\ Score$$

The issuer's adjusted risk score will then be used in the RA process to calculate RA payments and charges for the following benefit year.

Please see Appendix D – Error Estimation Example for an additional example of the Error Estimation process.

Section 8

HHS Risk Adjustment Data Validation Protocols

Non-Compliance Activities and Penalties

8 HHS Risk Adjustment Data Validation Non-Compliance Activities and Penalties

8.1 Non-Compliance Activities

As described in 45 C.F.R. § 153.620(b), an issuer that offers RA covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards (which includes HHS-RADV), for each benefit year for at least ten (10) years, and must make those documents and records available upon request to HHS, the OIG, the Comptroller General, or their designees for purposes of verification, investigation, audit or other review.

For the purposes of HHS-RADV, issuers, IVA Entities, and the SVA Entity are required to conform to the criteria set forth in the regulations and guidance implementing HHS-RADV. Failure to adhere to these criteria may result in enforcement actions related to non-compliance with HHS-RADV procedures. CMS will provide oversight over the HHS-RADV process, including taking certain actions in cases where issuers and/or their IVA Entity are not following these requirements.

Examples of instances that may result in enforcement actions due to non-compliance with HHS-RADV requirements include:

- Issuer did not Register for the Audit Tool – (Section 7.4.1); 45 C.F.R. § 153.630(a)
- Issuer Designated Incapable IVA Entity – (Section 7.4.2); 45 C.F.R. § 153.630(b)(2)
- IVA Entity Not Free of Conflict of Interest, or not in Good Standing – (Section 7.4.3); 45 C.F.R. § 153.630(b)(3) and (5)
- Incomplete Audit Results Submissions – (Section 7.4.4); 45 C.F.R. § 153.630(f)
- Supporting Documentation Not Provided by IVA Entity – (Section 7.4.5); 45 C.F.R. § 153.630(b)(6)
- Suspected Fraud in Submitted Data, and Follow-Up Actions – (Section 7.4.6); 45 C.F.R. § 156.630(b)(4)

8.1.1 Issuer did not Register for the Audit Tool

Consistent with 45 C.F.R. § 153.630(a), issuers of RA covered plans in states where HHS operates risk adjustment must comply with the HHS-RADV requirements.

Issuers are required to register for the audit tool with CMS to perform required activities of HHS-RADV. If an issuer does not register, the issuer is non-compliant with HHS-RADV.

8.1.2 Issuer Designated Incapable IVA Entity or did not Engage an IVA Entity

According to 45 C.F.R. § 153.630(b)(2), the issuer must ensure that the IVA Entity is reasonably capable of performing an IVA according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

Issuers must engage and designate an IVA Entity that is capable of performing the IVA audit effectively. The issuer is required to engage and designate an IVA Entity to perform the IVA for each state in which it offers RA covered plans. If an issuer does not engage and designate an IVA Entity the issuer will be unable to perform the IVA as required by HHS-

RADV.

8.1.3 IVA Entity Not Free of Conflict of Interest or not in Good Standing

As described in 45 C.F.R. § 153.630(b)(3), the issuer must ensure that each IVA Entity is 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. Consistent with 45 C.F.R. § 153.630(b)(5), an IVA must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

Issuers are responsible for performing due diligence to determine the status of an IVA Entity during the selection process. During this process, issuers are to make every reasonable effort to determine if an IVA Entity has any existing legal issue that has either resulted in the IVA Entity being put on the OIG exclusion list, HHS exclusion list, or a State exclusion list. Before engaging an IVA Entity, the issuer is expected to verify and document that any key individuals involved in supervising or performing the IVA have not been excluded from working with either the Medicare or Medicaid program. Issuers must also confirm that the IVA Entity is reasonably free of any conflicts of interest. HHS may elect to review the IVA Entity's qualifications and confirm if there are no conflicts of interest. This could include using external sources to assess potential conflicts of interest and confirm that the IVA Entity has the knowledge, skills, and abilities to conduct a high-quality IVA.

8.1.4 Incomplete Audit Results Submission

Consistent with 45 C.F.R. § 153.630(f), the issuer must ensure that the IVA and SVA data and source documentation are submitted to HHS in a manner and timeframe specified by HHS.

IVA Entities are required to complete their IVA, and submit the results using the audit tool, completing all required fields, and providing the required supporting documentation (if any). If an IVA Entity does not submit complete results, the SVA Entity will be unable to perform their SVA and will reject the incomplete IVA submission.

8.1.5 Supporting Documentation Not Provided to IVA

According to 45 C.F.R § 153.630(b)(6), the issuer must ensure that the SVA Entity has all relevant source enrollment documentation, all applicable non-EDGE claim and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample through the audit tool in a timely manner.

Issuers are required to provide their IVA Entity and SVA Entity with the appropriate enrollee demographic, enrollment, applicable non-EDGE claim, and medical record documentation. The IVA Entity should submit this documentation to the SVA through the audit tool in a timely manner to support the issuer's compliance with HHS-RADV requirements.

8.1.6 Suspected Fraud in Submitted Data, and Follow-Up Actions

Under 45 C.F.R. § 153.630(b)(4), the issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by CMS.

Issuers must follow the HHS-RADV requirements and refrain from any fraudulent activities when they submit supporting data and source documentation to the IVA Entity and the SVA Entity. If the issuer engages in suspected fraud in regard to the HHS-RADV process, the results from the IVA Entities and the SVA Entity will be inaccurate. If CMS suspects potential fraud, it will refer issuers to the appropriate Federal fraud enforcement entity and State agencies.

8.2 Non-Compliance Penalties

CMS may take enforcement action, including the imposition of civil monetary penalties (CMPs), in the event of non-compliance by an issuer of a RA covered plan or the issuer's IVA Entity. Subsections 7.5.1 and 7.5.2 provide information on two (2) penalties that can be imposed for non-compliance with HHS-RADV requirements and standards.

8.2.1 Civil Monetary Penalties

CMPs are a monetary penalty assessed to an issuer in the event of non-compliance. Amendments finalized in the 2019 Payment Notice clarify the non-compliance situations which may result in CMPs being imposed. For example, if an issuer does not engage an IVA Entity or submit the results of an IVA to CMS, CMPs may be imposed, as appropriate, under 45 C.F.R. § 153.630(b)(9)(i) and (ii). Additionally, CMPs may be assessed if an issuer engages in misconduct or substantial non-compliance with the RADV standards and requirements or intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS.

8.2.2 Default Data Validation Charge

A default data validation charge is a charge assessed to an issuer that is noncompliant with certain HHS-RADV requirements. Under 45 C.F.R. § 153.630(b)(10), if an issuer of a RA covered plan fails to engage an IVA Entity, or to submit the results of an IVA to CMS, CMS will impose a RADC. CMS will determine the amount of the RADC by using data from the benefit year for which the issuer fails to engage an IVA Entity or does not submit the results of an IVA. By way of example, the 2017 benefit year RADC imposed under 45 C.F.R. § 153.630(b)(10) would be based on the issuer's 2017 PMPM and enrollment.

Section 9

HHS-Operated Risk Adjustment Data Validation Protocols

Final Results Discrepancy Reporting and Administrative Appeals

9 HHS-Operated Risk Adjustment Data Validation Discrepancy Reporting and Administrative Appeals

9.1 Overview

At the conclusion of the HHS-RADV Audit process, CMS will distribute to each issuer its respective pairwise analysis results, SVA findings (as applicable, in the event there is insufficient agreement between the IVA and SVA results during the pairwise analysis and the SVA findings are used for the error rate calculation), issuer Error Rate, and supporting documentation of CMS' calculation of the issuer Error Rate for all of the issuer's HHS-RADV HIOS IDs. In addition, CMS will distribute HIOS ID-specific enrollee-level audit results, including adjusted risk scores and other supplemental data to support the findings of the HHS-RADV process. Issuer Error Rates determined by CMS and communicated to issuers are generally applied to issuers' RA covered plans' subsequent benefit year risk scores prior to calculating final risk adjustment transfers as part of the RA Transfer Calculation process. For example, the 2017 issuer Error Rates will generally be applied to the 2018 RA risk scores and resulting transfers.[26]

After receipt and review of HHS-RADV SVA findings (if applicable) and the issuer Error Rate for the applicable benefit year, issuers are required to confirm the SVA findings (if applicable) and issuer Error Rate and attest to the findings as stated in Section 8.2, or qualify the attestation by filing a discrepancy report to dispute the findings of the SVA (if applicable) or the calculation of the issuer Error Rate (see 45 C.F.R. § 153.630(d)(2)).

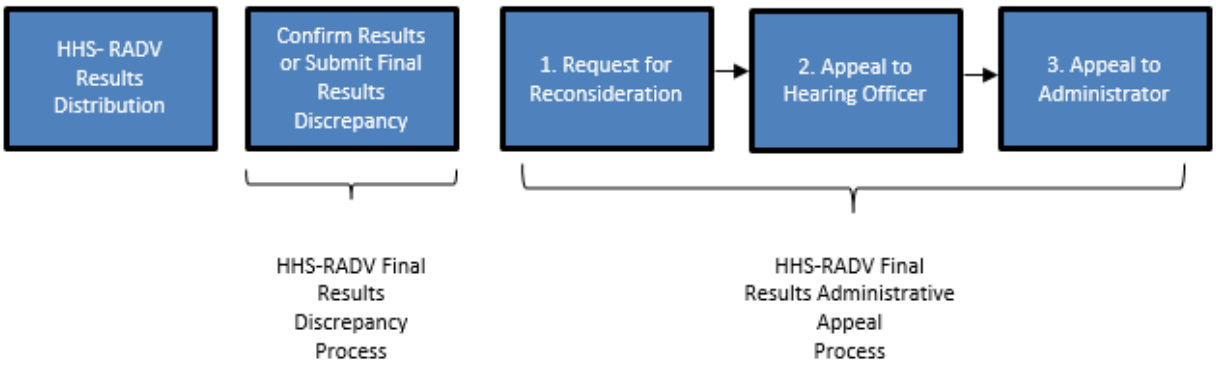
Issuers that file a final results discrepancy are permitted to file a request for reconsideration specific to the HHS-RADV SVA Findings (if applicable) and/or the issuer Error Rate, which is the first level in the Administrative Appeals process set forth in 45 C.F.R. § 156.1220. As noted in the 2018 Payment Notice, appealing IVA findings is not permitted.

Issuers may only file a reconsideration request to dispute the HHS-RADV SVA Findings (if applicable) or the issuer Error Rate on one or more of these three bases: (1) a processing error by HHS, (2) HHS's incorrect application of the relevant methodology, or (3) HHS's mathematical error. In addition, a request for reconsideration may be filed only if the amount in dispute is equal to or exceeds one (1) percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

As shown in Figure Five (5) below, the Administrative Appeals process begins after the HHS-RADV SVA findings (if applicable) and the issuer Error Rate are distributed and issuers have filed a final results discrepancy during the discrepancy submission window.

[26] As noted in Section 1, CMS will adjust 2017 benefit year risk scores and recalculate transfers if an issuer that is exiting the market in 2018 is found to have a non-zero Error Rate in 2017 benefit year HHS-RADV.

Figure 5



9.2 Attestations

After receipt and review of final HHS-RADV SVA findings (if applicable) and the issuer Error Rate for the applicable benefit year, all issuers are required to confirm and attest to the SVA findings (if applicable) and issuer Error Rate, or qualify that attestation by filing a discrepancy report to dispute the findings of the SVA (if applicable) or the calculation of the issuer Error Rate. Issuers must either attest to the SVA findings (if applicable) and issuer Error Rate, or qualify that attestation and file a discrepancy, within 30 calendar days of notification of the final results.

CMS requires issuers to attest to all SVA findings (if applicable) and issuer Error Rates unless otherwise qualified with a discrepancy.

All attestations must be provided by an individual who can legally and financially obligate the company.

9.3 Timeline

The HHS-RADV Final Results Discrepancy and Administrative Appeals processes will occur annually for each benefit year beginning with 2017 HHS-RADV. The 2017 benefit year is the first year of HHS-RADV for which the issuer Error Rates will be used to adjust RA risk scores and the resulting payment transfers. Planned activities and an estimated timeline for the HHS-RADV Final Results Discrepancy and Administrative Appeals Processes are documented in Table 21. Note that this timeline is subject to change. Please refer to https://www.regtap.info/reg_librarye.php?i=2456 for HHS-RADV Timeline activities and corresponding deadlines for the applicable benefit year.

Table 21: HHS-RADV Timeline Activities

Date	Description
End of May/Early June 2019	Results distributed to issuers.
End of May/Early June 2019	Final Results Discrepancy Reporting period opens
30 Calendar Days From When the Discrepancy Reporting Period Opens June/July 2019	Final Results Discrepancy Reporting period closes

Date	Description
July 2, 2019	Administrative Appeals Window opens
August 1, 2019	Administrative Appeals Window closes

9.4 Error Rate Adjustments during HHS-RADV Final Results Discrepancy and Administrative Appeals

We note that CMS will apply the 2017 issuer Error Rate to 2018 RA risk scores and resulting transfers for issuers who remain in the state risk pool market and to 2017 RA risk scores and resulting transfer for issuers who exited the state risk pool market during or at the end of the 2017 benefit year regardless of any pending discrepancies or appeals. If an issuer submits a successful discrepancy or appeal that requires a further adjustment to the RA risk scores and transfers, CMS will make this payment out of the 2018 RA holdback in the applicable State market risk pool.

9.5 Scope – Final Results Discrepancies and Administrative Appeals

As part of the HHS-RADV Final Results Discrepancy process, issuers may only file discrepancies related to the final HHS-RADV SVA Findings (if applicable) and the issuer Error Rate. Issuers may only file administrative appeals under 45 C.F.R. § 156.1220(a)(1)(vii) and (viii) to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error with respect to the findings of the SVA (if applicable), or the calculation of the issuer Error Rate. As noted above, as stated in the 2018 Payment Notice, appealing IVA findings are not permitted as the IVA Entity is under contract with the issuer and CMS does not produce the IVA results.

In addition, pursuant to 45 C.F.R. § 156.1220(a)(2) a request for reconsideration may be filed only if the amount in dispute is equal to or exceeds one (1) percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

9.6 Final Results Discrepancy Reporting

After receipt and review of HHS-RADV SVA Findings (as applicable) and the issuer Error Rate for the benefit year, issuers will have the opportunity to dispute the findings and file a final results discrepancy. Consistent with 45 C.F.R. § 153.630(d)(2), issuers must attest to the HHS-RADV SVA Findings (if applicable) and the issuer Error Rate, or qualify the attestation by filing a final results discrepancy to dispute the results, within 30 calendar days of notification of the HHS-RADV SVA Findings (as applicable) and the issuer Error Rate.

The issuer must provide a detailed description and sufficient evidence in support of the discrepancy filed to allow CMS to appropriately identify the issue or finding being disputed, the document location or associated reference to which the dispute is linked, and the evidence or support necessary to evaluate the discrepancy provided. No additional documentation that was not provided during the IVA Results Submission process to CMS and the SVA Entity, such as additional medical records or screenshots, will be accepted as part of the discrepancy reporting process. Upon review of a reported discrepancy, CMS may request that additional documentation, reference material, or other supplemental evidence be

submitted in support of the discrepancy. Additional documentation should only be submitted at the request of CMS.

CMS will review all discrepancies and provide the issuer with a Final Results Discrepancy Resolution Decision, containing the Discrepancy ID and CMS' final decision.

Issuers are not permitted to submit final results discrepancies related to the items set forth in Table 22 below.

Table 22: Prohibited Submissions in the HHS-RADV Final Results Discrepancy Process

Results or Findings of the IVA

- Issuers are not permitted to file a final results discrepancy regarding the results of the IVA or the findings determined by their contracted IVA Entity. The HHS Notice of Benefit and Payments Parameters for 2018 Final Rule states, "HHS will not permit an issuer to appeal the results of the initial validation audit, as the initial validation audit entity is under contract with the issuer and HHS does not produce the initial validation audit results." Therefore, if there is sufficient agreement between the IVA and SVA results after the pairwise analysis, CMS will use the IVA results to calculate the HCC failure rate, and subsequently the risk score error rate.
- All IVA findings are considered final following issuer sign-off on the *IVA Entity Audit Results (XML)* submission.

HHS-RADV Sampling Report or IVA Sample Related Discrepancies

- Issuers are not permitted to submit final results discrepancies related to the HHS-RADV sampling reports, or the IVA Sample.
- Issues related to HHS-RADV sampling reports or the IVA Sample must be submitted and resolved as part of the HHS-RADV Interim Discrepancy Reporting process.
- For more information on the HHS-RADV Interim Discrepancy Reporting process related to sampling please refer to ***Section 4.5***.

Additional Documentation

- Issuers should not submit additional medical record documentation, or supplemental documentation, which was not provided during the IVA Results Submission process to CMS and the SVA Entity, as part of a final results discrepancy.
- Final results discrepancies may only leverage documentation available to CMS and the SVA Entity during the SVA process.
- Issuers will be permitted to provide CMS with references to publicly available reference material (e.g. coding clinic references) to support final results discrepancies.
- Issuers will be permitted to provide CMS with IVA Entity coder notes created during the IVA audit to help support their findings.

9.7 Administrative Appeals

To file an administrative appeal, the issuer must have previously submitted a final results discrepancy (to the extent the issue could have been previously identified) through the process set forth in 45 C.F.R.§ 153.630(d)(2), and it was so identified and remains unresolved. See 45 C.F.R. § 156.1220(a)(4)(ii). Issuers that filed a final results discrepancy to dispute HHS-RADV SVA Findings (if applicable) or the issuer Error Rate are permitted to file a request for reconsideration (the first level of the HHS-RADV Final Results Administrative

Appeals process) to dispute the HHS-RADV SVA Findings (if applicable) or the issuer Error Rate on one or more of these three bases (1) a processing error by CMS, (2) CMS's incorrect application of the relevant methodology, or (3) CMS's mathematical error. See 45 C.F.R. § 156.1220(a)(1)(vii) and (viii).

In addition, a request for reconsideration may be filed only if the amount in dispute is equal to or exceeds one (1) percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or $10,000, whichever is less. See 45 C.F.R. § 156.1220(a)(2).

A company may submit multiple requests for reconsideration for the same or different HIOS IDs. Issuers may choose to submit a request for reconsideration if there is disagreement with the Final Results Discrepancy Resolution Decision provided by CMS, or a final results discrepancy has not been resolved by CMS by the close of the administrative appeals submission window.

Issuers are not permitted to submit administrative appeals related to the items set forth in Table 23 below.

Table 23: Prohibited Submissions in the HHS-RADV Administrative Appeals Process

Administrative Appeals without a Final Results Discrepancy

- Issuers may not file an administrative appeal if a discrepancy was not identified during the final results discrepancy reporting period, and this discrepancy could have been identified at the time.
- CMS will require all administrative appeals to be linked to a Discrepancy ID provided to issuers during the final results discrepancy reporting window, as long as the discrepancy could have been and was so identifiable during the Final Results Discrepancy Submission Window.

Administrative Appeals if under the Materiality Threshold

- Pursuant to 45 C.F.R. § 156.1220(a)(2), an issuer may file a request for reconsideration only if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge for RADV (i.e., the amount of the RADV adjustment) payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

Results or Findings of the IVA

- Issuers are not permitted to file an administrative appeal regarding the results of the IVA or the findings determined by their contracted IVA Entity. The HHS Notice of Benefit and Payments Parameters for 2018 Final Rule states, “HHS will not permit an issuer to appeal the results of the initial validation audit, as the initial validation audit entity is under contract with the issuer and HHS does not produce the initial validation audit results.” If there is sufficient agreement between the IVA and SVA results after the pairwise analysis, CMS will use the IVA results to calculate the HCC failure rate, and subsequently the risk score error rate.
- All IVA findings are considered final following issuer sign-off on the *IVA Entity Audit Results (XML)* submission.

HHS-RADV Sampling Report or IVA Sample Related Discrepancies

- Issuers are not permitted to submit an administrative appeal related to the HHS-RADV sampling reports or the IVA Sample.
- Issues related to HHS-RADV sampling reports or the IVA Sample must be submitted and resolved as part of the HHS-RADV Interim Discrepancy Reporting process.

- For more information on the HHS-RADV Interim Discrepancy Reporting process related to sampling please refer to ***Section 4.5***.

Additional Documentation Prohibited

- Issuers should not submit additional medical record documentation, or supplemental documentation, which was not provided during the IVA Results Submission process to CMS and the SVA Entity, as part of an administrative appeal.
- Administrative appeals may only leverage the data (i.e., the medical record documentation and any supplemental documentation) available to CMS and the SVA Entity during the SVA process.
- Issuers will be permitted to provide CMS with references to publicly available reference material (e.g. coding clinic references) to support administrative appeals.

9.7.1 Levels of Administrative Appeals

The HHS-RADV Final Results Administrative Appeals process under 45 C.F.R. § 156.1220 is composed of three (3) levels:

- *Request for Reconsideration*
- *Appeal to Hearing Officer*
- *Appeal to Administrator (or their delegate)*

Each of the three (3) levels of the HHS-RADV Final Results Administrative Appeals processes are described in the following sections.

9.7.1.1 Request for Reconsideration

If a final results discrepancy remains outstanding and/or the discrepancy could not have been identified during the final results discrepancy reporting period, an issuer may appeal the results of the final SVA findings (if applicable) and issuer Error Rate within 30 calendar days of the notice under 45 C.F.R. § 153.310(e) (i.e., the annual Summary Risk Adjustment report released no later than June 30 of the year following the applicable benefit year) by submitting a request for reconsideration. A request for reconsideration must be submitted within this timeframe regardless of any pending final results discrepancies. The issuer may only file a request for reconsideration to dispute the HHS-RADV SVA Findings (if applicable) or the issuer Error Rate on one or more of these three bases (1) a processing error by CMS, (2) CMS' incorrect application of the relevant methodology, or (3) CMS' mathematical error. Additionally, an issuer may only file a request for reconsideration if the amount in dispute is equal to or exceeds one (1) percent of the applicable payment or charge (here, the amount of the RADV adjustment) payable to or due from the issuer for the benefit year, or $10,000, whichever is less

A request for reconsideration must specify the findings or issues that the issuer challenges, and the reasons for the challenge. The issuer must provide sufficient evidence in support of the request for reconsideration to allow CMS to appropriately identify the issue or finding being disputed, the document location or associated reference to which the dispute is linked, and the evidence or support necessary to evaluate the dispute provided. All requests for reconsideration must link back to the original documents submitted during the IVA Submission process, and no new data (i.e., medical record or supplemental documentation) may be submitted to support the request for reconsideration.

In reviewing the reconsideration request, CMS will review the appropriate SVA findings (as applicable) or issuer Error Rate being challenged, the evidence and findings upon which the

determination was based, and any additional documentary evidence submitted by the issuer. CMS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

See 45 C.FR. § 156.1220(a)(5).CMS will inform the issuer of the reconsideration decision in writing. See 45 C.F.R. § 156.1220(a)(6).

9.7.1.2 Appeal to Hearing Officer

An issuer may request an informal hearing before a CMS hearing officer to appeal CMS' Reconsideration Decision. A request for an informal hearing must be made in writing and filed with CMS within 30 calendar days from the date of the Reconsideration Decision. The request for informal hearing must include a copy of the Reconsideration Decision and the issuer must specify the findings or issues in the decision that the issuer challenges, and its reasons for the challenge. CMS may submit a Statement in support of its Reconsideration Decision for review by the CMS hearing officer. The CMS hearing officer will neither receive testimony nor accept any new evidence that was not presented with the Reconsideration Request. The CMS hearing officer will review only the documentary evidence provided by the issuer and CMS, and the record that was before CMS when CMS made its reconsideration determination. The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact. The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer.

See 45 C.F.R. § 156.1220(b) for details on this second level of the HHS-RADV administrative appeals process.

9.7.1.3 Appeal to Administrator

Either the issuer or CMS may request review by the CMS Administrator of the Hearing Officer's decision. A request for review of the Hearing Officer's decision must be submitted to the CMS Administrator within 15 calendar days of the date of the Hearing Officer's decision, and must specify the findings or issues that the issuer or CMS challenges. The issuer or CMS may submit for review by the CMS Administrator a statement supporting the decision of the Hearing Officer. After receiving a request for review, the CMS Administrator has the discretion to elect to review the Hearing Officer's decision or to decline to review the Hearing Officer's decision. If the CMS Administrator elects to review the Hearing Officer's decision, the Administrator will also review the statements of the issuer and CMS, and any other information included in the record of the Hearing Officer's decision, and will determine whether to uphold, reverse, or modify the Hearing Officer's decision. The issuer or CMS must prove its case by clear and convincing evidence for issues of fact. The CMS Administrator will send the decision and the reasons for the decision to the issuer.

The CMS Administrator's determination is final and binding.

See 45 C.F.R. § 156.1220(c) for details on this third level of the HHS-RADV administrative appeals process.

Section 10

HHS Risk Adjustment Data Validation Protocols

Appendices

10 Appendices

Appendix A: ICD-10-CM Official Guidelines for Coding and Reporting

See CMS.gov for the latest ICD-10-CM guidelines at the following link:
https://www.cms.gov/medicare/coding/icd10/downloads/2016-icd-10-cm-guidelines.pdf

Appendix B: EDGE Server RADV Reports Resources

The EDGE Server HHS-RADV sampling reports consists of six (6) reports generated by the issuer's EDGE server:

- **RADV Population Summary Statistics Final (RADVPSF) Report**
  - Contains population statistics for an issuer's population included in RADV broken into sub-categories, known as "strata," which are based on enrollee age (infant, child, adult) and risk score (low, medium, high).
  - Contains only enrollees in a risk pool market where a risk adjustment transfer occurs and excludes enrollees in a risk pool market if the issuer is the only issuer in that risk pool market.
- **RADV IVA Statistics (RADVIVAS) Report**
  - Contains the sample statistics calculated at the strata-level for the enrollees selected for the RADV IVA sample.
  - Similar in layout to the RADVPS Report, but limited to the enrollees selected for the IVA sample.
- **RADV Detailed Enrollee (RADVDE) Report**
  - Identifies the issuer's enrollees selected for the RADV IVA sample.
  - Contains enrollee-level data for each enrollee selected for the RADV IVA sample, such as the sampled enrollee's risk score, demographic, and health status information.
- **RADV Enrollee Extract (RADVEE) Report**
  - Contains all active enrollment data that was submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Medical Claims Extract (RADVMCE) Report**
  - Contains all active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Supplemental Extract (RADVSE) Report**
  - Contains all active supplemental records for active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.

For further information about the RADV sampling reports, see the **Interface Control Document - Risk Adjustment and Reinsurance Addendum Version 05.00.19 (8/3/18)** available in the REGTAP Library. Additionally, the following Job Aids for validation of RA Reports and RADV Reports are located in the REGTAP library:

- Job Aid for Validation of RADVPS Reports (4/20/18)
- Job Aid for Validation of RADVPSF Report (05/21/18)
- Job Aid for Validation of RADVIVAS Reports (05/21/18)

See **XML/XSD Outbound Files (8/3/18) in the REGTAP Library** for the latest EDGE server outbound report XML examples and XSDs.

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Appendix C: Chronic Condition HCCs

The ICD-10-CM Official Coding Guidelines for Coding and Reporting and the Protocols must be followed when considering the applicability of the underlying diagnoses for chronic conditions. For purposes of HHS-RADV, CMS considers a chronic condition as lasting for one (1) year or more and requiring ongoing medical attention.

The following table is not exhaustive of all chronic conditions. Coders should utilize these Protocols and ICD-10-CM coding guidelines when determining chronicity of a diagnosis.

HHS-HCC	HHS-HCC Label
1	Human Immunodeficiency Virus (HIV)
20	Diabetes with Chronic Complications
26	Mucopolysaccharidosis
27	Lipidoses and Glycogenosis
28	Congenital Metabolic Disorders, Not Elsewhere Classified
29	Amyloidosis, Porphyria, and Other Metabolic Disorders
36	Cirrhosis of Liver
37	Chronic Hepatitis
46	Chronic Pancreatitis
48	Inflammatory Bowel Disease
56	Rheumatoid Arthritis and Specified Autoimmune Disorders
57	Systemic Lupus Erythematosus and Other Autoimmune Disorders
61	Osteogenesis Imperfecta and Other Osteodystrophies
62	Congenital/Developmental Skeletal and Connective Tissue Disorders
63	Cleft Lip/Cleft Palate
64	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2
66	Hemophilia
68	Aplastic Anemia
70	Sickle Cell Anemia (Hb-SS)
71	Thalassemia Major
73	Combined and Other Severe Immunodeficiencies
74	Disorders of the Immune Mechanism
82	Drug Dependence
87	Schizophrenia
88	Major Depressive and Bipolar Disorders
90	Personality Disorders
94	Anorexia/Bulimia Nervosa
96	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
97	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes
102	Autistic Disorder
103	Pervasive Developmental Disorders, Except Autistic Disorder
107	Quadriplegia

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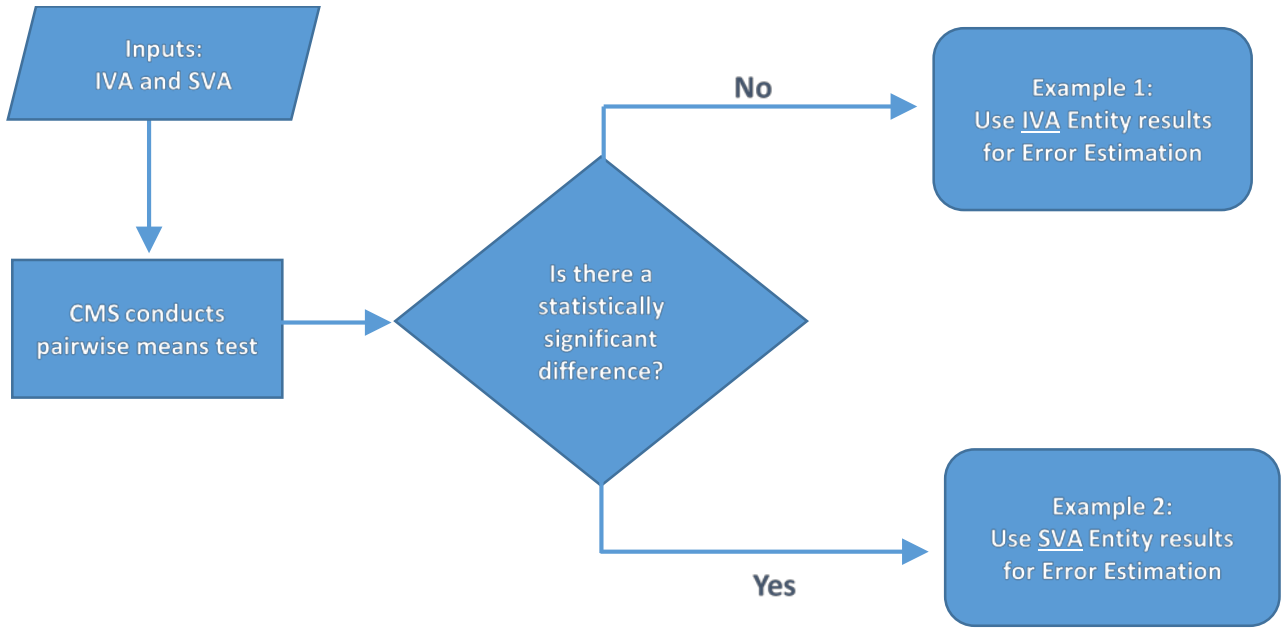
109	Paraplegia
111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
112	Quadriplegic Cerebral Palsy
114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
117	Muscular Dystrophy
118	Multiple Sclerosis
119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
121	Hydrocephalus
128	Heart Assistive Device/Artificial Heart
137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart
138	Major Congenital Heart/Circulatory Disorders
142	Specified Heart Arrhythmias
149	Cerebral Aneurysm and Arteriovenous Malformation
150	Hemiplegia/Hemiparesis
151	Monoplegia, Other Paralytic Syndromes
159	Cystic Fibrosis
160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
161	Asthma
184	End Stage Renal Disease
187	Chronic Kidney Disease, Stage 5
188	Chronic Kidney Disease, Severe (Stage 4)

Appendix D: Error Estimation Example

The purpose of this section is to provide stakeholders with an additional example of the Error Estimation process, supplemental to the information provided in Chapter 7 of the 2017 HHS-RADV Protocols. All examples are for illustrative purposes only and are not based on real HHS-RADV data.

Please note that the detailed issuer and enrollee information provided below may vary across examples. The information is intended to provide details of the components of the HCC Failure Rate methodology calculations.

1) Establish Final Enrollee Results



- Example 1: Outcome – Use IVA Results
  - Issuer 10001 has 200 IVA sampled enrollees
  - Issuer 10001 has passed the pairwise means test based on the 24 SVA sample, after failing at pairwise SVA 12 review

Compare IVA and SVA results

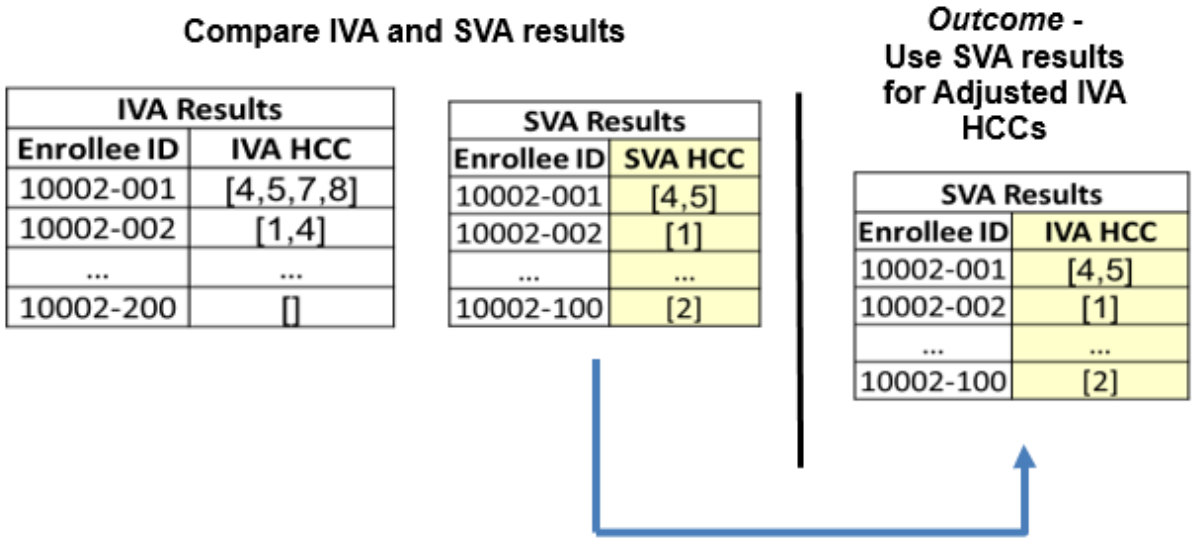
IVA Results	
Enrollee ID	**IVA HCC**
10001-001	[1,2,3]
10001-002	[4,5,6]
...	...
10001-024	[1,4]
...	...
10001-200	[2,5]

SVA Results	
Enrollee ID	**SVA HCC**
10001-001	[1,2]
10001-002	[4,5,6]
...	...
10001-024	[1,4]

***Outcome* - Use IVA results**

IVA Results	
Enrollee ID	**IVA HCC**
10001-001	[1,2,3]
10001-002	[4,5,6]
...	...
10001-024	[1,4]
...	...
10001-200	[2,5]

- Example 2: Outcome – Use SVA Results
  - Issuer 10002 has 200 IVA sampled enrollees
  - The pairwise test results in a significant difference between IVA and SVA results for the 100 enrollees reviewed and the SVA determined the precision to be high[27]



2) Determine HCC Groups, Calculate Issuer Group Failure Rates and Adjustments, and Determine Final Issuer Error Rates

- Example 3: Introduction
  - Assume there are 50,000 total enrollees sampled during one year's HHS-RADV process, across all issuers
  - The EDGE HCCs and adjusted IVA HCCs are stored as shown in the table

Enrollee ID	EDGE HCC	Adjusted IVA HCC
1	[30, 115, 138]	[30, 115]
2	[1, 30]	[1, 30]
...	...	...
50,000	[30, 57]	[57]

- Example 3 (a): Determine total HCC frequencies and calculate HCC failure rates

1 – (*Freq_IVA* / *Freq_EDGE*) = $Failure\ Rate^h$
Ex: 1 – (1,833 / 2,200) = **17%**

[27] In the event that the IVA fails pairwise 100, a precision analysis will be conducted to determine whether to use the SVA 100 level findings (a result of high precision) or expand to the full IVA sample of enrollees, which would then be evaluated by the SVA, and utilized for error estimation purposes.

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HCC	$*\ Freq\_EDGE^h$	$**\ Freq\_IVA^h$	$Failure\ Rate^h$
1	2,200	1,833	**17%**
12	2,500	1,700	32%
30	200	180	10%
37	2,000	1,100	45%
57	1,500	500	67%
115	700	607	13%
125	2,700	2,237	17%
130	3,000	2,300	23%
138	1,200	1,020	15%
248	1,700	1,428	16%
Total	17,700	12,905	27%

*Freq_EDGE = Total number of enrollees containing such HCC on EDGE
**Freq_IVA = Total number enrollees containing such HCC in the adjusted IVA results

- Example 3 (b): Tier HCCs nationally into Low, Medium, and High failure rate groups
  - The first boundary to segment Low and Medium failure HCCs is drawn between HCCs 248 and 1, because the total EDGE frequencies of the first four HCCs from the list (30, 115, 138, 248) makes the Group size close to 33.33% of all EDGE frequencies
  - The second boundary to segment Medium and High failure HCCs is drawn between HCC 130 and HCC 12, because the Group size is close to 67% of all EDGE frequencies

HCC	$Freq\_EDGE^h$	$Freq\_IVA^h$	FR^h	$Freq\_EDGE^h$ Cumulative Probability	Boundary	Group
30	200	180	10%	1%		Low
115	700	607	13%	5%		Low
138	1,200	1,020	15%	12%		Low
248	1,700	1,428	16%	21%	**33.33%**	Low
1	2,200	1,833	17%	34%		Medium
125	2,700	2,237	17%	49%		Medium
130	3,000	2,300	23%	66%	**67%**	Medium
12	2,500	1,700	32%	80%		High
37	2,000	1,100	45%	92%		High
57	1,500	500	67%	100%	100%	High
Total	17,700	12,905	27%			

HCC	Group
30	Low
115	Low
138	Low
248	Low
1	Medium
125	Medium
130	Medium
12	High
37	High
57	High

- Example 4: Introduction
  - Assume Issuers 10001 and 10002 each had 200 sampled enrollees
  - The EDGE HCCs and adjusted IVA HCCs are stored as shown in the left table
  - Recall the output of sub-process in Example 3 as shown in the right table

HIOS ID	Enrollee ID	EDGE HCC	Adjusted IVA HCC
10001	10001-001	[30, 115, 138]	[30, 115]
10001	10001-002	[1, 30]	[1, 30]
…	…	…	…
10001	10001-200	[248, 125]	[125]
10002	10002-001	[30, 57]	[57]
10002	10002-002	[125]	[125]
…	…	…	…
10002	10002-200	[37]	[37]

HCC	Group
30	Low
115	Low
138	Low
248	Low
1	Medium
125	Medium
130	Medium
12	High
37	High
57	High

- Example 4 (a): Determine Group Failure Rate
  - Notice that Issuers 10001 and 10002 enrollee HCCs have been replaced by their appropriate HCC Groups (Low, Medium, High) in the table below (left hand side)
  - Gather enrollee HCC Group level data to determine Freq_EDGE and Freq_IVA for each issuer
    - The issuer's HCC group frequency is determined by counting the instances of HCCs associated with each HCC Group for all enrollees for that issuer
    - For example, in the table below (left hand side), there are three (3) HCCs that are associated with the 'Low' HCC Group for HIOS ID 10001, Enrollee 10001-001 in EDGE, and two (2) HCCs associated with the 'Low' HCC Group in the adjusted IVA findings
    - After counting all instances across the issuer's enrollees, the total frequency recorded is shown in the table below (right hand side)

HIOS ID	Enrollee ID	EDGE HCC	Adjusted IVA HCC
10001	10001-001	[Low, Low, Low]	[Low, Low]
10001	10001-002	[Medium, Low]	[Medium, Low]
…	…	…	…
10001	10002-200	[Low, Medium]	[Medium]
10002	10002-001	[Low, High]	[High]
10002	10002-002	[Medium]	[Medium]
…	…	…	…
10002	10002-200	[High]	[High]

HCC Group	Issuer	$Freq\_EDGE^G$	$Freq\_IVA^G$
Low	10001	133	104
	10002	96	87
	⋮	⋮	⋮
Medium	10001	171	128
	10002	111	86
	⋮	⋮	⋮
High	10001	131	96
	10002	96	79
	⋮	⋮	⋮

  - Using the Freq_EDGE and Freq_IVA data collected above, calculate Group Failure Rate for each issuer's HCC Groups:

1– (Freq_IVA) / (Freq_EDGE) = Group Failure Rate (GFR)
Ex: 1 – (104 / 133) = **21.8%** for Issuer 100001 *(Group Low)*

HCC Group	Issuer	Freq_EDGE^G	Freq_IVA^G	GFR^G
Low	10001	133	104	**21.8%**
	10002	96	87	9.4%
	⋮	⋮	⋮	⋮
Medium	10001	171	128	25.1%
	10002	111	86	22.5%
	⋮	⋮	⋮	⋮
High	10001	131	96	26.7%
	10002	96	79	17.7%
	⋮	⋮	⋮	⋮

- Example 4 (b): Calculate weighted mean and standard deviation
  - For each HCC Group, calculate the weighted mean μ(GFR) and standard deviation Sd(GFR) using all individual issuers nationwide:
    - HCC Group G1 has a weighted mean of **11.8%** and a standard deviation of **3.0%**
    - HCC Group G2 has a weighted mean of **17.1%** and a standard deviation of **3.4%**
    - HCC Group G3 has a weighted mean of **25.9%** and a standard deviation of **4.0%**

HCC Group	HIOS ID	Freq_EDGE^G	Freq_IVA^G	GFR^G	μ(GFR^G)	Sd(GFR^G)
G1	10001	133	104	21.8%	**11.8%**	**3.0%**
	10002	96	87	9.4%		
	⋮	⋮	⋮	⋮		
G2	10001	171	128	25.1%	**17.1%**	**3.4%**
	10002	111	86	22.5%		
	⋮	⋮	⋮	⋮		
G3	10001	131	96	26.7%	**25.9%**	**4.0%**
	10002	96	79	17.7%		
	⋮	⋮	⋮	⋮		

- Example 4 (c): Create a decision boundary
  - Use the HCC Group weighted mean and standard deviation calculated in step (b) to create a two-sided 1.96 decision boundary:

Weighted Mean – Sigma Cutoff * Standard Deviation = Lower Boundary
11.8% - 1.96 * 3% = **5.9%** for G1
Weighted Mean + Sigma Cutoff * Standard Deviation = Upper Boundary
11.8% + 1.96 * 3% = **17.7%** for G1

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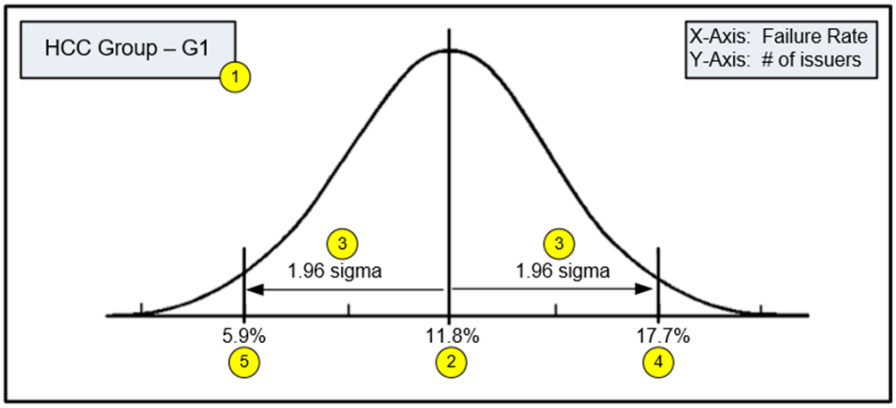
HCC Group	HIOS ID	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}	μ(GFR^{G})	Sd(GFR^{G})	sigma_cutoff	UB^{G}	LB^{G}
G1	10001	133	104	21.8%	11.8%	3.0%	1.96	**17.7%**	**5.9%**
	10002	96	87	9.4%					
	⋮	⋮	⋮	⋮					
G2	10001	171	128	25.1%	17.1%	3.4%	1.96	23.8%	10.4%
	10002	111	86	22.5%					
	⋮	⋮	⋮	⋮					
G3	10001	131	96	26.7%	25.9%	4.0%	1.96	33.7%	18.1%
	10002	96	79	17.7%					
	⋮	⋮	⋮	⋮					

G1 Group Distribution Example:



1 HCC Group | 2 Weighted Mean | 3 Sigma | 4 Upper Bound | 5 Lower Bound

HCC Group	HIOS ID	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}	μ(GFR^{G})	Sd(GFR^{G})	sigma_cutoff	UB^{G}	LB^{G}
G1	10001	133	104	21.8%	11.8%	3.0%	1.96	17.7%	5.9%
	10002	96	87	9.4%					
	⋮	⋮	⋮	⋮					

- Example 4 (d): Calculate adjustments for Group outliers
  - If the issuer's Group Failure Rate falls outside of the decision boundary, then an issuer's Group adjustment factor is calculated:

GFR – μ(GFR^{G}) = Group Adjustment
21.8% - 11.8% = **10%** for G1 (Issuer 10001)
25.1%-17.1% = **8%** for G2 (Issuer 10001)
17.7% -25.9% = **-8.2%** for G3 (Issuer 10002)

HCC Group	Issuer	Freq_EDGE^{G}	Freq_IVA^{G}	GFR^{G}	μ(GFR^{G})	Sd(GFR^{G})	sigma_ cutoff	UB^{G}	LB^{G}	Group Adjustment^{G}
G1	10001	133	104	21.8%	11.8%	3.0%	1.96	17.7%	5.9%	**10%**
	10002	96	87	9.4%						0
	⋮	⋮	⋮	⋮						…
G2	10001	171	128	25.1%	17.1%	3.4%	1.96	23.8%	10.4%	**8%**
	10002	111	86	22.5%						0
	⋮	⋮	⋮	⋮						…
G3	10001	131	96	26.7%	25.9%	4.0%	1.96	33.7%	18.1%	0
	10002	96	79	17.7%						**-8.2%**
	⋮	⋮	⋮	⋮						…

- If an issuer's HCC Group Failure Rate falls outside of its corresponding decision boundary, it will receive a non-zero adjustment
  - A positive (+) adjustment will reduce the risk score:
    - Ex: **8%** for G2 (Issuer 10001)
  - A negative (-) adjustment will increase the risk score:
    - Ex: **-8.2%** for G3 (Issuer 10002)
- If an issuer's HCC Group Failure Rate does not fall outside of its corresponding decision boundary, it will receive no adjustment
  - Ex: 0 for G1 (Issuer 10002) → *No calculation necessary because the GFR does not lie beyond the Upper or Lower Boundaries*

- <u>Example 5: Introduction</u>
  - As a result of Example 4, Issuer 10001 received the adjustment factors of 10%, 8%, and 0% for the three HCC Failure Groups (G1 - Low, G2 - Medium, G3 - High), respectively
  - Assume the first two sampled enrollees of Issuer 10001 have the detailed information in the table below:

Issuer	Enrollee	Stratum Size in Population	Sample Enrollees from the Stratum	Stratum Level	Plan Metal Level	Age Last (Infant or No HCCs)	HCCs
10001	10001-1	352	67	Infant-Medium	Silver	0	125,130,138,248
10001	10001-2	1418	37	Adult-High	Silver	-	1,12,30,37,57,115
10001	⋮	⋮	⋮	⋮			⋮

- <u>Example 5 (a): Determine enrollee-level adjustments</u>
  - Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
    - Enrollee 10001-1 has four (4) HCCs recorded on EDGE [125, 130, 138, 248]
    - For each EDGE HCC, compute the risk score for a single HCC using the logic defined in HHS Risk Adjustment Model table. Since the enrollee is an infant, the computation of the single HCC risk score takes into consideration the enrollee's actual maturity and severity levels. This results in risk scores for a single HCC as **6.402, 175.329, 41.549,** and **41.549**, respectively:

Enrollee	Stratum Level	Plan Metal Level	Age Last	HCC Failure Group	HCC	Severity Associated with HCC	Maturity Associated with HCC	Enrollee's Severity	Enrollee's Maturity	Variable Used for Risk Score Calculation	$RS_{i,e}^{hcc,G}$
10001-1	Infant-Medium	Silver	0	G1	138	4	Age 1	5	PREMATURE MULTIPLE	AGE1_X_SEVERITY4	6.402
					248		PREMATURE MULTIPLES			PREMATURE_MULTIPLES_X_SEVERITY5	175.329
				G2	125	5	Age 1			AGE1_X_SEVERITY5	41.549
					130	5	Age 1			AGE1_X_SEVERITY5	41.549

- Enrollee's Severity is the highest Severity Associated with HCC among all HCCs
- Enrollee's Maturity is the highest Maturity Associated with HCC among all HCCs
- Variable Used for Risk Score Calculation is the variable used to identify coefficient in HHS Risk Adjustment Model table
  - For HCCs associated with Severity level (e.g., 138, 125, 130), the variable is Enrollee's Maturity X Severity Associated with HCC
  - For HCCs associated with Maturity level (e.g., 248), the variable is Maturity Associated with HCC X Enrollee's severity

- Enrollee level adjustment factors are calculated using the weighted average from its Issuer's Group level adjustment factors
  - Enrollee 10001-1 HCCs are categorized in HCC Groups G1, G1, G2, and G2 respectively. They are associated with the Group level adjustment factors of 10%, 10%, 8% and 8%
  - Compute the enrollee adjustment score as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. This results in a weighted adjustment score of **9.4%**

Enrollee	Stratum Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$	Group $Adjustment_i^G$	Enrollee $Adjustment_{i,e}$
10001-1	Infant-Medium	G1	138	6.402	10.0%	9.4%
			248	175.329		
		G2	125	41.549	8.0%	
			130	41.549		

- Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
  - Enrollee 10001-2 has six (6) HCCs recorded on EDGE [30, 115, 1, 12, 37, 57]
  - For each EDGE HCC, compute the risk score of a single HCC using the logic defined in HHS Risk Adjustment Model. This results in risk scores for a single HCC as listed in the last column of the table:

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Enrollee	Stratum Level	Plan Metal Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$
10001-2	Adult-High	Silver	G1	30	**2.16**
				115	**5.29**
			G2	1	**5.302**
			G3	12	**3.117**
				37	**2.077**
				57	**1.066**

- Enrollee level adjustment factors are calculated using the weighted average from its Issuer's Group level adjustment factors
  - Enrollee 10001-2 HCCs are categorized in HCC groups G1, G1, G2, G3, G3, and G3 respectively. They are associated with the Group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0%
  - Compute the enrollee adjustment score as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. This results in a weighted adjustment score of **6.1%**

Enrollee	Stratum Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$	Group $Adjustment_i^G$	Enrollee $Adjustment_{i,e}$
10001-2	Adult-High	G1	30	2.16	10.0%	**6.1%**
			115	5.29		
		G2	1	5.302	8.0%	
		G3	12	3.117	0%	
			37	2.077		
			57	1.066		

- Example 5 (b): Adjust EDGE risk scores
  - Use the enrollees' adjustment factors to adjust the EDGE risk score for samples
    - Apply the enrollee level adjustment factor to the EDGE risk score of the sampled enrollee. Enrollees 10001-1 and 10001-2 have 9.4% and 6.1% adjustment factors applied to their EDGE risk scores, respectively:

Enrollee 10001-1 has an adjusted risk score of
(175.329 * (1 – 9.4%)) = **158.85**
Enrollee 10001-2 has an adjusted risk score of
(19.012 * (1 – 6.1%)) = **17.85**

Issuer	Enrollee	EDGE HCCs	$EdgeRS_{i,e}$	$Adjustment_{i,e}$	$AdjRS_{i,e}$
10001	10001-1	125,130,138,248	175.329	9.4%	**158.85**
10001	10001-2	1,12,30,37,57,115	19.012	6.1%	**17.85**

- Example 5 (c): Determine issuer Error Rate
  - For Issuer 10001, sum the EDGE risk scores and adjusted risk scores for all enrollees in the sample
  - For each stratum, compute the stratum weight as the ratio of stratum size in the issuer population on EDGE to the number of sampled enrollees from the stratum
  - Compute the issuer-level Error Rate for Issuer 10001 as one minus the stratum weighted sum of adjusted risk scores (20,538) over the EDGE risk scores (20,751).

Issuer 10001 has a final Error Rate of
(1 – 20,538/20,751) = **1.03%**

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	w_e	$w_e * EdgeRS_{i,e}$	$w_e * AdjRS_{i,e}$	$\sum w_e * EdgeRS_{i,e}$	$\sum w_e * AdjRS_{i,e}$	Error Rate
10001	10001-1	Infant-Medium	175.329	158.85	5.25	920	834	20751	20538	**1.03%**
10001	10001-2	Adult-High	19.012	17.85	38.32	729	684			
10001	⋮	⋮	⋮	⋮	⋮	⋮	⋮			

  - The table below depicts the results for HIOS ID 10001 calculated in the steps above, alongside additional example information for other HIOS IDs (10002; 10003).

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	w_e	Error Rate
10001	10001-1	Infant-Medium	175.329	158.85	5.25	1.03%
10001	10001-2	Adult-High	19.012	17.85	38.32	
10001	⋮	⋮	⋮	⋮	⋮	
10002	10002-1	Child-Medium	6.7	3.1	50.10	1.5%
10002	10002-2	Adult-Low	5	4.7	1.32	
10002	⋮	⋮	⋮	⋮	⋮	
10003	10003-1	Adult-Medium	17	15.3	15.53	0%
10003	10003-2	Adult-High	25	19.4	10.11	
10003	⋮	⋮	⋮	⋮	⋮	

- Example 6: Introduction
  - Output from Example 5 – enrollee level EDGE risk scores, adjusted risk scores, and stratum weightings
  - Assume Issuer 10001 pairwise test results indicated statistically significant differences between IVA and SVA100 findings

- Example 6 (a): Execute bootstrap resampling

- Draw 100 enrollees from Issuer 10001's sample of 100 enrollees with replacement at least 1,000 times and calculate the Error Rate for each sample.

Sample Enrollee	1	2	…	1,000
1	10001-27	10001-12	…	10001-32
2	10001-1	10001-92	…	10001-67
⋮	⋮	⋮	⋮…	⋮
100	10001-43	10001-85		10001-67
Error Rate:	0.96%	1.17%	…	1.09%

- Example 6 (b): Calculate standard errors and confidence intervals for issuers
  - Compute the bootstrapped standard error by calculating the sample standard deviation across the 1,000 samples
    - This results in a standard error of 0.12%
    - Standard Error: Standard deviation divided by the square root of the sample size
  - Determine the bootstrapped confidence intervals by identifying the 2.5th and 97.5th centiles of the 1,000 samples of resampled Error Rates
    - This results in a confidence interval of [0.83%, 1.23%]
  - CMS assesses the standard error and confidence intervals calculated, and will expand the SVA sample size to SVA200 in the event the bootstrap precision indicates poor precision. In the event the sample increases to 200 enrollees in this way, SVA200 findings will be used as final and the Error Estimation calculation will be re-run

Issuer	Error Rate	Standard Error	Confidence Interval	
			Lower	Upper
10001	1.03%	0.12%	0.83%	1.23%
10002	1.5%	0.27%	1.19%	1.78%
⋮	⋮	⋮	⋮	⋮

  - Following the conclusion of the HHS-RADV process, including the Discrepancy Reporting and Administrative Appeals process as described in Section 9, the issuer's error rate will be used to calculate the issuer's adjusted risk score during the RA payment transfer process, using the formula below:

(1-(error rate))*(plan liability risk score) = Adjusted Risk Score

  - The issuer's adjusted risk score will then be used in the RA process to calculate RA payments and charges for the following benefit year

Appendix E: Glossary of Terms, Acronyms and Definitions

Term	Acronym	Definition
Acceptable Risk Standards	ARS	CMS guidance to its contractors as to the minimum level of required security controls that they must implement to protect CMS information and information systems.
Advanced Premium Tax Credit	APTC	Eligible consumers may use an Advanced Premium Tax Credit through the Exchange to lower their monthly health insurance premium.
Agency for Healthcare Research and Quality	AHRQ	The Agency for Healthcare Research and Quality is the lead Federal agency charged with improving the safety and quality of America's health care system.
American Academy of Professional Coders	AAPC	The American Academy of Professional Coders is a national medical coding training and certification association.
American Health Information Management Association	AHIMA	The American Health Information Management Association is an association of health information management professionals.
American Hospital Association	AHA	The American Hospital Association is the national organization that represents and serves all types of hospitals, health care networks, and their patients.
Center for Consumer Information and Insurance Oversight	CCIIO	The Center for Consumer Information and Insurance Oversight is charged with helping implement many reforms of the Affordable Care Act, the historic health reform bill that was signed into law March 23, 2010. CCIIO oversees the implementation of the provisions related to private health insurance. In particular, CCIIO is working with states to establish new Health Insurance Marketplaces. CCIIO works closely with the state regulators, consumers, and other stakeholders to ensure the Affordable Care Act best serves the American people.
Centers for Medicare & Medicaid Services	CMS	Centers for Medicare and Medicaid Services is a Federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards.
Chief Executive Officer	CEO	A chief executive officer is the highest-ranking person in a company, organization or other institution that is ultimately responsible for managerial decisions.
Chief Financial Officer	CFO	A chief financial officer is a senior executive with responsibility for the financial affairs of a company, organization or other institution.
Chronic Obstructive Pulmonary Disease	COPD	Chronic Obstructive Pulmonary Disease is a medical condition involving the constriction of the airways and difficulty or discomfort in breathing.

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Term	Acronym	Definition
Civil Monetary Penalties	CMP	A civil monetary penalty is a monetary penalty the Centers for Medicare & Medicaid Services may impose for non-compliance.
Coordinator	CO	Issuers and Initial Validation Audit Entities identify a representative within their organization to conduct certain HHS_RADV activities.
Conflict of Interest	COI	A situation that has the potential to undermine the impartiality of a person, company or organization because of the possibility of a clash between the person's self-interest and professional interest or public interest.
Confidence Level	CL	The confidence level is the probability that the value of a parameter falls within a specified range of values.
Congestive Heart Failure	CHF	Congestive Heart Failure is a medical condition involving weakness of the heart that leads to a buildup of fluid in the lungs and surrounding body tissues.
Cost-sharing Reduction	CSR	Cost-sharing Reductions are discounts for eligible consumers through the Exchange that lowers the dollar amount of health insurance deductibles, copayments, coinsurance.
Current Procedural Code/Healthcare Common Procedure Coding System	CPT/HCPCS	CPT/HCPS® codes are the United States' standard for how medical professionals document and report medical, surgical, radiology, laboratory, anesthesiology, and evaluation and management (E/M) services.
Date of Birth	DOB	The month, day and year a person was born.
Date of Service	DOS	A medical record date of service defines when an enrollee received medical treatment from a physician, permitted provider, medical facility, or telehealth visit
Demographic & Enrollment	D&E	Demographic & Enrollment data describes an enrollee's demographics and enrollment status.
Diabetes Mellitus	DM	Diabetes Mellitus is a medical condition is which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine.
Do It Yourself	DIY	The Do It Yourself Software is a tool that includes SAS software and the Department of Health and Human Services Developed Risk Adjustment Model Algorithm. The software instructs issuers how to simulate their enrollee populations' benefit year risk scores within the risk adjustment model. This software is only as supplemental guidance for issuers to better understand and simulate the calculation of plan liability risk scores for their enrollees.
Extensible Markup Language	XML	A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine readable.

Term	Acronym	Definition
External Data Gathering Environment	EDGE	Issuers in states where HHS operates an RA program are required to submit enrollment, pharmaceutical claims and medical claim information on enrollees from issuers' proprietary systems to an issuer-distributed data collection server (also known as an EDGE server). An EDGE server runs HHS-developed software designed to verify submitted data, execute RA processes and submit summary reports to CMS.
EDGE Server Business Rules	ESBR	The EDGE Server Business Rules defines the rules under which data is submitted to EDGE servers.
Finite Population Correction	FPC	The Finite Population Correction factor is used to define both the standard error of the mean and the standard error of the proportion.
Health and Human Services	HHS	The U.S. Department of Health & Human Services mission is to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services.
Health Insurance Oversight System ID	HIOS ID	ID assigned by HIOS to a validated insurance issuer. HIOS was created to facilitate several types of data collections from the Department of Insurance for states/territories as well as insurance issuers that sell health insurance coverage. The collected data is aggregated with other data sources and made public on the consumer-facing website.
Health Insurance Portability and Accountability Act	HIPPA	The Health Insurance Portability and Accountability Act is a federal law that was enacted in 1996 that protects continuity of health coverage when a person changes or loses a job, that limits health plan exclusions for preexisting medical conditions, that requires patient medical information be kept private and secure, that standardizes electronic transactions involving health information, and that permits tax deduction of health insurance premiums by the self-employed.
Hierarchical Condition Category	HCC	Hierarchical Condition Category coding is a payment model that identifies health conditions documented by health professionals and assigns a risk score factor.
History of Present Illness	HPI	The History of Present Illness refers to a detailed interview prompted by a presenting symptom that documents the history of that presenting symptom.
Human Immunodeficiency Virus	HIV	Human Immunodeficiency Virus is a medical condition that damages the immune system and can lead to acquired immunodeficiency syndrome.
Information Security	IS	Information security is the practice of preventing unauthorized access, use, disclosure, disruption, modification, inspection, recording or destruction of information. It is a general term that can be used regardless of the form the data may take (e.g. electronic, physical).
Initial Validation Audit	IVA	Validation audit of enrollment and health status data submitted by the issuer to HHS for RA-covered plans. This audit is conducted by an independent audit entity hired by the issuer. Findings from the IVA must be submitted to CMS for review during the Second Validation Audit.

Term	Acronym	Definition
International Classification of Diseases, Clinical Modification, Tenth edition	ICD-10-CM	The National Center for Health Statistics is a federal agency responsible for the use of The International Classification of Diseases, Clinical Modification, Tenth edition and has developed a clinical modification of the classification for morbidity purposes.
Internal Revenue Service	IRS	The Internal Revenue Service is the nation's tax collection agency and administers the Internal Revenue Code enacted by Congress.
Inter-rater Reliability	IRR	Inter-Rater Reliability is a process to determine the accuracy of the abstraction diagnoses by Primary Coders when compared to Senior Coders.
Medication Administration Record	MAR	The Medication Administration Record serves as a legal medical record of drugs administered to a patient.
National Center for Health Statistics	NCHS	The National Center for Health Statistics is a federal agency within the United States Centers for Disease Control.
Non-EDGE Claim	NEC	A claim that is not present in the Risk Adjustment Data Validation Medical Claim Extract Report generated by the EDGE server.
Office of Federal Contract Compliance Programs	OFCCP	The Office of Federal Contract Compliance Programs is part of the U.S. Department of Labor. OFCCP is responsible for ensuring that employers doing business with the Federal government comply with the laws and regulations requiring nondiscrimination.
Office of Inspector General	OIG	The Office of Inspector General's protects the integrity of Department of Health & Human Services programs as well as the health and welfare of program beneficiaries.
Office of Management and Budget	OMB	The Office of Management and Budget serves the President of the United States in overseeing the implementation of his vision across the Executive Branch. Specifically, OMB’s mission is to assist the President in meeting his policy, budget, management and regulatory objectives and to fulfill the agency’s statutory responsibilities.
Past Medical History	PMH	In a medical encounter, a past medical history is the total sum of a patient’s health status prior to the presenting problem.
Patient Protection and Affordable Care Act	PPACA	The PPACA reforms certain aspects of the private health insurance industry and public health insurance programs, including increasing insurance coverage of pre-existing conditions and expanding access to insurance to Americans, while mandating an increase in total national medical expenditures.
Payment Error Rate Measurement	PERM	The Payment Error Rate Measurement program measures and reports a national improper payment rate for Medicaid and the Children’s Health Insurance Program.

RETIRED

Term	Acronym	Definition
Personally Identifiable Information	PII	Personally Identifiable Information is information that identifies or describes an individual, including but not limited to name, address, telephone number, social security number, credit card number, and personal characteristics that make the individual's identity easily discoverable.
Portable Document Format	PDF	A Portable Document Format is a file format that provides an electronic image of text, or text and graphics, that looks like a printed document and can be viewed, printed, and electronically transferred.
Protected Health Information	PHI	Any information about health status, provision of health care, or payment for health care that is created or collected by "Covered Entity" and can be linked to a specific individual.
Registration for Technical Assistance Portal	REGTAP	The Registration for Technical Assistance Portal is used by the Centers for Medicare & Medicaid Services to provide technical assistance and training related to Exchange and Premium Stabilization program guidance and operations.
Risk Adjustment	RA	The Risk Adjustment program is a premium stabilization program established by the Patient Protection Affordable Care Act. The overall goal of RA 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. RA accomplishes this by transferring funds from issuers with lower risk enrollees to plans with higher risk enrollees.
Risk Adjustment Default Charge	RADC	Under 45 CFR §153.740(b), if an issuer of a risk adjustment covered plan fails to establish an EDGE server or fails to provide HHS with access to the required data on the EDGE server, such that CMS cannot apply the Federally certified risk adjustment methodology, a default risk adjustment charge will be assessed.
Risk Adjustment Data Validation	RADV	Risk Adjustment Data Validation an HHS-established data validation process to validate a statistically valid sample of enrollment and health status data for all issuers that submit data for risk adjustment.
Risk Adjustment Risk Score Details	RARSD	The Risk Adjustment Risk Score Details Report contains the risk score result.
Risk Adjustment Data Validation Detailed Enrollee Report	RADVDE	Risk Adjustment Data Validation Detailed Enrollee Report contains enrollee-level data for each enrollee selected for the RADV IVA sample such as the sampled enrollee's risk score, demographic, and health status information.
Risk Adjustment Data Validation Enrollment Extract Report	RADVEE	Risk Adjustment Data Validation Enrollment Extract Report contains all active enrollment data that was submitted by the issuer for each enrollee included in the RADV IVA sample.

Term	Acronym	Definition
Risk Adjustment Data Validation Initial Validation Audit Statistics	RADVIVAS	The Risk Adjustment Data Validation Initial Validation Audit Statistics Report contains the sample statistics calculated at the strata-level for the enrollees selected for the Risk Adjustment Data Validation Initial Validation Audit sample. The report is similar in layout to the Risk Adjustment Data Validation Population Summary Statistics Report, but limited to the enrollees selected for the IVA sample.
Risk Adjustment Data Validation Medical Claims Extract Report	RADVMCE	The Risk Adjustment Data Validation Medical Claims Extract Report contains all active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample. The report contains claim line information of the active RA eligible claims from sampled enrollees.
Risk Adjustment Data Validation Supplemental Extract	RADVSE	The Risk Adjustment Data Validation Supplemental Extract Report contains all active supplemental records for active Risk Adjustment eligible medical claims that were submitted by the issuer for each enrollee included in the Risk Adjustment Data Validation Initial Validation Audit sample.
Risk Adjustment Data Validation Population Summary Statistics	RADVPS	The Risk Adjustment Data Validation Population Summary Statistics Report contains population statistics for the issuer's total population separated into sub-categories, or "strata," based on enrollee age (infant, child, adult) and risk score (low, medium, high). The RADVPS Report provides issuer level data, including total enrollees and plans, number of enrollees in each risk pool market (individual, small group, catastrophic), strata-level data (including number of enrollees in each of the specific stratum), and summary statistics for each of the specific stratum, including mean (average), minimum (min), and maximum (max) risk scores for enrollees in the stratum.
Risk Adjustment Data Validation Population Summary Statistics Final	RADVPSF	The Risk Adjustment Data Validation Population Summary Statistics Final Report contains the same data elements as the Risk Adjustment Data Validation Population Summary Statistics Report (as listed above), but is generated by the Risk Adjustment Data Validation Report command after the RA transfer calculation and the Issuer Reference Table is populated with risk pool markets included in the RADV sampling logic (RADV population). The new report removes markets in which the issuer is the only issuer in that risk pool market within a state, limiting the report to risk pool markets that are included in the RADV population.
Second Validation Audit	SVA	CMS contracts with an approved vendor which performs an independent, third-party audit for CMS of the IVA Entity Audit results.
Senior Official	SO	Issuers and Initial Validation Audit Entities identify a representative Senior Official within their organization to conduct certain HHS_RADV activities.
Subjective, Objective, Assessment, and Plan	SOAP	The SOAP note is an optional method for medical record documentation utilized by some clinicians.
Third-Party Administrator	TPA	A third-party administrator is an organization that processes insurance claims or certain aspects of employee benefit plans for a separate entity.

Term	Acronym	Definition
Unique Enrollee Identification	UID	The unique enrollee identification is a number associated with a specific enrollee to use as an identifier without sharing personally identifiable information.