Centers for Medicare & Medicaid Services

U.S. Department of Health and Human Services

Center for Consumer Information and Insurance Oversight

Protocols for Benefit Year 2015

ACA HHS - Operated Risk Adjustment Data Validation

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Document Version History

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11.02.00	7/14/16	CMS/CCIIO	Added RADVIVAS Sampling Report validation process steps Streamlined Chapter 4 to remove text previously covered in the Payment Notice
11.03.00	10/28/16	CMS/CCIIO	Updated Primary and Senior Reviewer section Updated ACA HHS-RADV Process Activities Timeline for the 2015 Benefit Year NUL Updated section 5.3.3: Perform Demographic and Enrollment Validation Updated section 5.4: Health Status Data Validation Test Procedures Updated section 6.0: Inter-rater Reliability

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Section 1
HHS Risk Adjustment Data Validation Protocols

Preface

The Risk Adjustment (RA) program is one of three premium stabilization programs established by the Affordable Care Act (ACA). 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 plans with lower risk enrollees to plans with higher risk enrollees. To ensure the integrity of the RA program, the U.S. Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) will perform HHS Risk Adjustment Data Validation (HHS-RADV) for each benefit year on behalf of any state that chooses not to implement its own state-based risk adjustment program.

This guidance is specific to the pilot 2015 benefit year RADV. This document will be updated to reflect future benefit years of HHS-RADV. This document defines protocols for the HHS-RADV program. The purpose of the HHS-RADV protocols is to provide all parties involved with information pertaining to the HHS-RADV process. The HHS-RADV protocols set forth requirements and guidance for the entire HHS-RADV process beginning with selection of an Initial Validation Audit (IVA) entity and ending with potential adjustments. The protocols are effective July 1, 2016, and apply to the 2015 benefit year validations. HHS will communicate all updates and amendments to the protocols as they become available. For questions regarding the HHS-RADV protocols, please contact HHS-RADV Operations at CCIIOACARADataValidation@cms.hhs.gov.

2015 HHS-RADV Pilot Year:

In the HHS Notice of Benefit and Payment Parameters for 2014 (78 FR 15410), HHS stated that in conducting the HHS-RADV program, it would adjust RA payments and charges based on the results of the HHS-RADV program in 2018 for 2016 benefit year data. HHS explained that issuers and auditors would have two (2) preliminary years in which to implement and test the HHS-RADV program, and adjust their audit procedures in response to that experience. RA payments and charges will continue to be adjusted in 2018 for 2016 benefit year data, in keeping with the original schedule. However, HHS did not conduct HHS-RADV on 2014 data, originally one of two preliminary testing years.[1] HHS will still conduct HHS-RADV in 2016 for 2015 benefit year data; thus, issuers and auditors will have one preliminary testing year instead of two in which to implement and test the HHS-RADV program, and adjust their coding and audit procedures in response.

[1]Regtap.info FAQ ID 11290a. 03/07/2016

1 HHS Risk Adjustment Data Validation Overview

1.1 Purpose

This HHS-RADV Overview provides the background, regulations, roles, and responsibilities of issuers and HHS and their respective contractors; a process summary; and the timeline for HHS-RADV. HHS-RADV promotes confidence in the RA program by providing assurance with respect to the integrity and quality of data provided from issuers operating in state markets under the HHS-operated RA program. The regulation at section 45 Code of Federal Regulations (CFR) §153.350 and 153.630 require states, or HHS on behalf of states, to validate enrollee demographic and health status information of a statistically valid sample of enrollees for issuers that submit data for RA annually, and provide issuers in the HHS-RADV program an appeals process which will be applicable beginning with the 2016 benefit year. Beginning with Benefit Year 2016 HHS-RADV, the results of HHS-RADV will be used to adjust 2017 RA payment transfers.

1.2 Regulatory References

The requirements related to HHS-RADV are included in 45 CFR 153.350 and 45 CFR 153.630. Further guidance and additional detail on HHS-RADV can be found in the following references:

- *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 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)

- Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper (White Paper), June 22, 2013 – HHS addressed HHS-RADV and provided preliminary guidance and requested stakeholder feedback on a number of topics covered in these protocols.
  https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5C R_062213.pdf

1.3 HHS-RADV Participants, Roles, and Responsibilities

The HHS-RADV process requires active participation and coordination between multiple stakeholders. The participants in the HHS-RADV process are HHS, issuers, Initial Validation Audit (IVA) Entities, and the Second Validation Audit (SVA) Entity. For the purpose of this document, the terms “IVA Entity” and “SVA Entity” refer to the auditors performing the HHS-RADV audit steps as detailed in Sections 1.3.3 and 1.3.4. The terms “IVA” and “SVA” refer to the audits. The following is a list of HHS-RADV program participants, including a description of their roles and responsibilities.

1.3.1 HHS

HHS is responsible for implementing the RA premium stabilization program for states that do not elect to perform RA. States that elect to perform RA must apply to HHS, and submit an RA methodology to HHS for approval. In implementing RADV, HHS will complete the following tasks:

- Regulate the HHS-RADV process for HHS-operated RA programs, including the issuance of this guidance;
- Acknowledge submission of all IVA Entities (Section 2);
- Develop and implement RA systems, including the External Data Gathering Environment (EDGE) server and the HHS-RADV protocols (including the HHS-RADV Audit Tool, which is part of the protocol and approve actions and data within the EDGE server and protocols (Section 3);
- Provide validation logic for selecting and providing the sample of enrollees to issuers (Section 4);
- Conduct the SVA (Sections 5 and 6);
- Communicate all HHS-RADV updates to issuers and IVA Entities; and
- Provide HHS-RADV training to all applicable entities, as needed.

1.3.2 Issuers

Issuers are an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance. RA covered plans are any non-grandfathered health insurance plans providing ACA-compliant health insurance offered in the individual or small group markets, both inside and outside of the Marketplace. The individual and small group markets are where individuals, families, and small businesses can obtain health insurance, either through the State Marketplaces or private insurers. For HHS-RADV, issuers' responsibilities include to the following:

- Engage an independent auditor to conduct the IVA;
- Use the Audit Tool to designate and authorize their IVA Entities through the IVA Designation Form (Section 2);
- Ensure that the selected IVA Entity is reasonably capable of performing the audit (Section 2);
- Attest that the selected IVA Entity is reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner with its impartiality not reasonably open to question (Section 2);
- Ensure that all IVA Entity contractual obligations are met and that HHS-RADV protocols are applied (Section 2);

- Register for and obtain access to the HHS-RADV Audit Tool (Section 3);
- Review and approve the HHS-RADV population summary (HHS-RADVPS) report (Section 4);
- Upload all enrollment and claims data to the EDGE server in a timely manner and attest to HHS on the completeness and accuracy of all data (Section 5);
- Provide the IVA Entity access to applicable process documentation, systems, and source documentation for claims, Medical Records and enrollment documentation for sampled enrollees and any required attestations to account for missing signatures on Medical Records (Section 5);
- Allow for the IVA Entity to view the live system data and document screen shots from the required enrollment and claim systems (Section 5);
- Ensure that the IVA is completed in the manner and time frame established by HHS (Section 5); and
- Ensure the IVA results and requested supporting source documentation is submitted to HHS in the manner and time frame specified (Section 7) (Note: section to be included in future release).

1.3.3 IVA Entity

The IVA Entity is an independent organization hired by an issuer to conduct the validation of enrollment and health status data submitted by the issuer to HHS for RA covered plans. The IVA Entity must conduct the validation independently and within the time frame specified. The issuer will hire an IVA Entity and submit their information to CCIIO for review at a date to be determined by CCIIO and must conduct the validation of enrollment and health status information based on the requirements outlined in these protocols including in particular Section 5. Once the IVA Entity completes the audit, the results along with supporting documentation are entered into the Audit Tool, discussed further in Section 5.

1.3.4 SVA Entity

The SVA Entity works with HHS to validate the issuer enrollment and health status data on a sub-sample of the IVA sample. The SVA validates a sub-sample of issuer enrollment and health status data for all IVA submissions. The SVA validation of enrollment and health status information for the sub-samples follows the same steps and requirements outlined in these protocols including in particular Section 5. For HHS-RADV, the SVA Entity's responsibilities include, but are not limited to, the following:

- Review and approve of population summary and sample reports (Section 4);
- Conduct the SVA independently according to the protocols – Test Procedures and Reporting Requirements for HHS-RADV (Section 5); and
- Perform Inter-Rater Reliability (IRR) assessments between abstraction coders as part of quality assurance (Section 6).

The IVA and SVA audit process is comprised of two levels of validations: EDGE data to demographic, enrollment, and claims data validation (Section 5.2), and health status validation (Section 5.3). Individuals performing the EDGE data to demographic, enrollment, and claims data validations and the medical record intake portion of the health status validations (Section 5.3.1) are henceforth referenced as "Primary and Senior Reviewers." Individuals performing the health status review are henceforth referenced as "Primary and Senior Coders."

1.3.5 Primary and Senior Reviewers

The EDGE data validations (Section 5.3) are completed by personnel within the IVA and SVA Entities that are deemed to be competent to perform validation steps between Medical Records and EDGE server data (except for abstraction code validation). The primary and senior reviewer can be, but are not required to be, certified medical coders as outlined below in Section 1.3.6. Note that health status validations (Sections 5.4.4 – 5.4.7) must be performed by personnel within the IVA and SVA Entities with the proper medical coding certification as described in Section 2.5 under "Personnel Qualifications." However, Validation HS-2, "comparison of acceptable date of medical record or claim," may also be performed by Primary and Senior Reviewers.

The role of the senior reviewer is to review errors encountered during the Medical Record Intake process and HS-2 (Sections 5.4.1 and 5.4.3) and note any final errors. The senior reviewer performs a review of the source documents obtained from the issuer but is not able to review the primary intake reviewer's results before performing their review. The only differences in requirements between the primary and senior reviewers are that they are separate reviewers. The primary and senior reviewers may perform:

- A validation of demographic and enrollment data to issuer systems (Section 5.3.3);
- A validation of a sample of EDGE claims data to issuer systems (Section 5.3.4);
- A comparison of medical record demographics to validated demographics and enrollment data (Validation HS-1) (Section 5.4.1); and
- A comparison of acceptable date of medical record or claim (Validation HS-2) (Section 5.4.3).

1.3.6 Primary and Senior Coders

The health status review (specifically Sections 5.4.1 – 5.4.7) is completed by medical coders 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). The IVA and SVA Entity must be staffed with at least one (1) primary and one (1) Senior Coder. A Senior Coder must be a certified coder with at least three (3) years' experience for benefit year 2015 HHS-RADV. (Note: Beginning with Benefit Year 2016 HHS-RADV, the Senior Coder must have at least five (5) years' experience.) While the Primary Coder will perform validation steps on the entire sample, the role of the Senior Coder is to re-perform validation steps that do not match the EDGE data and note any findings of an RA data error. Senior Coder re-performance is used to confirm or refute RA data error findings identified by Primary Coders.

Upon completion of all required Primary Coder and Senior Coder abstraction code validations

for the sample (Section 5.3.7), the Senior Coder performs IRR on a sample of diagnoses for all Primary Coders in order to determine if a Primary Coder meets the required accuracy rate. See Section 6, "Inter-Rater Reliability," for detail surrounding the IRR process. The primary and Senior Coders perform the following validations:

- Acceptable medical record source (Validation HS-3) (Section 5.4.4);
- Acceptable service code (Validation HS-4) (Section 5.4.5);
- Acceptable medical record signature (Validation HS-5) and credentials allowable (Validation HS-6) (Section 5.4.6); and
- Diagnosis abstraction (Validation HS-7) (Section 5.4.7).

1.4 HHS-RADV Process

HHS-RADV consists of IVA and SVA Entities' testing a sample of issuers' enrollees to determine if an error estimate is to be applied to the issuer's plan average risk score(s) based on test results. HHS-RADV includes six (6) stages – sample selection, IVA, SVA, error estimation, appeals, and payment transfer adjustments – that are discussed in further detail throughout this document, with the caveat that during the 2015 Pilot Year for HHS-RADV, there will be no appeals or payment transfer adjustments.

1.4.1 Sample Selection

The first stage in the HHS-RADV process is the selection of a sample of an issuer's enrollees. HHS selects a sample size 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. The protocols regarding sample selection for HHS-RADV are discussed in further detail in Section 4.

1.4.2 IVA

The second stage of the HHS-RADV process is the IVA. In this stage, issuers are required to engage one (1) or more independent auditor entities to perform a validation of demographics, enrollment data, and health status information for the HHS-defined sample of enrollees as indicated in these protocols (Section 5). The IVA process includes primary and Senior Coders performing medical record reviews, with the Senior Coder having at least three (3) years of experience for the 2015 benefit. The Primary Coder does not have specific experience requirements, but must be a certified medical coder as stated above. The Senior Coders perform IRR on a sample of Primary Coder files to ensure accuracy of the Primary Coder results. Once the Senior Coder performs IRR, the IVA Entity determines if the Primary Coder has met the accuracy rates as stated in Section 6 of this document. Once the results of the IVA have been completed, the IVA Entity submits their results to the Audit Tool as stated in Section 7 (this section will be noted in a future version of this document).

1.4.3 SVA

The SVA Entity re-performs the validation steps executed by the IVA Entity on a sample of enrollees tested by the IVA Entity to verify the accuracy of the IVA Entity's results. The initial SVA sample must be sufficiently large to determine the statistical significance of any differences

between the IVA Entity and SVA Entity results by pair-wise means[2] testing. If the pair-wise means test results conclude that the difference in enrollee risk score results between the IVA and SVA is not statistically significant, then the IVA error results are used for the calculation of an adjustment for each of the issuer's RA-covered plan average risk scores. Plan average risk score is the weighted average risk of all enrollees in a plan in a geographic rating area based on demographic and health status.

If pair-wise means test results conclude there is a statistically significant difference, then the SVA Entity will expand the sampling previously performed on the validation steps to a larger sample of the enrollees previously subject to the IVA. The results from the SVA Entity's larger sample are compared to the results of the IVA using the pair-wise means test.

Further details regarding the SVA procedures are included in Sections 5 and 6.

1.4.4 Error Estimation

The fourth stage in the HHS-RADV process is error estimation, which determines any statistically significant differences between the IVA and SVA test results. Upon completion of the IVA and SVA, HHS determines an issuer-level risk score adjustment and confidence interval using statistical analysis. This adjustment is used to adjust the plan average risk score for each RA covered plan offered by the issuer. HHS plans to provide each issuer with enrollee-level results and the error estimates. While HHS does plan to provide error rates resulting from the review of 2015 benefit year data, those error rates will not be used to adjust RA payments.

1.4.5 Appeals

Appeals will begin on the first year for which HHS-RADV will impact payments, or the data from the 2016 benefit year. Appeals will not be accepted for the 2015 benefit year of HHS-RADV as it is a pilot year.

1.4.6 Payment Transfer Adjustments

RA payment transfer adjustments are based on plan average risk scores adjusted for error estimation based on HHS-RADV results. Payment adjustments will not occur for the 2015 RADV pilot year.

1.5 ACA HHS-RADV Process Activities Timeline

HHS will deliver training for issuers and IVA Entities covering the HHS-RADV process and the applicable standards for performing the IVA. Following the close of the benefit year, at a date determined by HHS, issuers are required to register for the Audit Tool and then submit the IVA Entity's identity to HHS for approval in accordance with § 153.630(b)(1) through the *IVA Designation Form.*

HHS uses the data submitted to the issuers' EDGE servers by issuers for RA and applies the

[2] Pair-wise 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.

sampling methodology as described in Section 4, "Sampling," to select each issuer's sample of enrollees. HHS provides the sample to issuers and IVA Entities for review.

Once the IVA has concluded, HHS begins the SVA process. Since the 2015 benefit year is the first year of implementation of HHS-RADV, HHS expects to report on lessons learned from these activities and to use this information to improve the HHS-RADV process.

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

Figure 1 –ACA HHS-RADV Process Activities Timeline for the 2015 Benefit Year

Date*	Description
January 2016 – May 2016	Issuers select IVA Entities.
March 15, 2016	HHS-RADV Senior Official (SO) designation PDF e-mailed to EDGE CEO designate.
April 25, 2016	SO designation PDF due back to HHS.
Late April 2016	SOs provided Audit Tool access.
Late April – Early May 2016	SOs complete IVA Entity Designation form in Audit Tool and download IVA Entity Attestation form for CEO signature.
May 9, 2016	Issuer SOs submit CEO-signed IVA Entity Attestation to HHS for review.
Early June 2016	HHS pushes HHS-RADV sampling command to EDGE servers; issuers execute command.
Early June 2016	IVA Entities provided Audit Tool access.
June 2016	HHS validates IVA samples.
July 1, 2016	HHS releases the HHS-RADV sample reports to issuers via EDGE server.
July 2016 – December 2016	IVA conducted.
November 7 – November 15	IVA Entities submit IRR Results to the Audit Tool.
November 17 – December 1	IVA Entities submit IVA Submission Package 1 to the Audit Tool.
December 15	IVA Entities submit IVA Submission Package 2 to the Audit Tool.
December 2016 – March 2017	SVA is conducted.
Spring 2017	Pilot results and lessons learned will be released, including 2015 error rates.

*These dates are subject to change—see https://www.regtap.info/ for updates.

1.6 Record Retention Policy

HHS, issuers, IVA Entities, and SVA Entities must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the data submitted for at least 10 years, and make that evidence available upon request from HHS, the Office of the Inspector General (OIG), the Comptroller General, or their designees, to any such entity, for verification of RA data submissions (see 45 CFR § 153.620[b]).

1.7 Protected Health Information Security

The Health Insurance Portability and Accountability Act (HIPAA) information Security Rule requires that a covered entity, which includes issuers, apply appropriate administrative, technical, and physical safeguards to protect the privacy of Medical Records and other protected health information (PHI). The HIPAA Privacy Rule requires appropriate safeguards to protect the privacy of PHI and limits the permissible uses and disclosures of PHI. These rules, which are found at 45 CFR 164, apply to the period such information is maintained by a covered entity, including disposal of the information. The HIPAA Privacy and Security Rules apply to issuers and certain service providers of issuers that are business associates under the HIPAA privacy and security regulations such as IVAs. Issuers and IVAs are responsible for complying with 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 SVA Entities.

Section 2
HHS Risk Adjustment Data Validation Protocols
Initial Validation Audit Entity Selection

2 Initial Validation Audit 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, unless otherwise indicated by HHS. The issuer must document the IVA Entity's capability of performing an IVA. Additionally, the issuer must document that the IVA Entity and its staff are not subject to any conflicts of interest. HHS has defined conflicts of interest standards between an issuer and IVA Entity (see Section 2.8).

Once an IVA Entity is selected, the issuer provides HHS with information regarding the IVA Entity. The acceptance or rejection of the issuer's IVA Entity submission is to acknowledge HHS receipt of the submission. By accepting an issuer's submission, HHS is not approving the IVA. See Section 2.10 below for further information regarding the information and documentation required by HHS for IVA Entity selection. In addition, see Section 2.2.3 below for further information regarding HHS's oversight methods and review of the IVA Entity selection. The issuer and IVA Entity must sign a mutual agreement to perform the IVA, which is retained by the issuer and IVA Entity.

2.2.2 IVA Entity

The IVA Entity details for the issuer its technical capabilities and approach to performing the IVA and submits its findings in the time frame specified by HHS, along with information regarding its independence. Once selected by the issuer, the IVA Entity enters into a contract with the issuer and certifies its independence from the issuer. The IVA Entity's responsibilities for HHS-RADV include the following:

- Provide issuers with detailed information on organization and individual qualifications, capabilities, and independence;
- Remain free from organizational and individual conflicts of interest as defined by 45 CFR §153.630, and section 2 with the issuer, SVA Entity, and HHS/CCIIO;
- Provide qualified personnel to perform data validation steps, demographics reviews, and health status data validation;
- Ensure medical coders maintain current certifications;
- Ensure that the medical coders are able to perform work on inpatient and outpatient/professional Medical Records, and have coders trained and certified for both settings;

- Ensure that, at a minimum, two (2) coders are available to perform medical record reviews, with at least one (1) of them being a Senior Coder having three (3) years' experience for the first year of RA (2015 benefit year) and five (5) years' experience for benefit years 2016 and beyond;

- Register for and obtain access to the HHS-RADV Audit Tool (Section 3);

- Conduct the IVA independently according to the protocols documented in Section 5;

- Create and maintain the IVA Audit Matrix documentation of the IVA audit procedures (Section 5);

- Perform a validation, on a sample basis, of EDGE server claims data in comparison with issuer's enrollment and claims/encounter system(s) data (Section 5);

- Perform IRR assessments between medical coders as part of quality assurance (Section 6);

- Submit audit test results with issuer-specific information documentation to the Audit Tool (Section 7) (Note: section to be included in future release); and

- Attend all required training related to the HHS-RADV program specified by HHS as required to perform the IVA role.

2.2.3 HHS

HHS 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.

HHS monitors and reviews the IVA Entity selection by verifying the attestation provided by the issuer and by performing checks against the OIG exclusions list.

2.3 IVA Entity Requirements

Issuers have considerable autonomy in selecting the IVA Entity. In accordance with section CFR 45 §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 HHS defined audit standards;

- Is reasonably free of conflicts of interest 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; these proposed requirements would ensure the IVA is conducted according to HHS validation criteria, and the IVA Entity transmits necessary information to HHS; and

- Employs medical coders to conduct the IVA who are certified and in good standing by a nationally recognized accrediting agency such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC).

2.4 Timeline of IVA Entity Selection

For each benefit year, HHS instructs issuers and IVA Entities to begin preparing for the selection process, and communicates timing requirements via https://www.regtap.info/. Please refer to https://www.regtap.info/ for the HHS-RADV timeline and corresponding deadlines for the applicable benefit year, or to Section 1.5, ACA 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.

As part of the IVA Entity selection process, the issuer should consider assessing the IVA Entity's capabilities based on certain factors. The evaluation of the IVA Entity's capabilities should be documented by the issuer in the event HHS seeks additional documentation regarding the selection.

Each year, the issuer must provide HHS an attestation that states the issuer has used a documented process to ensure that there is no conflict of interest between the issuer and the IVA Entity. The IVA Entity must certify that there is an absence of a conflict of interest at both the organization and the staff levels, and must provide signed documentation to the issuer.

In addition to a review of the conflict of interest attestation provided by the issuer, HHS 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 conflict of interest.

The following section outlines requirements which should be used by issuers to evaluate the IVA Entity's potential conflicts.

Conflict of Interest Requirements:

- IVA Entity certified that there is an absence of a conflict of interest 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. Immediate family may contain both biological relatives and those related through marriage, such as a brother-in-law.

- 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 initial validation audit 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 IVA.
    - The IVA Entity may not perform any SVA activities on behalf of HHS.

Please see *Appendix 7.1 – IVA CEO* Attestation form which is to be submitted by issuers.

2.6 Additional Reasons for IVA Entity Exclusion

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

- The IVA Entity, its owners, or staff engaged to work on the IVA are listed on the HHS Office of the OIG Exclusions List using the following link: HHS OIG Exclusions List [http://exclusions.oig.hhs.gov/].
- 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 within the following link: [https://www.dol.gov/ofccp/regs/compliance/preaward/debarlst.htm].
- The IVA Entity is listed on a State's OIG Exclusions List using the following link: State Exclusions List [http://www.gsaig.gov/index.cfm/suspension-and-debarment-listed-by-state/].

2.7 Required Documentation for IVA Entity Selection

Issuers are required to complete the IVA Attestation Form regarding their selection of an IVA Entity in the Audit Tool. On the form, the issuer will provide the IVA Entity name, IVA Entity Health Insurance Oversight System (HIOS ID) (if applicable), and IVA Entity Tax Identification Number (TIN), and representative's contact information. Additionally, the issuer will confirm compliance with the following criteria in the attestation form:

1. Ensure IVA Entity is Reasonably Capable of Performing Risk Adjustment Data Validation and has Certified Medical Coders 45 CFR 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 HHS defined audit standards under 45 CFR 153.630(b)(2) and (b)(5)-(8), and in accordance with HHS-RADV data validation 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 conflict of interest 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 Office of the Inspector General (OIG) exclusion list, or are under investigation with respect to any HHS 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 serve 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 CFR 153.630(b)(1), (2), and (4)]

   a. The issuer of an RA covered plan engages one or more independent auditors to perform the IVA of a sample of its RA data selected by HHS.

   b. The issuer ensures that the IVA Entity auditors are reasonably capable of performing the IVA audit according to the standards established by HHS for such audit and ensures that the audit is so performed.

   c. The issuer ensures validation of the accuracy of the RA data for a sample of enrollees selected by HHS.

d. The issuer ensures that the IVA findings are submitted to HHS in a manner and timeframe specified by HHS.

In addition to the attestation form, the issuer must maintain a written agreement with the IVA Entity, a conflict-of-interest form signed by the IVA Entity and issuer, and documentation that the IVA Entity was submitted and reviewed according to HHS regulations and guidance.

HHS reviews IVA Entities on a rolling basis, i.e., as they are provided by the issuers. HHS may exclude an IVA Entity based on the criteria above. In the event that HHS has excluded an IVA Entity, the issuer has until the deadline to procure the services of a different IVA Entity that meets all requirements. HHS will communicate to the issuer the outcome of the review in order to assist the issuer in selecting an eligible IVA Entity. Please refer to the www.regtap.info for HHS-RADV timeline and corresponding deadlines for the applicable benefit year. If the issuer does not contract with an IVA Entity, a default RA charge is assessed.

2.8 Implications of Non-selection

Pursuant to § 153.630(b)(1), 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 HHS. This provision also requires the issuer to provide HHS 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 HHS. Please refer to https://www.regtap.info/ for HHS-RADV timeline activities for the applicable benefit year.

If an issuer of a RA covered plan fails to engage an IVA Entity by the required date, HHS may impose a default RA charge. 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 HHS with access to the required data (see 45 CFR 153.710).

Section 3
HHS Risk Adjustment Data Validation Protocols
Audit Tool Overview

3 Audit Tool Overview

3.1 Purpose and Reference Documentation

The purpose of this section is to provide an overview of the Audit Tool[3] for the HHS-RADV process. For all detailed procedures pertaining to Remote Identity Profiling/Multifactor Authentication, Audit Tool Registration, and IVA Entity Designation procedures, please refer to the Audit Tool User Guide, located in the Audit Tool library.

The Audit Tool registration process consists of three sequential steps: Issuer registration, IVA Entity designation, and IVA Entity registration. All three steps must be completed during the HHS specified time frame and prior to the start of the IVA. Registration for access to the Audit Tool is restricted to authorized users who represent either an issuer, an approved IVA Entity, or HHS. The Audit Tool is used by issuers to designate an IVA Entity, to receive notifications regarding their status in the HHS-RADV process, and to communicate with HHS. Please refer to Section 1.5, ACA HHS-RADV Process Activities Timeline, for details regarding Audit Tool registration and IVA designation milestones.

Audit Tool users should refer to the Audit Tool User Guide which contains detailed information regarding the Issuer and IVA registration process, including registration requirements, trouble shooting, and error resolution. The comprehensive Audit Tool User Guide will be disseminated to all Senior Officials (SOs) who are granted access to the Audit Tool, as SOs are the primary individuals responsible for oversight and organizational representation within the Audit Tool. For additional information on Audit Tool user groups, including the SO user group, please refer to the additional details provided in the Audit Tool User Guide.

[3] The Audit Tool allows sensitive information such as medical records, medical claims, enrollment files, IVA results, and SVA results to be securely submitted and transmitted between all authorized users. The Audit Tool also facilitates communications between all HHS-RADV stakeholders (i.e., HHS, SVA Entity, IVA Entities, issuers, and the Audit Tool Contractor).

Section 4
HHS Risk Adjustment Data Validation Protocols
Sampling

4 Sampling

4.1 Purpose of Sampling Plan

The purpose of this section is to establish an appropriate sample for the HHS-RADV program's initial benefit year 2015.

HHS will select a sample of 200 enrollees for each issuer[4] of an RA eligible plan. These procedures will help to ensure that the HHS-RADV process reviews an adequate sample size 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 certain sampling assumptions around a stratified sampling design, assumed populations, and other error rate and variance assumptions.
- Sample Size (Section 4.3): provides the formulas used to calculate and allocate an overall sample size of 200, why and how this is an appropriate sample size, and discussion of precision analysis.
- Future Years' Sample Size Refinement (Section 4.4): discusses how the initial year assumptions may not be relevant in future years once there is concrete actual data available.
- Sample Review (Section 4.5): explains how HHS will verify the risk scores of an issuer's sample.

4.2 Sample Design

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

- Stratification – discusses how and why HHS stratified the sample
- Proxy Sampling Frame – discusses how HHS created an assumed average issuer population
- Actual 2015 Population – discusses what assumptions will change once HHS has actual issuer populations.

As stated above, HHS-RADV for 2015 will be used to gain insight on the HHS-RADV process. No payment adjustments will be made based on the first year proxy sampling assumptions or

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

the resulting error rates.

4.2.1 Stratification

In order to account for the variation in risk scores, each issuer population is divided into mutually exclusive groups or "strata" based on recorded risk scores, age, and presence of Hierarchical Condition Categories (HCCs). This is done to achieve 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, HHS 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. For the base year, each issuer's enrollee population will be grouped into 10 strata based on presence of HCCs, age, and risk level. Table 1 provides a listing of assigned strata by risk level for each age group.

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 will not be further stratified by age or risk level, as this stratum is assumed to have a uniformly low error rate.

Table 1: 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

A number of comments received in response to the White Paper suggested that HHS also consider stratifying based on plan types and other characteristics. HHS will consider other sampling strategies in the future, but at this time there is not enough experience with the RA process to warrant a modification to the sampling approach. Thus, a simple age and risk score stratification will be used for at least the initial year of the HHS-RADV program.

4.2.2 Proxy Issuer Population

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

HHS used the 2014 summary data from the EDGE servers as a proxy population for the 2015 sample design. The EDGE server summary data included stratified populations of each issuer.

4.2.3 No-HCC Assumptions

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

HHS 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-sided 95 percent Confidence Level), even under the more conservative assumptions.

4.2.4 Actual 2015 Population

Before any samples are selected for Benefit Year 2015, HHS will have actual enrollee data, which will alleviate the risk of assuming a distribution of enrollees that may not reflect the true distribution of the population to be sampled per issuer. HHS will use actual 2015 issuer demographic population distributions for each issuer to allocate sample size appropriately among each stratum (e.g., the frequency will represent the actual issuer's total enrollee count).

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 first year of the HHS-RADV program (2015 benefit year), the enrollee sample that will be selected for IVA will include 200 enrollees from each issuer to estimate a risk score error related to RA. The assumptions discussed above in Section 4.2 along with the precision and confidence level targets discussed in Section 4.3.1 support the year-one 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).

4.3.1 Precision and Confidence Level

For the initial year, HHS will target a 10 percent relative sampling precision (or margin of error) at a two-sided 95 percent confidence level (*CL*). The use of a 10 percent targeted precision was selected based on a survey of guidance of the Office of Management and Budget (OMB), the Internal Revenue Service (IRS), and the HHS developed Payment Error Rate Measurement (*PERM*) program. This target will be re-evaluated in subsequent years based on actual results. Thus, HHS needs to obtain a sample size such that 1.96[5] multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less.

$$Precision = (1.96 * SE)/RS_{Adj}$$

Where *SE* is the standard error, which is the square root of variance and RS_{Adj} is the estimated adjusted risk score.

[5] Critical value for the two-sided 95 percent confidence level

OMB guidance[6] on improper payments establishes a targeted precision range of 2.5 percent (two-sided 90 percent CL) to 3.0 percent (two-sided 95 percent CL) while the IRS sampling guidance[7] establishes a targeted precision of 10 percent (two-sided 90 percent CL). HHS developed the PERM program[8] in accordance with guidance issued by OMB, since OMB identified Medicaid and the Children's Health Insurance Program (CHIP) as high-priority programs at risk for significant improper payments. The PERM program measures improper payments in Medicaid and CHIP and produces error rates for each program. The PERM program sample size must be sufficient to meet the precision requirement of 3.0 percentage points (two-sided 95 percent CL).

4.3.2 Sample Size Formulas

To illustrate the underlying sample size equation[9], consider the following notations:

Variable	Description
n	Overall sample size
H	Number of strata
N_h	Population size of the h^{th} stratum
Y	Adjusted total risk score estimate
S_h	Standard deviation of risk score error amount for the h^{th} stratum
Prec	Desired precision level
CI	Confidence interval associated with the desired level, which is 1.96 for a two-sided 95 percent confidence level

[6] OMB Memorandum M-11-16. In addition to the precision targets above, an error rate of less than 1.5 percent would also be required to be considered not susceptible to improper payment risk
[7] Revenue Procedure 2011-42
[8] Payment Error Rate Measurement Manual Version 1.1
[9] The sample size formula can be found in Section 5.9: *Cochran, William G., Sampling Techniques, third edition, John Wiley & Sons*, 1977.

4.3.2.1 Overall Sample Size

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

$$n = \frac{\left(\sum_{k=1}^{H} N_k S_k\right)^2}{\sum_{k=1}^{H} N_k S_k^2 + \left(\frac{Prec \times Y}{CI}\right)^2}$$

HHS selected a stratified mean estimator to determine the overall IVA sample size since it is more conservative than other commonly used estimators, such as the stratified separate ratio estimator. The principal objective of a stratified sample is to reduce sampling error; variance from an efficient stratified sample is lower than that from a simple random sample. HHS uses an adjusted total risk score estimate (*Y*) in the sample size formula rather than the issuer's current year recorded risk score (unadjusted). Utilizing the previous year's risk score error rates to make an adjustment to the issuer's current year risk score is more appropriate than just taking the issuer's recorded risk score as is, since the prior year's error rates provide insight into how recorded risk scores may differ from audited (adjusted) risk scores.

4.3.2.2 Neyman Allocation

Once the overall sample size is determined, the individual sample size per stratum (*nh*) will be determined using the Neyman optimal allocation method[10]. 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).

The sample size for each stratum is calculated from:

$$n_k = n \times \frac{N_k S_k}{\sum_{k=1}^{H} N_k S_k}$$

HHS determined that a sample size of up to 200 enrollees is adequate to achieve the targeted precision threshold based on the given assumptions documented above in Section 4.2.

4.3.3 Alternate Sample Sizes

While a sample size of 200 is adequate based on the assumptions presented above for the initial year, a smaller sample size will be calculated for issuers with a small number of enrollees.

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

In such cases, a Finite Population Correction (FPC) will be used to adjust the sample size[11]:

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

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 (i.e., more than 5 percent of the population is sampled) so that n/N > 0.05. Consequently, any issuer with an enrollee population size less than 4,000 (since 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.

4.3.4 SVA Sample Sizes

In addition to the IVA sample size of 200, there will be two (2) alternate samples sizes used for the purposes of the SVA process. The two (2) SVA sample sizes will consist of an initial sample of 12 enrollees and an expanded sample of 88 enrollees for a total of 100 enrollees. Since pair-wise testing could be performed on both SVA samples, 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 samples must be large enough to validate testing results.

In the cases where pair-wise means testing of the SVA sample of 12 enrollees fails, HHS will increase the second SVA sample by 88 enrollees for a total of 100 enrollees so that based on the second pair-wise means test results, the sample would be large enough to extrapolate. A sample size of 100 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 sample size of 12 and an expanded SVA sample size that is one-half the IVA sample size.

[11] 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 Year's Sample Size Refinement

The data used to make the above assumptions applies only to the base year (2015) of the HHS-RADV program. Beyond Benefit Year 2015, HHS will have summary-level data to support refinement of sampling assumptions needed for future years. The stratification design is expected to remain consistent with nine (9) HCC strata and one (1) No-HCC stratum. However, the specific size and allocation of the sample among each stratum may be refined based on average issuer enrollee risk score distributions once the data becomes available.

HHS will obtain snapshots of issuer populations throughout the first few years and may refine the sampling assumptions and strategy for Benefit Year 2016 and beyond by using a combination of the best available data and the year-one assumptions. Although final risk score error estimates may not be available in 2016, there will likely be sufficient sample results from the 2015 IVA/SVA process to use for the 2016 sampling plan. As the program progresses, HHS expects to gain experience over time that may inform comprehensive sampling processes to improve the reliability of the error estimates by more effectively estimating areas at high risk for error. HHS 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 year(s) or current year (if available) will be used in place of the past year's data; and
- Actual issuer demographics from the prior year(s) or current year (if available) will be used in place of assumed number of enrollees and issuers.

HHS may adjust the sample size requirements for future years using the best available data in combination with the year-one assumptions. 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. HHS is also considering varying the sample sizes based on actual data submitted for RA for average "large," "medium," and "small" issuer populations. 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, small) to follow when selecting the sample. Any changes made to the IVA design and sample size may affect the SVA sub-sample'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

4.5.1 Review of Population (RADVPS)

Once HHS transmits the final RA command to EDGE servers, issuers will have access to the RADV Population Summary Statistics (RADVPS) report. Issuers should review this report to ensure the data on it is accurate compared to their knowledge of their enrolled populations, and that the stratification is representative of their population. As the error rate determined through review of a sample derived from this population may be used for extrapolation onto the entire

population, it is essential that issuers review the RADVPS report. If an issue is identified, issuers must communicate that issue to HHS through the RA formal discrepancy reporting process. Once the discrepancy period has closed, the population statistics are not subject to appeals. HHS then transmits the command to the EDGE servers to perform the HHS-RADV sampling calculations; the issuer runs the commands and sample reports are sent to HHS. The sample reports are reviewed by HHS to determine if they are representative of the issuer's populations through comparison to the RADVPS report. If the samples are approved, the two SVA samples are drawn and finally the IVA sample is released to issuers via their EDGE servers.

4.5.2 Review of RADV Sample (RADVIVAS)

Each year, HHS will select a sample of up to 200 enrollees from eligible RA issuers for HHS-RADV. The RADV IVA Statistics (RADVIVAS) report contains a summary of the issuer's sample at the stratum-level. The RADVIVAS report is in the same format and contains the same data elements as the RADVPS report. However, the RADVIVAS report contains only the information on the RADV sampled enrollees, whereas the RADVPS report contains information on the issuer's population. Issuers are able to validate the RADV IVA sample generated by HHS, based on the RADVPS Report, by following the nine (9) steps outlined in the section below. By following these steps, issuers can confirm that the HHS-RADV process has selected a statistically valid sample size of enrollees for the issuer, including the expected number of enrollees assigned to each of the ten (10) stratum, and one (1) which is representative of the their population. 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 population:

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

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

  - $\bar{rs}$ 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, HCC, and CSR factors.

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 RADVPS report and applying the following criteria:

- If the issuer population is 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 51 or greater and less than 4,000, then the larger of 50 or the result of the Finite Population Correction (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 1-9 is two-thirds of the total IVA sample size calculated in Step 2. The target sample size for strata 1-9 can be calculated by using the following formula:

HCC target sample size for strata 1-9 = IVA target sample size * 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 1-9
The issuer should execute the Neyman formula for strata 1-9 using the HCC target sample size. Use the following formula (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 2015 payment year). 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.

Calculation of 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 (RS) is the mean risk score for stratum *h*.

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

Risk Stratum	Variance of Error
Low	0.095
Medium	0.201
High	0.654

While HHS does not anticipate the expected variance of net error to be uniform across all age groups, this level of data will not be available for the initial year. Thus, the values above are merely a year-one assumption. 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 first year.

Step 5: Calculate the Number of Enrollees of the IVA 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 6: Calculate Total Actual Sample Size for Strata 1-9

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

Table 2 below contains an example of the resulting sample size per strata. Note that the issuer population is less than 4,000, so the IVA sample size will be less than 200 enrollees. For example, the issuer population is 3,999, so the IVA target sample size is 190. The HCC target sample size is two-thirds of the IVA target sample size, so the HCC target sample size is 127.

Table 2: Example of IVA Sample

IVA Sample Size by Strata				
Age	**Risk Level**	**Stratum**	**Population (N)**	**Calculated Number IVA Enrollees n_h (IVA)**
Adult	Low	1	963	10
	Medium	2	569	14
	High	3	226	26
Total Adult			**1,758**	
Child	Low	4	196	3
	Medium	5	125	4
	High	6	79	7
Total Child			**400**	
Infant	Low	7	369	13
	Medium	8	95	18
	High	9	95	32
Total Infant			**559**	
No HCC			***1,282***	
Total IVA (1-9)			**2,717**	**127**

Step 7: 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.

Step 8: Re-Execute Neyman Allocation for Strata 1-9 if Sample Selected is less than the Original Target for Strata 1-9
The issuer should add one (1) to the target HCC sample size and re-execute the Neyman allocation for stratum 1-9 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 9: Calculate the Number of Enrollees of the IVA to Assign to Stratum 10
The issuer should determine the number of enrollees to assign to stratum 10.

For stratum 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.

Section 5

HHS Risk Adjustment Data Validation Protocols

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

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

5.1 Purpose

Section 5 provides the validation items, testing procedures, and reporting requirements to be performed by the IVA and SVA Entities to validate the selected sample of enrollee demographics, enrollment and health status information used in the RA process, and the issuer's enrollee-level risk score calculation. IVA and SVA Entities are to document the results of the validation of these data elements using the *IVA Audit Matrix* and associated submission packages.

This section is divided into two (2) validation groups. First, demographic, enrollment, and claims data elements are validated to issuer source systems (Sections 5.2 and 5.3). Second, Medical Records are matched to those elements validated in Sections 5.2 and 5.3 and then abstracted to determine valid diagnosis codes (Section 5.4).

5.2 Issuer and IVA Entity Interaction

During the demographics, enrollment, and claims validation process, 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, it is anticipated that 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 permitted to communicate regarding the validity of the error or finding. The IVA Entity is allowed to interact with the issuer when potential findings have been identified, and the issuer is permitted to present evidence which mitigates the findings. Additional documentation generated for these purposes must always be documented within workpapers and submitted along with the audit results.

5.3 Demographic, Enrollment, and Claims Validation

During the demographic, enrollment, and claims validation process, IVA Entities will need to validate that the data submitted to the EDGE server matches enrollment and claims data stored within the issuer's source systems. Issuers must also link the masked unique enrollee ID from the EDGE server HHS-RADV IVA Sample Report to the issuer's enrollment system enrollment file.

Figure 2: Demographic, Enrollment, and Claims Validation

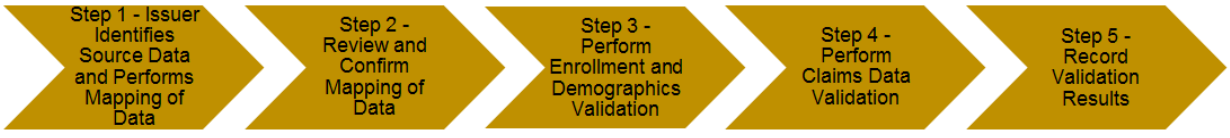


Figure 2 illustrates the process for the entities to perform the demographic and enrollment validation. Validation of these key demographic, enrollment, and claims factors is essential to the reliability of the RA calculation and the accuracy of the RA process. Therefore, it is important for issuers to provide the most current source information to the IVA Entity. The SVA reviews the information collected by the IVA Entities and submits to the Audit Tool.

5.3.1 Step 1. Issuer Identifies Source Data and Performs Mapping of Data from Source Systems to EDGE

The initial step in the demographic, enrollment, and claims validation process is for the issuer to document, or gather existing documentation, which maps issuer source system data to EDGE data submissions. The documentation provided from the issuers must indicate:

- Which screens contain the information necessary to validate specific EDGE data elements;
- Navigational steps necessary to access each relevant screen; and
- Any internal code sets used for any relevant elements.

Documentation required to demonstrate this understanding must consist of a detailed process narrative and may include supporting documentation, such as process flows, data mapping tables, screen shots, or other information that would allow for a third party to understand the processes and to map the data without additional inquiry. This mapping must be documented by linking each data element (and their EDGE acceptable values) to the corresponding element in the issuer's source systems via screen shots. The EDGE data elements that must be mapped to source systems/processes fall into two (2) categories: Enrollment Data Elements (Table 3) and Claims Data Elements (Table 4). The following tables outline the data elements (Column 1), the corresponding XML element in the RADV Detail Reports (Column 2), and the EDGE Sampling Detail Report on which that data element is found (Column 3).

Table 3: EDGE Enrollment Data Elements

Enrollment Data Elements (ICD)	XML Element Ref.	EDGE Sampling Detail Report Ref.
Unique Enrollee ID	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 DOB	insuredMemberBirthDate	RADVEE
Enrollee Gender	insuredMemberGenderCode	RADVEE
Plan ID, which includes: • HIOS ID • CSR (Cost-sharing Reduction Factor)	insurancePlanIdentifier	RADVEE
Enrollment Start Date	coverageStartDate	RADVEE
Enrollment End Date	coverageEndDate	RADVEE
Premium Amount	insurancePlanPremiumAmount	RADVEE
Rating Area	ratingAreaIdentifier	RADVEE

Table 4: EDGE Claims Data Elements

Claims Data Elements	XML Element Ref.	EDGE Sampling Detail Report Ref.
Unique Enrollee ID	insuredMemberIdentifier	RADVMCE
Claim System Data linked to Validated Enrollee Data: • Member ID • Enrollee First Name • Enrollee Last Name • Enrollee DOB • Enrollee Gender	N/A	N/A - VALIDATED ENROLLMENT DATA
Bill Type	billTypeCode	RADVMCE
Statement Covers From	statementCoverFromDate	RADVMCE
Statement Covers Through	statementCoverToDate	RADVMCE
Service Code Qualifier	serviceTypeCode	RADVMCE
Service Code	serviceCode	RADVMCE
Service Code Modifier	serviceModifierCode	RADVMCE
Place of Service	serviceFacilityTypeCode	RADVMCE
Final Adjudication Status	N/A	N/A - IVA ENTITY TO IDENTIFY

In the event the data does not exactly match an EDGE 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 unique enrollee IDs between EDGE and their source data systems. Additional detail is provided in the section below. This documentation will be leveraged in the analysis and validation of demographics, enrollment, and claims data elements and is essential for both the IVA and SVA Entities to complete audit activities.

Mapping EDGE Unique Enrollee ID to Source System Member ID

An essential step in the mapping of data from source systems to EDGE is the documentation of a crosswalk between masked EDGE Unique Enrollee ID and the source system Member ID, which is not contained in the EDGE data. For both enrollee level data and claims level data, a mapping of the masked "EDGE Unique Enrollee ID" to source system "Member ID" must be documented to allow a reviewer to crosswalk enrollee and claims data, linked to a specific masked ID in EDGE, to the corresponding individual in the source system. This crosswalk should provide an IVA Entity reviewer or SVA Entity reviewer the ability to identify the corresponding enrollee when provided with the EDGE Unique Enrollee ID. 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" would be an acceptable form of mapping for the enrollment system. An additional table could be constructed for the claims system, with the values "EDGE Unique Enrollee ID" and "Claims Source System – Member ID."

Documentation of Capitated Encounter Data

Issuer capitated encounter data may be selected during the IVA claim sample selection process. In Section 5.3.2, Step 2, Review and Confirm Mapping of Data from Source Systems to EDGE, 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 working papers 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 identified within the IVA Audit Matrix in the 'Additional Documentation' section of Tab 'Steps 1 & 2 Documentation'.

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

Mapping of Supplemental Diagnosis

HHS 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 data submission, issuers have been provided specific business rules for the submission of supplemental Diagnosis Codes. If supplemental diagnosis files are used, 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.

This documentation should be identified within the IVA Audit Matrix in the 'Additional Documentation' section of Tab 'Steps 1 & 2 Documentation'.

5.3.2 Step 2. Review and Confirm Mapping of Data from Source Systems to EDGE

Once the issuer has provided the source documents to map to the EDGE elements, the next step is for the IVA Entity to review and discuss with the issuer the contents of the issuer's provided documentation to gain an understanding of the issuer's environment, and the issuer's enrollment, premium, and claims source systems. This documentation will be leveraged in the analysis and validation of demographics, enrollment, and claims data elements and is essential for both the IVA and SVA Entities to complete audit activities.

Workpapers will be drafted as required throughout Step 3 (Perform Demographic and Enrollment Validation) and Step 4 (Perform Claims Data Validation) by the IVA Entity, which will combine issuer documentation with the IVA Entity's procedural steps taken to validate the issuer data using screenshots. The IVA Entity will validate the workpapers with the issuer to ensure the procedures align with the issuer's systems and processes.

5.3.3 Step 3. Perform Demographic and Enrollment Validation

In the third step of the demographics and enrollment validation process, source documentation

must be obtained which will enable the validation of the key demographics and enrollment factors by the IVA and SVA Entities for 100 percent of enrollees in the IVA sample. Issuers must first use the information captured in Steps 1 and 2 to link the masked unique enrollee ID from the EDGE server HHS-RADV IVA Sample Report to the actual enrollee Member ID within the source system.

IVA Entities then must work with issuers to obtain evidence from issuer systems that include the demographics and enrollment data for the selected enrollees in the issuer's plans. This evidence, referred to as source documentation, is expected to be in the form of screenshots of the actual data in the issuer source system(s). At this time, the IVA Entity is not required to have physical or logical access to systems, and is not required to oversee the screenshot process in real time. However, all screenshots taken, if not performed by the IVA Entity, must be understandable in the context of an audit. That is, the screen shot should provide sufficient information to allow a reviewer the ability to confirm the accuracy of the data being validated with no additional inquiry required. If in the event a data element has been manipulated before submitting to EDGE, or the corresponding source system value is unlike the EDGE data format, workpapers should be drafted by the IVA Entity which explain how the documented data is interpreted to arrive at the corresponding EDGE value. These workpapers should be directly based on supporting documentation provided by the issuer to substantiate the manipulation of the source data.

Any data elements that exist in an issuer's source system must be documented from that source system using the screenshot requirements stated above. Issuers may provide workpapers and source elements from another system only if a data element is not stored in the issuer's source system. For example, if the issuer's source systems contain required data elements, a data warehouse extract is not acceptable as source system documentation. VA Entities must obtain documentation for the most correct and complete set of enrollment records for each enrollee in the sample. For example, if the enrollee had changes to name or residency or plan cancellation, it is imperative that the IVA Entity review the most updated source information. If the most updated enrollment information is not obtained, the review by the IVA and SVA Entities will not match the data submitted by the issuer to the EDGE server and will be shown as an error in the IVA Audit Matrix. All enrollment periods for sampled enrollees must also be captured in the event a sampled enrollee has multiple enrollment periods. Documentation of enrollment periods may differ across issuers, For example, a 12-month enrollment may be captured as one continuous period or 12 separate monthly enrollments. As long as the dates provide the same coverage, the validation can be recorded as "Yes - With Transformation".

The demographics and enrollment validation process continues once the EDGE report and the source documents are obtained for the sampled enrollees. In this step, the IVA and SVA Entities are responsible for comparing the source data to the EDGE report data and documentation of the results.

Specifically, the data elements to be validated within the demographics and enrollment validation process include the following fields, which are captured and referenced in the IVA Audit Matrix:

- Unique Enrollee ID
- Member ID (Non-EDGE Data Element)
- Enrollee First Name (Non-EDGE Data Element)
- Enrollee Last Name (Non-EDGE Data Element)
- Enrollee Date of Birth (DOB)

- Enrollee Gender
- Plan ID (which contains the issuer HIOS ID and the Cost-sharing Reduction Factor (CSR)
- Enrollment Start Date
- Enrollment End Date
- Premium Amount
- Rating Area

Please note that the demographics and enrollment validation process requires the identification of three (3) Non-EDGE data elements for each enrollee selected, from within the source enrollment system (Member ID, Enrollee First Name, and Enrollee Last Name). This information is used in the claims data validation and the health status validation to ensure the medical record and claims are for the correct enrollee.

Additionally, please note that the requirement to validate Subscriber ID and Subscriber Indicator data elements during the IVA is for issuers to provide evidence to support premium amount submitted to the EDGE server, through the submission of screenshots or other documentation.

Validating Data Elements and Documenting Results

The validation of issuer source system data, and subsequent documentation of data elements within the IVA Audit Matrix requires IVA Entities to first document the data element value as observed in the source system. Second, the IVA Entities must substantiate how data submitted to the EDGE server correctly or incorrectly corresponds to the information within the issuer's source system. Third, the IVA Entity will confirm the data element validation result (see section 'Confirmation of Data Element Validations' below).

Issuer source system data may not directly correlate to values submitted to the EDGE server, either due to the manner in which data is represented in the source system (e.g., identification of Gender using '1' for Male, and '2' for Female), or as a result of required manipulation to satisfy EDGE server submission requirements (e.g., Aggregation of Premium amounts for subscribers and dependents).

Validation of the data element 'Premium Amount' requires different methods of validation, dependent upon the enrollee sampled. CMS requires that Premium Amount of sampled Subscriber enrollees be performed and documented. CMS does not require validation of Premium Amount for sampled Non-Subscriber enrollees. Below are detailed explanations regarding the validation of Premium Amount values for both Subscriber and Non-Subscriber enrollees.

<u>Premium Validation – Sampled Subscriber Enrollees</u>

CMS requires that the premium amount reported to the EDGE server on the subscriber enrollment record is validated to insure it correctly captures the monthly total rated premium charged for a subscriber's policy, including the Advanced Premium Tax Credit (APTC) amount. For example the issuer must provide evidence to substantiate that the premium amount submitted on the subscriber enrollment record to the EDGE server is the correct amount for that policy, including the advanced premium tax credit (APTC), if applicable. Additionally, since premium amount is only reported to the EDGE server on subscriber enrollment records, issuers must provide evidence of any dependents' premiums aggregated to the subscriber's reported

premium for the policy. The issuer is required to provide the IVA Entity with sufficient information to be able to validate the premium amount submitted to the EDGE server.

For the 2015 benefit year HHS-RADV, the premium amounts for sampled subscriber enrollees require validation as this amount may differ from what is captured on the RADVEE report that depicts EDGE server submitted data. As such, while screenshots are not required, sufficient evidence must be provided to the IVA Entity, and subsequently made available to the SVA Entity, to enable the validation of the submitted premium amount for the sampled enrollee. Based on this validation, screenshots are recommended and preferred, but it is up to the issuer and IVA Entity to determine the required level of detail needed to fulfill this process. The IVA Entity must then use this information to perform the validation of the policy premium amount submitted and document their work within a workpaper.

Workpaper documentation should describe any scenario where the IVA Entity totaled values to arrive at the "EDGE Premium Amount". Additionally, workpaper documentation submitted by the IVA Entity should show how evidence provided by the issuer was used to arrive at the EDGE server submitted policy premium amount for the subscriber sampled. Additional detail on workpaper documentation requirements is provided in **Section 5.3.6**.

Premium Validation – Non-Subscriber Enrollees

Validation of premium amount is not required when a non-subscriber/dependent is the sampled enrollee. For non-subscribers/dependents, the value "N/A" should be reported in the "Source System Value" Column Z of the IVA Audit Matrix. Columns "EDGE Value" (Column Y) and "Confirmed?" (Column AA) should be left BLANK. No documentation is required for these sampled enrollees.

Newborn Verifications with No Source System Support

Newborns may not have complete data within the issuer's source system. The IVA Entity must confirm that the EDGE Server Business Rules (ESBR) were followed appropriately for handling newborn coverage. The issuer would provide evidence of newborn coverage through workpaper documentation, if there are no screenshots.

Confirmation of Data Element Validations

Issuer source system data may not directly correlate to values submitted to the EDGE server, either due to the manner in which data is represented in the source system (e.g., identification of Gender using '1' for Male, and '2' for Female), or as a result of required manipulation to satisfy EDGE server submission requirements (e.g., Aggregation of Premium amounts for subscribers and dependents). In the IVA Audit Matrix, the comparison of EDGE values to source system values is to be confirmed with one of the following responses:

- Yes – Without Transformation,
- Yes – With Transformation, or
- No – No Match.

These responses are used to indicate if a source system value required additional interpretation or manipulation in order to match the corresponding EDGE data value.

The response 'Yes – Without Transformation' indicates a direct match between EDGE server data and the data observed and documented within the issuer source system. Once documented via screenshots, no additional documentation is required to support the validation.

The response 'Yes – With Transformation' indicates a non-direct match between EDGE server data and the data observed and documented within the issuer source system. In these instances, workpapers should be cited or provided which indicate how the observed data was manipulated or interpreted to arrive at the successful comparison between EDGE server data and source system data.

The response 'No – No Match' indicates that the IVA Entity, based on the data observed in the issuer source system, could not match EDGE server data to the issuer's source system data. Data element validations resulting in the 'No – No Match' are captured as errors.

These confirmation responses are applicable to enrollment and demographics data validations, as well as claims data validations.

Note: If an error is identified during the Demographics and Enrollment validation portion of the IVA process, the enrollee will still continue to the Claims Validation and Health Status Validation processes.

Changes to Enrollment Records Following RA Data Submission

In certain circumstances, it is possible that enrollee information was 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 demographics and 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. Timing errors identified during enrollment and demographics data validation in this manner will influence the final calculation of the enrollee's risk score.

Unallowable Alternative Capture Methods

Documentation of enrollment and claim source system data must be captured in the form of a screenshot of the system in which the data originates. As such, alternative methods for data aggregation and reporting (e.g., screen scrapes or data warehouse extracts) are not acceptable forms of documentation.

Screenshot Automation

HHS 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. Automation of the screenshot process is not required. Please be aware that HHS 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
- Format: PDF document.

In the event an automated process is utilized, the IVA Entity is responsible for evaluation of 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 should be 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 as a PDF document.

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

File Naming Considerations – Demographics and Enrollment Documentation

Please refer to the IVA Comprehensive User Guide within the Audit Tool File library for additional information pertaining to file naming considerations and unique file naming situations. Examples include the naming conventions for documentation files related to enrollees with Unique Enrollee IDs containing special characters, and claim IDs with duplicate trailing ClaimID numbers.

5.3.4 Step 4. Perform Claims Data Validation

Issuers are not required to have all claims data validated against source systems. IVA Entities can use the sampling methodology below to meet the claims validation requirement. This section outlines the methodology for the approach and the process for the selection of the sample for EDGE claims validation by the IVA Entity.

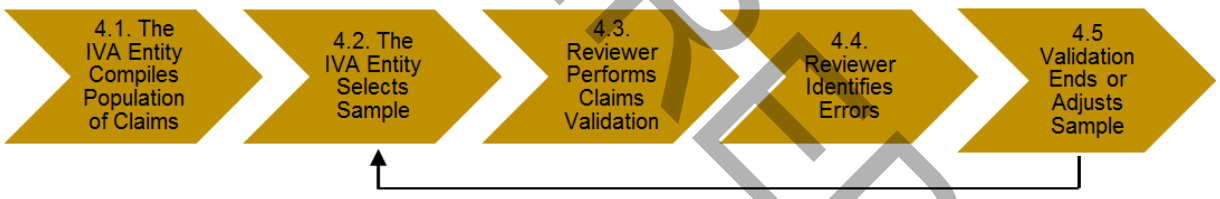


Figure 3: Perform Claims Data Validation – Claims Review Process Steps

Figure 3 contains the five main steps of the EDGE claims review process, which are described below. The steps are linear with a feedback loop based on the number of claims with errors identified.

4.1 – The IVA Entity Compiles Population of Claims

The IVA Entity compiles all claims in the IVA sample which can be found in the RADV Medical Claim Extract (RADVMCE) Report. This report contains all EDGE claims and their associated data elements that were accepted by the EDGE server for all enrollees in the IVA sample.

4.2 – The IVA Entity Selects Sample

The IVA Entity selects an initial sample of claims, consisting of a minimum of 15 claims and a maximum of 130 claims (IVA Claims Sample) for Benefit Year 2015.

The IVA Entity will be required to follow HHS guidelines for selecting the random sample of claims for review, as well as follow the process for expanding the size of the IVA Claims Sample, if applicable.

Sampled Population

The sampled population is made up of claims and their associated data elements that were submitted to the EDGE server and are associated with enrollees that are within the IVA sample.

Sample Selection

This section outlines the definition of the population, the sample size, and adjustments to the sample size to meet the required accuracy rate. Sample sizes must be defined for each issuer and may potentially increase based on the number of claims identified as containing one or more errors. A "claim with errors" is defined as when the reviewer finds:

- An inexplicable mismatch between the EDGE claim and source system; and/or
- An unsourced data element.

The IVA Entity obtains the claims for all enrollees in the IVA sample on the EDGE Server –RADVMCE. The IVA Entity then determines the initial sample size of claims for the issuer.

The sample sizes for claims validation were determined using the same statistical formulas underlying the controls sample size tables in the GAO Federal Audit Manual (FAM) Section 450, Sampling Controls Tests. Specifically, *Figure 450.1* in GAO FAM includes sample size tables that outline the acceptable deviations for various sample sizes at a 90 percent confidence level and a tolerable error rate of 5 percent (or 95 percent accuracy rate) and 10 percent (or 90 percent accuracy rate). The GAO FAM sample size tables assume a large population of over 2,000 items. We adjusted the sample size formulas to accommodate the smaller assumed population size and desired accuracy rate (which could be different than 95 percent or 90 percent as specified in GAO FM *Figure 450.1*). The various sample sizes allow the auditor to determine the number of acceptable deviations at each given sample size.

For HHS-RADV, "deviations" is represented by the number of "claims with errors" as unique claims are the basis for the validations performed. As such, under the 90 percent confidence/85 percent required accuracy rate scenario, a sample size of 15 claims would allow for 0 acceptable claims with errors to conclude that the required accuracy rate is at least 85 percent, with 90 percent confidence.

To select the sample, the IVA Entity performs the following:

- Begins with a list of the claims for the IVA sample;
- Uses a random number generator to assign random numbers to each claim subject to sample selection;

- Sorts the claims by the random number from smallest to largest; and
- Selects the necessary number of claims from smallest to largest random number until the maximum possible sample size of 130 is obtained, and records the claims identified in the IVA Audit Matrix. (Please note that while not all of these claims may be utilized, it is required that the sample be drawn only once.)

Table 5 details the acceptable number of claims with errors for each sample size. The reviewer should start with the smallest sample size and increase the sample based on the number of claims with errors noted. Table 5 includes the sample sizes of claims and acceptable number of claims with errors for benefit year 2015.

As the sample sizes increase, the sample is inclusive of the sample taken before it. For example, the sample of 25 includes the initial sample of 15 that was already sampled. Thus the reviewer will select 10 additional claims if one (1) claim is identified as containing errors. The same process applies for additional claims with errors noted as outlined in the Table 5.

Table 5: Sample Sizes and Acceptable Number of Claims with Errors (Benefit Year 2015)

Sample Size (# Claims)	Acceptable Number of Claims with Errors
15	0
25	1
34	2
43	3
51	4
60	5
68	6
76	7
84	8
91	9
99	10
107	11
115	12
122	13
130	14

4.3 – The IVA Entity Performs Claims Validation

The IVA Entity reviewer will view, document, and obtain source documents for all associated claims data elements for those claims in the IVA Claims Sample. Claims data elements for each claim must be validated via source documentation.

First, the IVA Entity reviewer will view, document, and obtain screenshots of each of the following 14 Claims Data Elements for each claim selected:

- Unique Enrollee ID
- Member ID (Non-EDGE Data Element)
- Enrollee First Name (Non-EDGE Data Element)
- Enrollee Last Name (Non-EDGE Data Element)
- Enrollee Date of Birth (DOB) (Non-EDGE Claims Data Element)
- Enrollee Gender (Non-EDGE Claims Data Element)
- Bill Type
- Statement Covers From
- Statement Covers Through
- Service Code Qualifier
- Service Code
- Service Code Modifier
- Place of Service

- Final Adjudication Status

After the appropriate documentation has been obtained, the following steps of the claim data validation process should be performed:

- link claim to validated source system enrollee data; and
- Compare claims data elements to EDGE claims data.

First, the following data elements below are compared to validated enrollment data for the enrollees to confirm that the claim selected has been appropriately linked to the correct enrollee:

- Unique Enrollee ID
- Member ID (Non-EDGE Data Element) in the Claim System
- Enrollee First Name (Non-EDGE Data Element)
- Enrollee Last Name (Non-EDGE Data Element)
- Enrollee Date of Birth (DOB) (Non-EDGE Claims Data Element)
- Enrollee Gender (Non-EDGE Claims Data Element).

The Unique Enrollee ID is used as the basis of comparison and must be identified first in the IVA Audit Matrix. Based on the Unique Enrollee ID entered, the corresponding validated enrollment data (confirmed during the Step 3, Perform Demographics and Enrollment Validation) will populate. Reviewers will then compare the remaining five (5) Non-EDGE claims data elements to the validated enrollment data and identify the number of elements which match.

IVA Entity reviewers should then use professional judgment to determine if the claim identified has been linked to the correct enrollee. Please note that the number of matches between the Non-EDGE Claims Data Elements to validated enrollment data elements should be used as a guide when considering acceptance of the matching. Additionally, non-matches between these data elements do not count towards the "Claims with Error" determination.

However, if the reviewer, based on the evaluation of matched data elements, determines that the claim cannot be linked to the indicated EDGE Unique Enrollee ID, an error will then be recorded. Please note that if a claim fails this mapping, the remaining claim data elements still should be validated against the EDGE claims data.

Next, the IVA Entity reviewer performs the validation of the claims data elements which correspond to EDGE server claims data. The following data elements are utilized in this validation:

- Bill Type
- Statement Covers From
- Statement Covers Through
- Service Code Qualifier
- Service Code

- Service Code Modifier
- Place of Service
- Final Adjudication Status (Non-EDGE Claim Data Element).

Documented values for the above data elements are compared to EDGE data found on the RADVMCE Report. Here, any element that cannot be validated is considered an error.

Final Adjudication Status – Additional Detail

Similar to Enrollee Name, Gender, DOB, and so on, "Final Adjudication Status" is not a direct EDGE Claim Data Value. However, per EDGE server submission requirements, all submitted claims are assumed to be paid and adjudicated before they are eligible for RA. Issuers and IVA Entities should provide documentation from the source system that the claim was paid and adjudicated, and provide confirmation within the Audit Matrix.

The IVA Audit Matrix can be leveraged to facilitate the comparison of EDGE server data values (and validated enrollment data values) vs. source system claims data elements. Once the reviewer performs the validation, any errors vs. the EDGE server submissions are identified and the sample is adjusted as needed.

If no errors are identified, the IVA Entity will document the results and concludes the claims data validation process.

Claim Service Line Documentation in the IVA Audit Matrix

For the purposes of the current 2015 RADV Benefit Year, two potential approaches for documenting claim service lines within the IVA Audit Matrix may be used:

> Option 1) Follow original guidance provided by CMS and number the first service line of the claim with a [BLANK] value, with successive service lines numbered starting with "1"…"2"…etc. within the IVA Audit Matrix.
>
> Option 2) Utilize the 'serviceLineNumber' data element as reported to the EDGE server. If this method is used, all service lines documented in the IVA Audit Matrix should be populated, beginning with "1", and should match the claim 'serviceLineNumber' in the RADVMCE Report.

Please note that the IVA Entity must consistently document all claims and service lines in the IVA Audit Matrix. Either approach is acceptable and will allow for interpretation and analysis of IVA results by CMS and the SVA.

For additional information regarding documentation of claim information in the IVA Audit Matrix, please refer to webinar reference materials and the IVA Audit Matrix Example Narrative, contained within the Audit Tool File Library.

4.4 – Reviewer Identifies Errors

For the purposes of HHS-RADV and the IVA Claims Sample selection methodology, a claim will be marked as containing errors if one (1) or more of the claims data elements cannot be validated when compared to the EDGE data submission.

During the process of sample size expansion, the indicated number of claims with errors allowed in a sample of claims pertains to unique claims and not individual data elements within the sample.

- **Example 1**
  - For Claim #1, linking data elements are compared to validated enrollment data (Member ID, Enrollee First Name, Enrollee Last Name, Enrollee DOB, and Enrollee Gender). Two of five (5) elements are linked when compared to the validated enrollment data. Using professional judgment, the IVA reviewer determines that the claim is not for the identified enrollee per the Unique Member ID, and marks the error.
  - The reviewer performs the review over the remaining data elements, and notes that one (1) additional claim data element could not be validated when compared to the EDGE server data.
  - Result: One (1) Claim with Errors (Claim #1)
- **Example 2**
  - For Claim #2, linking data elements are compared to validated enrollment data (Member ID, Enrollee First Name, Enrollee Last Name, Enrollee DOB, and Enrollee Gender). Three (3) of five (5) elements are linked when compared to the validated enrollment data. Using professional judgment, the IVA reviewer determines that the claim is for the identified enrollee per the Unique Member ID, and continues to perform the review.
  - For Claim #2, one (1) claim data element could not be validated when compared to the EDGE server data.
  - Result: One (1) Claim with Errors (Claim #2)
- **Example 3**
  - For Claim #3, linking data elements are compared to validated enrollment data (Member ID, Enrollee First Name, Enrollee Last Name, Enrollee DOB, and Enrollee Gender). Four (4) of five (5) elements are linked when compared to the validated enrollment data. Using professional judgment, the IVA reviewer determines that the claim is for the identified enrollee per the Unique Member ID, and continues to perform the review.
  - For Claim #3, three (3) claims data elements could not be validated when compared to the EDGE server data.
  - Result: One (1) Claim with Errors (Claim #3)
- **Example 4**

- For Claim #4, linking data elements are compared to validated enrollment data (Member ID, Enrollee First Name, Enrollee Last Name, Enrollee DOB, and Enrollee Gender). Three (3) of five (5) elements are linked when compared to the validated enrollment data. Using professional judgment, the IVA Reviewer determines that the claim is for the identified enrollee and continues to perform the review.
- For Claim #4, all other claims data elements are validated when compared to the EDGE server data.
- Result: No Errors (Claim #4)

In summary, if one or more claims data elements cannot be validated when compared to the EDGE server data, the claim is marked as a claim with errors. Please refer to Section 4.3 for additional detail regarding which data elements do and do not result in an error.

The reviewer identifies and documents all errors in the IVA Audit Matrix. The number of claims with errors is used in the following step to determine if the claims data threshold is met, if an additional sample is needed, or if testing cannot progress due to exceeding the maximum number of claims with errors.

RA Submission Timing Issues

During the process of claims data validation, it is possible that claim information submitted by a provider resulted in a modification to a claim, following the final data submission for RA. In the event issuers can adequately support these situations with documentation from source systems, IVA Entity reviewers will document the post submission updated claim 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. These occurrences will not result in a claim with errors, and therefore will not influence increases in claims sample size.

Please note that in the event supporting documentation is unclear, and cannot be reasonably interpreted per the workpaper requirements, SVA reviewers may be unable to substantiate the suggested post-submission updated claim data value, and would reject the updated claim data value resulting in a claim with errors.

4.5 - Validation Ends or Adjusts Sample

Again, the number of claims with errors is used in the following step to determine the next actions performed by the IVA Entity reviewer within the claims data validation process.

The number of claims with errors identified in Step 4 is used to determine one (1) of the three (3) potential outcomes:

- **Outcome 1** – If the claims data threshold is met;
- **Outcome 2** – If an additional sample is needed; or
- **Outcome 3** – Testing cannot progress due to exceeding the maximum number of claims with errors.

Outcome 1: Claims Data Threshold is Met
If no errors were noted in the validation of the claims data elements, the reviewer has completed the review and records the results in the *IVA Audit Matrix*. No further sampling is required.

Outcome 2: An Additional Sample is Needed
If errors were noted in the validation of the claims data elements, the reviewer must increase the sample size of the IVA Claims Sample (returning to Step 2 of the claims data validation process in this table). The reviewer reviews the "Sample Size and Acceptable Number of Claims with Errors Table" and adjusts the sample size based upon the number of claims with errors identified. In the event the sample size is larger than the remaining population, the reviewer reviews all remaining claims.

- **Example**
  - If the reviewer noted one (1) claim with errors in the sample of 15 claims, the reviewer would select an additional 10 claims, resulting in a new sample total of 25 claims

The IVA Entity reviewer selects the additional number of required claims for analysis and performs Steps 2–5 for the adjusted sample size.

Outcome 3: Testing Cannot Progress Due to Exceeding the Maximum Number of Claims with Errors
If the number of claims with errors noted exceeds the allowable amount, then testing must conclude that the data reported is not accurate and testing cannot proceed. For Benefit Year 2015 HHS-RADV, the maximum allowable number of claims with errors within the IVA Claims Sample is 14 claims.

If 15 or more claims with errors are identified, then the IVA Entity will cease testing of claims data, and is required to notify HHS that the issuer has failed to meet the required accuracy target of the claims data validation process. The IVA Entity may notify HHS via the Audit Tool if the maximum number of claims with errors is exceeded during claims data validation. IVA Entity Audit Tool users should refer to the Audit Tool User Guide within the Audit Tool library which contains detailed information regarding forum posts, which should be utilized in communicating directly with HHS.

HHS will review the details of the communications internally, and may reach out to IVA Entities to gain clarification prior to contacting issuers directly. HHS will then contact issuers directly to address the issue on a case-by-case basis.

Note: In the event an IVA Entity determines that an issuer's data has failed claims data validation, this does not preclude the execution of all other required data validation activities and audit steps (i.e., health status validation). The IVA Entity should continue to perform the required IVA processes while the claims data validation failure is reviewed by HHS.

The results of the data validation (and subsequent failure) should be documented in the IVA Audit Matrix. CMS should then be contacted via email at CCIIOACARADataValidation@cms.hhs.gov to identify the failure in the claims data validation process. Please include the applicable HIOS ID in the subject line of the email and indicate that a "Claims Data Validation Failure" has occurred. Again, even if the issuer fails claims data validation, Health Status Validation will still continue.

Interpreting Differences in Source System Data Values vs. EDGE

In certain instances, as documented in the ESBR, data elements are able to differ from source systems. This is applicable to both enrollee level data and claims level data. These differences are acceptable as long as they are properly mapped and any differences are documented.

Example: All institutional claims submitted on a medical claim file must include a Bill Type. However, to streamline file processing, only a subset of Bill Types are accepted by the EDGE server. Issuers must assess and convert, where appropriate, any Bill Type with a frequency code other than xx1, xx7, or xx8 for such claims to be considered for RA and RI. See the ESBR, published in the REGTAP Library for additional information on this example.

Source System Bill Type Code:

Unique Enrollee ID	Claim ID	Bill Type	Statement Covers From	Statement Covers Through	Diagnosis Code(s)	Total Amount Paid	Claim Processed Date Time
B99Pn5	123a	112	4/4/2014	4/30/2014	4254	127850	2014-05-14T14:50:11
B99Pn5	123b	113	4/4/2014	5/30/2014	4254 6954	221950	2014-06-12T22:12:00
B99Pn5	123c	114	4/4/2014	6/28/2014	4254 6954	482339	2014-07-17T08:05:52

Converted Bill Type Code: The full inpatient stay must be submitted as one (1) occurrence, for the entire statement coverage period and include all Diagnosis Codes and the aggregated Total Amount Paid for the stay with Bill Type 111 as shown.

Unique Enrollee ID	Claim ID	Bill Type	Statement Covers From	Statement Covers Through	Diagnosis Code(s)	Total Amou nt Paid	Claim Processed Date Time
B99Pn5	123c	111	4/4/2014	6/28/2014	4254 6954	482339	2014-07-17T08:05:52

In this example, the claim data element of 'Bill Type' should be confirmed in the IVA Audit Matrix

using the 'Yes – With Transformation' confirmation.

5.3.5 Documentation of Claims Not Accepted in EDGE

For the HHS-RADV pilot year, HHS will allow issuers to submit Medical Records for which no claim was accepted in EDGE. If issuers wish to have medical files 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 Audit Matrix. Similar to those claims selected for validation during the Claims Validation Process, IVA Entity reviewers must document all claims data elements within the issuer source system via screen shot. However, unlike the claims data validation process, these values will not be compared to EDGE server values (as no EDGE server values for these additional claims will exist).

5.3.6 Record Validation Results

At the conclusion of the demographics, enrollment, and claims validation process, results of source data vs. EDGE data comparisons will be documented in the IVA Audit Matrix.

This includes the results of the demographics and enrollment validation, and the claims data validation. Supporting documentation and workpapers generated during Steps 1 – 4 must be submitted in the final submission package along with the IVA Audit Matrix at the conclusion of the initial validation audit.

Workpaper Documentation Guidance

Workpapers will be drafted as required throughout Step 3 (Perform Demographic and Enrollment Validation) and Step 4 (Perform Claim Data Validation) by the IVA Entity, which combines issuer-provided documentation (Steps 1 and 2) with the IVA's procedural steps taken to validate the issuer data using screenshots. The IVA Entity will validate the workpapers with the issuer to ensure the procedures align with the issuer's systems and processes.

Documentation of procedures in workpapers must be prepared such that documentation is sufficient to enable an experienced auditor, having no previous connection to the audit, to understand:

- Its purpose and source;
- The nature, timing, and extent of the audit procedures performed to comply with these standards;
- The results of the audit procedures performed, the audit evidence obtained, and the conclusions reached; and
- Significant findings and issues arising during the audit, actions taken to address them (including additional audit evidence obtained) and the basis for the conclusions reached, and significant professional judgments made in reaching those conclusions).

For workpaper guidelines and sample documentation to be leveraged during the workpaper documentation process, please refer to the Workpaper Documentation Sample.

File Naming Considerations – Claim Documentation

Please refer to the HHS-RADV Audit Tool Comprehensive User Guide within the Audit Tool File Library for additional information pertaining to file naming considerations and unique file naming situations. Examples include the naming conventions for documentation files related to

enrollees with Unique Enrollee IDs containing special characters, and claim IDs with duplicate trailing Claim ID numbers.

5.4 Health Status Data Validation Test Procedures

Following completion of demographics, enrollment, and claims validation, the IVA and SVA Entity will then perform the Health Status Validation test procedures on 100 percent of the samples selected for testing.

Figure 4: Health Status Data Validation

Figure 4 illustrates the process for the IVA and SVA Entity to perform the health status data validation. The issuer or IVA Entity links Medical Records for the enrollee with one claim per medical record, and the issuer provides the medical record to the IVA Entity to perform the IVA. The linked claim may be a claim on the RADVMCE report, or a Non-EDGE claim submitted via the NEC Tab of the IVA Audit Matrix.

At a minimum, Medical Records are needed to substantiate each HCC reported in the RADVDE Report for the enrollees in the IVA Sample. Note that if there are Medical Records associated with Non-EDGE Claims, then those records should be provided as well. As long as HCCs are substantiated through the submitted Medical Records, not every claim identified in the RADVMCE report requires a Medical Record to be requested.

For the 2015 pilot year, HHS will be allowing the submission of Medical Records that do not have an associated EDGE claim, but for which the issuer did bear a financial risk. The IVA Entity should ensure that all required EDGE data elements for these non-EDGE claims are documented in the IVA Audit Matrix and evidence of the source systems, including adjudication, is provided with the results.

Additionally, screenshot documentation of claims are not required to be provided along with the Medical Record for the purposes of Health Status Validation procedures. Refer to the Claims Data Validation and Non-EDGE Claims sections for guidance regarding screenshot documentation requirements for claims data.

Medical Record and Chart Retrieval

The timely and thorough retrieval of Medical Records from providers is a key component of the Health Status Data Validation test procedures. Without access to the relevant Medical Records, the ability of IVA Entities to accurately validate submitted EDGE data will be hindered. In the event a Medical Record is not available for the IVA and is the only source for validating an EDGE submitted HCC, it will result in an HCC error during the Diagnosis Abstraction (HS-7) process.

Issuers and contracted entities should attempt to retrieve Medical Records and documentation sufficient to provide evidence of HCCs from providers. Failure to retrieve a Medical Record may impact audit results in the event a diagnosis is unable to be substantiated. Additionally, any legitimate medical record may both validate an existing diagnosis and provide evidence of an

unreported RA-eligible diagnosis. To assist issuers and IVA Entities in the chart retrieval process, HHS will provide a memo template, on HHS letterhead, to be utilized for the requesting issuer and sent to the relevant providers. The memo will identify the purpose of the request and will underscore the necessity of providers to deliver the requested documentation. This memo shall not be altered in any way and shall not be used by the issuer or IVA for any purpose other than retrieval of documentation to support HHS-RADV. The Medical Record Provider Request memo will be provided via the Audit Tool for issuers and IVA Entities.

Issuers and IVA Entities should submit only the relevant pages of the medical record needed to validate the HCC. Please refer to the Audit Tool Comprehensive User Guide located in the Audit Tool File Library for information regarding file size.

After the Medical Records and claims documentation are obtained, the IVA and SVA Entities use data from the Medical Records and claims and compare them to the demographic and enrollment validation data elements and the EDGE server report. The following sections provide specific test procedures for the enrollee Medical Record and claim validation.

The process for testing health status validation is broken into two sections: (1) Medical Record intake (Section 5.4.1) and (2) Medical Record review and diagnosis validation (Sections 5.4.2 – 5.4.7). The IVA and SVA Entities will perform the review of both sections for all sampled enrollees that have claims submitted to the EDGE, or with claims substantiated through screenshots.

Medical Record intake ensures the Medical Record matches to the enrollee in the IVA Sample Report and matches to one of the enrollee's claims identified in the EDGE server reports, or as documented in the source system evidence. Medical Record intake is not required to be completed by certified medical coders, and can be completed by a role designated as primary or senior intake reviewers. Medical Record review and diagnosis abstraction involves review of the medical record to ensure it meets HHS requirements regarding facility type, service code, service type, provider credentials, and signature. Diagnosis abstraction is required to be completed by certified medical coders.

Documenting Strata 1-9 Enrollees without Medical Records

The issuer should prepare a document listing the enrollees in Strata 1-9 for whom they are unable to receive a Medical Record. This is to document that a claim and diagnosis was submitted to the EDGE server and an HCC was assigned, but a Medical Record was unable to be obtained to support the diagnosis or HCC.

For Strata 1-9, enrollees for whom no Medical Record was reviewed by the IVA Entity and was not included on the IVA Audit Matrix (despite having submitted diagnoses/being assigned HCCs on the EDGE server), the issuer or IVA Entity should provide a document identifying these enrollees. Please note that this is only required for enrollees with EDGE server HCCs for whom no Medical Records were reviewed.

The document should be captured in the "Miscellaneous Documentation" section of the IVA Audit Matrix in the Steps 1 & 2 Documentation Tab, and should contain the following:

- Unique Enrollee ID (REQUIRED)
- 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 (REQUIRED)

- Explanation of why the enrollee's Medical Record was not reviewed (OPTIONAL)
    - Example: "Unable to obtain record from provider"

The issuer will not include any other documentation for the missing Medical Records on the Intake (HS-1) & HS-2 through HS-6, HS-7a Primary Coder HCCs, or HS-7b Senior Coder HCCs Tabs.

Medical Record Indicator Number (MR #) - IVA Audit Matrix Data Element and Identifier

Documentation of Medical Records in the IVA Audit Matrix requires the assignment of a unique identifier to the record. This value, the Medical Record Indicator Number (MR #) must be a unique value for each Medical Record. For example, Medical Records for two enrollees may utilize the following numbering scheme:

- Enrollee 1 -
    - MR 1
    - MR 2
- Enrollee 2 -
    - MR 3
    - MR 4
    - MR 5

Please note that as long as the number is able to uniquely identify the MR being submitted, any number is acceptable. Only numbers should be utilized for the MR #.

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 Risk Adjustment, as defined on page 13760 of the HHS-RADV 2015 Payment Notice.

5.4.1 Medical Record Intake

The purpose of medical record intake in the health status validation process is to ensure Medical Records are submitted for the appropriate enrollee in the IVA sample and associated to claims submitted to the EDGE server or documented through source system screen shots for that enrollee. It involves a three (3)-way match between the demographics on the Medical Record, the demographics on the claim, and the demographics and enrollment data (which was previously validated in the demographic and enrollment validation process).

If discrepancies are found by the primary intake reviewer, medical record intake requires a

senior intake 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 Intake Reviewer: The primary intake reviewer verifies the enrollee's demographics data on the Medical Records, claims, within the sample to ensure that all recorded fields match. 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 wrong record. If no provider errors are identified, and discrepancies persist between the Medical Record and the enrollee, the primary intake reviewer will flag the Medical Record as an error. After review, the files marked as errors are then sent to the senior intake reviewer.

- Senior Intake Reviewer: The senior intake reviewer revalidates steps for any sampled enrollees that do not match the enrollment and demographics data. They will then compare the results from the Medical Record and claim to the demographic enrollment data. If there is a discrepancy, the senior intake reviewer will flag the enrollee as an error. The senior intake reviewer then records the validation results.

The Medical Record intake portion of the health status validation process consists of the following:

Link Medical Record to the Validated Enrollment Data (Validation HS-1A)

- Intake reviewers will review the Medical Record to validate the Medical Record is for the correct enrollee.

- Medical record information will be compared to the validated enrollee data (Section 5.3.3) by the intake reviewer, who will determine, using professional judgment, the acceptability of the Medical Record for the sampled enrollee. During this comparison, the following data elements will be documented in the IVA Audit Matrix and compared between the Medical Record and the validated enrollee data:

    - Member ID, Enrollee First Name, Enrollee Last Name, Enrollee DOB, and Enrollee Gender.

- In this process, the enrollee's Member ID, first name, last name, date of birth, and gender should reasonably match between the Medical Record and validated enrollment data based upon the IVA Entity reviewer's professional judgment. For example, one source may show the name as Michael Smith, whereas the second source may show Mike Smith – a discrepancy that would be acceptable. In the event that three or more data elements cannot be corroborated between the enrollee's validated enrollment data and the data on the medical record, the IVA Entity must perform necessary due diligence to contact 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 indicate the unmatched elements within the IVA Audit Matrix and forward to the senior intake reviewer to determine if a final error is present.

Medical Record Intake Detail – Procedures

1. The Primary Reviewer records the Member ID, first and last name, date of birth, and gender from the Medical Record in the *IVA Audit Matrix*.

2. The Primary Reviewer then compares the results from the Medical Record to the validated demographic and enrollment data captured in the demographics and enrollment validation process 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, the Primary Reviewer records the results as final in the IVA Audit Matrix and documents within the 'MR Linked by IVA Reviewer to Applicable Enrollee' field a 'Yes' response. No additional review is necessary.

    b. If there are differences, the Primary Reviewer marks the errors on the IVA Audit Matrix, and continues their review of all enrollee files assigned to the Primary Reviewer for Health Status Data Validation.

    c. Chart Request Feedback Loop

    For enrollee Medical Records for which errors 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 to step 4.a within the table.

    d. Once the Primary Reviewer completes the review of all files of sampled enrollees for the Health Status Data Validation testing, the senior review begins revalidation and review of the files marked as errors.

3. The Senior Reviewer records the Member ID, first and last name, date of birth, and gender from the Medical Record and claim separately on the *IVA Audit Matrix* for enrollees marked as errors by the Primary Reviewer.

4. The Senior Reviewer compares the results from the Medical Record to the validated demographic and enrollment data captured in the demographics and enrollment validation process to ensure that all fields recorded reasonably match.

    a. If there is agreement, and the Senior Reviewer determines using professional judgment that the fields reasonably match, the Senior Reviewer records the results as final in the *IVA Audit Matrix* and documents within the 'MR Linked by IVA Reviewer to Applicable Enrollee' field a 'Yes' response. No additional review is necessary.

    b. If there is a difference, and if the *Chart Request Feedback Loop* has been completed, the Senior Reviewer documents the errors as final in the *IVA Audit Matrix* and documents within the 'MR Linked by IVA Reviewer to Applicable Enrollee' field a 'No' response.

5.4.2 Medical Record Review and Diagnosis Abstraction

The purpose of this step in the health status validation process is to verify that the Medical Record meets HHS requirements to validate the issuer-submitted data for enrollee risk scores. Certified medical coders must verify 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.

The Primary Coder has several tasks to perform during Medical Record review and diagnosis abstraction. The Primary Coder should identify whether the Medical Record and claim designate an institutional or professional facility. This information is then utilized during the evaluation of the validity of the source and services provided. They should compare the facility type and bill type to the RA allowable list. They should also identify the type of provider credentials on the medical record and compare to the allowable list, identify International Classification of Diseases, Ninth Revision (ICD-9)/ International Classification of Diseases, Tenth Revision (ICD-10) diagnoses from the medical record, and code according to the official ICD-9/ICD-10 Coding Guidelines. The Primary Coder will need to record the results and send the enrollees with identified errors to the Senior Coder.

The Senior Coder should perform revalidation of all discrepant records by comparing the facility type and bill type to the RA allowable list, identifying the type of provider credentials from the medical record and comparing to the allowable list, and identifying the ICD-9/ICD-10 diagnosis from the medical record and code according to the official ICD-9/ICD-10 Coding Guidelines. The Senior Coder should also perform IRR on a sample of diagnoses for all Primary Coders and record the results of all revalidations.

The Senior Coder should verify the acceptable date of medical record is acceptable by verifying that the “statement covers from date” and “statement covers through date” from both the Medical Record and the claim fall within the claimed dates of service.

Next, the Medical Record source is validated against the claim by comparing the place of service on the Medical Record to the claim to determine that the chart reflects a site of service consistent with the claim bill type. The medical record source is valid if the provider is either hospital inpatient, outpatient treatment, or professional medical treatment.

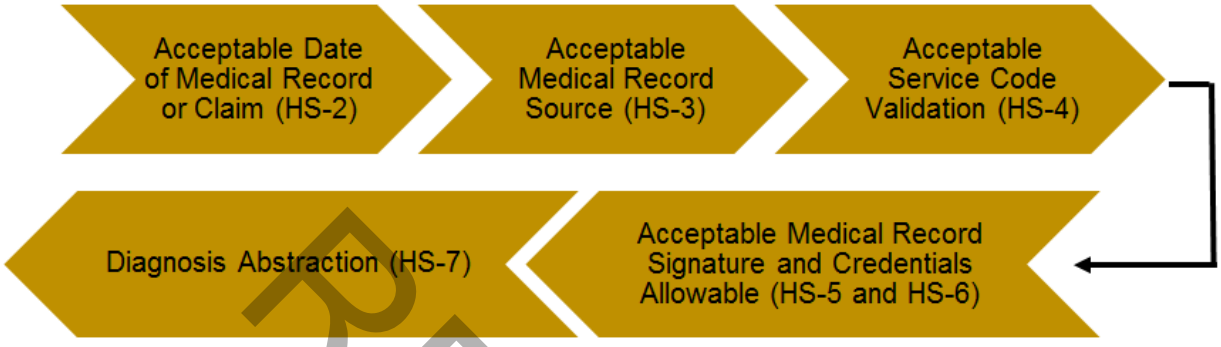
The Medical Record is then reviewed to determine if the record supports that an allowable RA service was provided. The final step is to ensure that an acceptable provider signed off on the document. A provider is defined as a physician or any qualified healthcare practitioner who is legally accountable for establishing the patient’s diagnosis. All Medical Records must have an acceptable provider signature displayed on the record or an attestation signed by the provider. Issuers and the IVA Entity should establish a process and determine the party responsible for retrieving attestations for unsigned Medical Records, or Medical Records with unallowable signatures per HHS-RADV requirements (see Validation HS-5 and Validation HS-6 for additional detail regarding allowable signatures and attestation documentation). Medical records without acceptable signatures or credentials should still be abstracted and coded (Validation HS-7).

Enrollee Medical Record review and diagnosis abstraction, also known as health status validation, consists of the following steps:

- Validate an acceptable date of medical record or claim (Validation HS-2) (Section 5.3.3);

- Validate an acceptable Medical Record Source (bill type code) (Validation HS-3) (Section 5.3.4);
- Validate an acceptable Service Code (Validation HS-4) (Section 5.3.5);
- Validate an acceptable Medical Record Signature (Validation HS-5) and Credentials Allowable (Validation HS-6) (Section 5.3.6); and
- Perform diagnosis abstraction (Validation HS-7) (Section 5.3.7).

Figure 5: Medical Record Review and Diagnosis Abstraction



5.4.3 Acceptable date of medical record or claim (Validation HS-2)

The Primary Reviewer compares the statement covers from/through (for inpatient claims, it is admission date and discharge date) on the medical record to determine if they were provided on an acceptable date. The actual date the claim is sent can be after the end of the coverage period as long as the statement covers from/through is within the coverage end dates.

The statement covers from/through defines when an enrollee received medical treatment from a physician, credentialed non-physician provider, or medical facility. For inpatient records, the reviewer should use the statement covers from/through or admission and discharge dates that are on the medical record and claim and not the dates of services. This ensures that the same dates are being used between the EDGE and the reviewers when reviewing the Medical Record and claim.

For outpatient and physician services, the from date and through date 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, such as physical therapy sessions where the from date and through date will not be the same. The IVA Entity reviewer must determine that valid RA services were provided within the statement covers from/through dates on the claim.

For inpatient services, the dates may be different from each other, and reflect the dates of admission to and discharge from a facility, due to the services being performed over multiple days. For a claim to be allowable, the date of discharge must be in the benefit year. For example, if an enrollee is admitted to a hospital in December 2014 and is discharged in January 2015, the services performed that occurred in both December 2014 and January 2015 are considered in the 2015 benefit year for calculation of enrollee risk scores for RA.

Medical Record with EDGE Coverage Start and End Dates Testing

All Medical Records submitted must have statement covers from/through that occurred within the coverage period and benefit year, and align to demographic and enrollment testing. Additionally, valid RA services must be confirmed as being provided within the statement covers from/through dates on the claim.

1. The Primary Reviewer identifies 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.

    a. The Primary Reviewer records the statement covers from (admission date) and through (discharge date) from the Primary Reviewer in the *IVA Audit Matrix*.

    b. The Primary Reviewer records the statement covers from (admission date) and through (discharge date) from the EDGE claim in the *IVA Audit Matrix*. If an EDGE claim is not found, record the data element from provided source system data and identify as an error.

    c. The Primary Reviewer reviews the claim to determine if valid RA services were provided within the statement covers from/through dates on the claim.

2. The Primary Reviewer compares the results of the medical record to the EDGE report to ensure that all fields recorded match using professional judgment.

    a. If there is agreement, the Primary Reviewer records their results as final in the *IVA Audit Matrix*. No additional review is necessary.

    b. If there is a difference, the Primary Reviewer marks the enrollee file as an error on the Form, and continues their review of all enrollee files assigned to the Primary Reviewer for Health Status Data Validation.

    c. Once the Primary Reviewer completes the review of all files of sampled enrollees for the Health Status Data Validation testing, the senior review begins revalidation and review of the files marked as errors.

3. 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 and EDGE.

4. The Senior Reviewer compares the results of the medical record to the EDGE report to ensure that all fields recorded match, using professional judgment.

    a. If there is agreement, the Senior Reviewer records their results as final in the IVA Audit Matrix. 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 from the provider error.

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 will record the results in the IVA Audit Matrix, but should NOT note a final error.

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 document the error and record the results as final in the IVA Audit Matrix.

Example of IVA Entity Senior Reviewer – Professional Judgment in Accepting Dates of Service

If a single date of service between a medical record and claim do not agree, the Senior Reviewer, using professional judgment, may determine that the discrepancy is a result of a billing error. In this example, if the Senior Reviewer determines that all facts regarding the services rendered are consistent between Medical Record and claim (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. 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.

5.4.4 Acceptable Medical Record Source (Validation HS-3)

The IVA and SVA Entities 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, the IVA and SVA Entities review the bill type code to determine if the claim is allowable. For a professional claim, the IVA and SVA Entities note that the claim is a professional claim and no additional review is necessary.

Table 6 – Allowable Bill Type Codes for Institutional Claims Table

Stay Type	Description	Bill Type Code	Allowable?
Inpatient	Short Term Hospitals	11X	Yes
	Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria)	4XX	No
	Long Term Hospitals	11X	Yes
	Rehabilitation Hospitals	11X	Yes
	Children's Hospitals	11X	Yes
	Psychiatric Hospitals	11X	Yes
	Medical Assistance Facilities/Critical Access Hospitals	85X	No
	Skilled Nursing Facilities	21X	No
	Hospital Swing Bed Components	18X	No
	Intermediate Care Facilities	15X or 16X	No
	Hospice	81X or 82X	No

Stay Type	Description	Bill Type Code	Allowable?
Outpatient	Short Term Hospitals	13X	Yes
	Medical Assistance Facilities/Critical Access Hospitals	85X	No
	Community Mental Health Facilities	76X	Yes
	Federally Qualified Health Centers	77X	Yes
	Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria)	3XX	No
	Long Term Hospitals	13X	Yes
	Rehabilitation Hospitals	74X or 75X	No
	Children's Hospitals	13X	Yes
	Psychiatric Hospitals	13X	Yes
	Rural Health Clinics	71X	Yes
	Ambulatory Surgical Centers	83X	No
	Home Health Care	33X	No
	Renal Dialysis Facilities	72X	No

Allowable Facility Type Testing

1. 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.

    b. If the type is professional, the Primary Coder does not need to consult the table, and will record a 'Yes' response in the 'MR and Claim – Valid RA Source' column of the IVA Audit Matrix, record a 'No' in the 'Errors?' column, and continues their review of all enrollee files assigned to the Primary Coder for Health Status Data Validation.

2. The Primary Coder, based on the review performed, determines if the claim is from a valid RA source, and records the result in the IVA Audit Matrix.

    a. If the claim is from a valid RA Source, the Primary Coder will record a 'Yes' response in the 'MR and Claim – Valid RA Source' column of the IVA Audit Matrix, record a 'No' in the 'Errors?' and 'Final Errors?' columns, and continues their review of all enrollee files assigned to the Primary Coder for Health Status Data Validation.

    b. If the claim is not from a valid RA Source, the Primary Coder will record a 'No' response in the 'MR and Claim – Valid RA Source' column of the IVA Audit Matrix, and records a 'No' in the 'Errors?' column, and continues their review of all enrollee files assigned to the Primary Coder for Health Status Data Validation.

    c. Once the Primary Coder completes the review of all files of sampled enrollees for the

Health Status Data Validation testing, the Senior Coder begins revalidation and review of the files marked as errors.

3. The Senior Coder identifies if institutional or professional type from the medical record and claim.

   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 a 'Yes' response in the 'MR and Claim – Valid RA Source' column of the *IVA Audit Matrix*, and records a 'No' in the 'Final Errors?' column.

4. 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 Audit Matrix*.

   a. If the claim is from a valid RA Source, the Senior Coder will record a 'Yes' response in the 'MR and Claim – Valid RA Source' column of the *IVA Audit Matrix*, and record a 'No' in the ' Final Errors?' column.

   b. If the claim is not from a valid RA Source, the Senior Coder will record a 'No' response in the 'MR and Claim – Valid RA Source' column of the *IVA Audit Matrix*, and records a 'No' in the 'Final Errors?' column.

Validating Medical Records Which do not Include Bill Type (Validation HS-3) or Service Code (Validation HS-4)

In the instance where the MR does not contain specific information or detail necessary to confirm the Health Status Validation being performed (e.g. a Service Code/Bill Type not in a MR, but on a claim form), reliance may be placed on the RADVMCE assuming that claims data validation is successful. Obtaining additional claim documentation or billing documentation is not required for Health Status Validations if this requirement (successful validation of claims data) is met. 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.

The IVA Entity would 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, a claim data file may be used for evaluation in these instances where information being validated is not present in the Medical Record. For Health Status Validations HS-3 and HS-4, procedure steps referencing the "claim" may be replaced with the RADVMCE Report reference.

KEY POINT: The use of the RADVMCE Report is contingent upon successful completion of (i.e., not failing) the Claims Data Validation process. In the event the Claims Data Validation process fails, CMS may require that original claims be validated and submitted for all Medical Records submitted as part of HHS-RADV.

5.4.5 Acceptable Service Code Validation (Validation HS-4)

The service code is validated from the medical record to ensure that the service code is acceptable per the RA business rules. The service code qualifier identifies if the code is Current Procedural Code/Healthcare Common Procedure Coding System (CPT/HCPCS). In EDGE, the

service code displays the code that was used for the procedure performed during the visit by the enrollee. Lastly, the service code modifier is a two-digit code that further helps identify the service code on a CPT/HCPCS. 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.

Please note that the purpose of Service Code Validation (HS-4) 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).

1. The Primary Coder identifies the service code qualifier, service code, and service code modifier on the medical file or claim.

2. The Primary Coder compares the results service code qualifier, service code, and service code modifier from the medical file or claim to the EDGE report.

3. The Primary Coder determines if the service provided per the analysis of the medical record or claim is a valid RA service.

    a. If the service is a valid RA service, the Primary Coder will record a 'Yes' response in the 'MR and Claim – Valid RA Service' column of the *IVA Audit Matrix*, and records a 'No' in the 'Errors?' and 'Final Errors?' columns, and continues their review of all enrollee files assigned to the Primary Coder for Health Status Data Validation.

    b. If the service is not a valid RA service, the Primary Coder will record a 'No' response in the 'MR and Claim – Valid RA Service' column of the *IVA Audit Matrix*, records a 'Yes' in the 'Errors?' and 'column, and continues their review of all enrollee files assigned to the Primary Coder for Health Status Data Validation.

    c. Once the Primary Reviewer completes the review of all files of sampled enrollees for the health status data validation testing, the senior review begins revalidation and review of the files marked as errors.

4. The Senior Coder identifies the service code qualifier, service code, and service code modifier on the medical file or claim.

5. The Senior Coder compares the results service code qualifier, service code, and service code modifier from the medical file or claim to the EDGE report.

6. The Senior Coder determines if the service provided per the analysis of the medical record or claim is a valid RA service.

    a. If the service is a valid RA service, the Senior Coder will record a 'Yes' response in the 'MR and Claim – Valid RA Service' column of the *IVA Audit Matrix*, and records a 'No' in the 'Final Errors?' column.

    b. If the service is not a valid RA service, the Senior Coder will record a 'No' response in the 'MR and Claim – Valid RA Service' column of the *IVA Audit Matrix*, and records a 'Yes' in the 'Final Errors?' column.

5.4.6 Acceptable Medical Record Signature (Validation HS-5) and Credentials Allowable (Validation HS-6)

When gathering Medical Records in support of an HCC from providers, issuers and IVA Entities must be aware of the various provider types and physician sources that are deemed as acceptable for the HHS-RADV testing.

5.4.6.1 Acceptable Medical Record Signature (Validation HS-5)

All Medical Records must have an acceptable provider signature and credentials displayed on the document or an HHS approved attestation attached to the document when submitted to the IVA Entity for validation.

Medical encounters that are recorded on a provider's documentation or attestation will be allowable. If the Medical Record is signed, but the provider's name and credentials are not furnished on the documentation, it would be unacceptable because the reviewers are unable to determine whether the beneficiary was evaluated by an acceptable provider. This type of Medical Record documentation is incomplete and unacceptable for RA and, therefore, will be counted as a RA error. The criteria for an allowable Medical Record or attestation that is signed by a provider are as follows:

Table 7: Allowable Provider Signature Types

Type	Allowable
Hand-written signature or initials, including credentials	Full Name: Mary C. Smith, MD; or Initials: MCS, MD
Electronic signature, including credentials	Requires authentication by the responsible provider (for example, but not limited to, "Approved by," "Signed by," "Electronically signed by")
Signed Attestation*, including credentials	Attestation provided on the HHS-approved template.

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

Table 8: Unacceptable Signature Types

Type	Unallowable unless…
Typed name	Authenticated by the provider as prescribed in the above table
Signature stamp, including credentials	N/A
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 name on provider's stationery as prescribed in the above table

Signature Testing

1. The Primary Coder identifies the type of signature from the Medical Record.
    a. The Primary Coder records the type of signature in the IVA Audit Matrix.
2. The Primary Coder identifies if a signature attestation is required.
    a. The Primary Coder records 'Yes' or 'No' in the 'Attestation required?' field in the IVA Audit Matrix.
    b. If yes, the Primary Coder records the Attestation Documentation File reference in the IVA Audit Matrix.
3. The Primary Coder compares the result of the signature type to the allowable list above.
    a. If it is allowable, the Primary Coder records their results as final in the *IVA Audit Matrix*, by recording a 'Yes' in the 'Signature Allowable' field and a 'No' response in the 'Error?' and 'Final Error' fields. No additional review is necessary.
    b. If it is an unallowable signature, or a required attestation was not provided, the Primary Coder marks the enrollee file as an error on the *IVA Audit Matrix* by recording a 'No' in the 'Signature Allowable' field and a Yes' in the 'Error?' field, and continues their review of all enrollee files assigned to the Primary Coder for health status data validation.

c. Once the Primary Coder completes the review of all files of sampled enrollees for the health status data validation testing, the Senior Coder begins revalidation and review of the files marked as errors.

4. The Senior Coder identifies the type of signature from the Medical Record.

   a. The Senior Coder records the type of signature in the IVA Audit Matrix.

5. The Senior Coder identifies if a signature attestation is required.

   a. The Senior Coder records 'Yes' or 'No' in the 'Attestation required?' field in the IVA Audit Matrix.

   b. If yes, the Senior Coder records the Attestation Documentation File reference in the IVA Audit Matrix.

6. The Senior Coder compares the result of the signature type to the allowable list above.

   a. If it is allowable, the Senior Coder records their results as final in the IVA Audit Matrix, by recording a 'Yes' in the 'Signature Allowable' field and a 'No' response in the 'Final Error' fields. No additional review is necessary.

   b. If it is an unallowable signature, or a required attestation was not provided, the Senior Coder marks the enrollee file as an error on the IVA Audit Matrix by recording a 'No' in the 'Signature Allowable' field and a Yes' in the 'Final Error?' field.

Medical Record Attestations

Medical record documentation is required to be generated in the course of a face-to-face or telehealth visit documented and authenticated by a permitted provider. Per HHS-RADV guidance, the method used to authenticate must be handwritten or an electronic signature, while stamp signatures are not acceptable.

HHS will also accept attestations to authenticate medical documentation that was not authenticated at time of service. Specifically, if a signature is illegible, reviewers may consider evidence in a signature log or attestation statement to determine the identity of the author of a medical record entry.

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

If a signature is missing, reviewers should accept a signature attestation from the author of the medical record entry. In order for an attestation statement to be considered valid for HHS-RADV review purposes, it must be signed, dated, and contain all requisite information per HHS-RADV Attestation acceptance guidelines.

Claims reviewers 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 individuals are in the same group, one may not sign for the other in

medical record entries or attestation statements. Table 9, Provider Contact Situations for Medical Record Attestations, summarizes the situations where signature requirements are acceptable and situations where issuers may want to contact the provider to submit an attestation statement or signature log:

Table 9 – Provider Contact Situations for Medical Record Attestations

		Signature Requirement Met	Signature Attestation May Apply
1	Legible Full signature	X	
2	Legible first Initial and Last Name	X	
3	Illegible signature over a typed or printed name.	X	
4	Illegible signature where the letterhead, addressograph or other information on the page indicates the identity of the signator. Example: An illegible signature appears on a prescription. The letterhead of the prescription lists 3 physicians' names. One of the names is circled.	X	
5	Illegible signature NOT over a typed/printed name and NOT on letterhead, but the submitted documentation is **accompanied** by: a) a signature log b) an attestation statement	X	
6	llegible Signature NOT over a typed/printed name, NOT on letterhead and the documentation is **UNaccompanied** by: a) a signature log b) an attestation statement		X
7	Initials over a typed or printed name	X	
8	Initials NOT over a typed/printed name but **accompanied** by: a) a signature log b) an attestation statement	X	
9	Initials NOT over a typed/printed name but **UNaccompanied** by: a) a signature log b) an attestation statement		X
10	Unsigned typed note with provider's typed name. Example: John Whigg, MD		X
11	Unsigned typed note without providers typed/printed name.		X
12	Unsigned handwritten note, the only entry on the page.		X
13	Unsigned handwritten note where other entries on the same page in the same handwriting are signed.	X	
14	"Signature on File"		X

In all situations listed above, the provider's credential(s) are required to fulfill the signature requirement. If the proper credential(s) are missing, an attestation is needed to fulfill the

signature requirement.

The issuer or IVA Entity should include the Medical Record Signature Attestation in the Medical Record PDF, supplied during IVA results submission. As the Medical Record Signature Attestation would then be attached within the Medical Record documentation provided, that same file name would then be reference in the "Attestation Documentation Reference" column of the IVA Audit Matrix 'Intake (HS-1) & HS-2 - HS-6' Tab.

The HIOS ID is the only issuer identifying information which needs to be included on the Medical Record Signature Attestation provided. Please do not include the issuer name on the Medical Record Signature Attestation provided.

5.4.6.2 Credentials Allowable (Validation HS-6)

Medical record documentation is required to be generated in the course of a face-to-face or telehealth visit documented and authenticated by a permitted provider. A provider means a "physician or any qualified healthcare practitioner who is legally accountable for establishing the patient's diagnosis."[12] The definition of a qualified non-physician practitioner (NPP) varies by state. In general, there are non-physician practitioners (with various specialties) including Nurse Practitioners (NP), Physician Assistants (PA), and other healthcare professionals, who may be qualified by their state to prescribe and diagnose independently or with additional information supported by a Medical Doctor (MD), Doctor of Osteopathy (DO), or a signature attesting to the diagnoses and assessment.

It is the responsibility of the issuer and IVA Entity to verify the credential is acceptable within the state the service was provided. Each state has varying acceptance surrounding licensed providers. The issuer and the IVA Entity will need to verify this information for the state associated with the Medical Record under review.

Valid Telehealth Services

For the purposes of HHS RA data submission and subsequent data validation under HHS-RADV, any service provided through telehealth that is reimbursable under the state law of the state of licensure of the issuer 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.

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 by 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

[12] ICD-9-CM Official Guidelines for Coding and Reporting, Appendix 7.2

is located.

3. Verify the diagnosis and procedure code(s) for which the telehealth service was rendered and follow all applicable coding guidelines.

The IVA Entity will utilize a medical coder with proper certification to perform the tests steps (see Section 2.6 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.

Credentials Testing

1. The Primary Coder identifies the credentials from the Medical Record.
    a. The Primary Coder records the credentials in the IVA Audit Matrix.
2. The Primary Coder compares the result of the credentials to the allowable list above (or state-specific lists if applicable).
    a. If the credential is allowable, the Primary Coder records a response of 'Yes' in the 'Credentials Allowable?' field, and a 'No' response in the 'Errors?' and 'Final Error?' fields in the IVA Audit Matrix. No additional review is necessary.
    b. If it is an unallowable credential, the Primary Coder records a response of 'No' in the 'Credentials Allowable?' field, and a 'Yes' response in the 'Errors?' field of the IVA Audit Matrix, and continues their review of all enrollee files assigned to the Primary Coder for health status data validation.
    c. Once the Primary Coder completes the review of all files of sampled enrollees for the health status data validation testing, the Senior Coder begins revalidation and review of the files marked as errors.
3. The Senior Coder identifies the credentials from the Medical Record.
    a. The Senior Coder records the credentials in the IVA Audit Matrix.
4. The Senior Coder compares the result of the credentials to the allowable list above (or state-specific lists if applicable).
    a. If it is allowable, the Senior Coder records a response of 'Yes' in the 'Credentials Allowable?' field, and a 'No' response in the 'Final Error?' field in the IVA Audit Matrix.
    b. If there is an unallowable signature, the Senior Coder records a response of 'No' in the 'Credentials Allowable?' field, and a 'Yes' response in the 'Final Error?' field in the IVA Audit Matrix.

5.4.7 Diagnosis Abstraction (Validation HS-7)

The final step in the health status validation is to review the diagnosis. 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 and determine HCCs used to calculate the enrollee's risk score.

The International Classification of Diseases-9th/10th Edition-Clinical Modification (ICD-9/10-CM) diagnosis codes are used to describe the clinical reason for a patient's treatment. The coders will use ICD-9 for Medical Records until September 30, 2015 and will use ICD-10 from October 1, 2015 onward. ICD-9/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-9/10-CM code set.

Once the ICD-9/ICD-10CM codes are substantiated from all of the enrollee's Medical Records, the codes need to be mapped to HCCs to allow for error identification versus EDGE server data. As a reference, the ICD-9/ICD-10-CM to HCC mappings can be found on the CCIIO homepage located at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-tables-1092015.xlsx, and the corresponding instructions are located at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-instructions-10-16-15.pdf.

Once the full population of HCCs has been determined for an enrollee, results will be documented within the IVA Audit Matrix. At this point, the comparison to EDGE data may begin. Please note that the determination of diagnosis codes and HCCs are to be performed in full prior to comparison to EDGE server data to determine errors.

Enrollee HCCs are then compared to enrollee level EDGE server detail report data found in the RADV Detailed Enrollee Report (RADVDE). The RADVDE 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.

For the purposes of Diagnosis Abstraction (HS-7), newly identified HCCs and unsupported HCCs will be considered errors, as they do not align with the submitted EDGE server data for the enrollee. If an error is identified by the IVA, a Senior Coder must re-perform the review.

Diagnosis Validation

1. The Primary Coder identifies the ICD-9/ICD-10 diagnoses from the Medical Record, for all of the enrollee's Medical Records.
    a. The Primary Coder records all of the ICD-9/ICD-10 diagnoses in the IVA Audit Matrix.
2. The Primary Coder maps the identified ICD-9/ICD-10 diagnoses from the Medical Records to their corresponding CCs.
    a. The Primary Coder records all of the mapped CCs in the IVA Audit Matrix.

3. The Primary Coder collates CCs for each enrollee, removes duplicate CCs identified, and documents the results in the IVA Audit Matrix.

4. The Primary Coder compares the HCCs to the EDGE report HCCs.

    a. The Primary Coder identifies supported HCCs (HCCs which are supported by the EDGE data). A supported HCC is considered an agreement.

    b. The Primary Coder identifies newly identified HCCs (HCCs which are determined as valid based on identified diagnosis codes, but which are not present in the EDGE data). Newly identified HCCs are considered a New Finding.

    c. The Primary Coder identifies unsupported HCCs (HCCs which are present in the EDGE data, but were not identified during the review of the enrollee's Medical Records). Unsupported HCCs are considered an error.

    d. The Primary Coder records the results in the IVA Audit Matrix.

5. 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 data, the Primary Coder records their results as final in the IVA Audit Matrix. No additional review is necessary.

    b. If an error or new finding is noted, either by a newly identified HCC or an unsupported HCC, the Primary Coder marks the enrollee as containing an HCC error/New finding in the IVA Audit Matrix.

    c. Once the Primary Coder completes the review, the Senior Coder begins revalidation and review of the enrollees marked as having HCC errors and new HCC findings.

6. For those enrollees for which errors or new HCC findings were identified, the Senior Coder identifies the ICD-9/ICD-10-CM diagnoses from the Primary Coder, for all of the enrollee's Medical Records.

    a. Record all of the ICD-9/ICD-10 diagnoses in the IVA Audit Matrix.

7. The Senior Coder maps the identified ICD-9/ICD-10-CM diagnoses from the Medical Records to their corresponding CCs.

    a. Record all of the mapped CCs in the IVA Audit Matrix.

8. The Senior Coder collates CCs for each enrollee, removes duplicate CCs identified, and documents the results in the IVA Audit Matrix.

9. The Senior Coder compares the HCCs to the EDGE report.

    a. The Senior Coder identifies supported HCCs (HCCs which are supported by the EDGE data). A supported HCC is considered an agreement.

    b. The Senior Coder identifies newly identified HCCs (HCCs which are determined as valid based on identified diagnosis codes, but which are not present in the EDGE

server data). Newly identified HCCs are considered a New Finding.

c. The Senior Coder identifies unsupported HCCs (HCCs which are present in the EDGE server data, but were not identified during the review of the enrollee's Medical Records). Unsupported HCCs are considered an error.

d. The Senior Coder records the results in the IVA Audit Matrix.

10. The Senior Coder documents final findings in the IVA Audit Matrix.

a. If all HCCs are supported by EDGE server data, the Senior Coder marks the enrollee as containing no HCC errors and records their results as final in the IVA Audit Matrix.

b. If an HCC is unsupported, the Senior Coder marks the enrollee as containing an HCC error and records their results as final in the IVA Audit Matrix.

c. If a new finding is noted from a newly identified HCC, the Senior Coder marks the enrollee as containing a 'New Finding' and records their results as final in the IVA Audit Matrix.

For all health status and diagnosis validations performed over sampled enrollees, Primary Coders and Senior Coders are required to work in tandem to validate and review errors identified, and to complete IRR (Section 6). As stated previously, the IVA Entity must have at least two (2) coders to perform medical record reviews, with at least one Senior Coder having three (3) years of experience for the first year of HHS-RADV and five (5) years for years 2016 and beyond. The Primary Coder does not have specific experience requirements, and a Senior Coder may act as the Primary Coder during the review process. However, 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 performing to the IRR rate, as with all Primary Coders (Section 6).

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

Errors with Positive Risk Score Impact

If an issuer or an IVA Entity discovers a diagnosis code during the IVA that was not reported to the EDGE server and a new HCC is validated, the comparison of HCCs identified by the IVA Entity to EDGE HCCs will result in an error. However, that error has the potential to result in a positive impact to the issuer.

While discovery of a new HCC is technically an error, HCCs discovered during the IVA may count as a positive error and have a positive impact for the issuer. During the pilot year of HHS-RADV, CMS will not adjust payments. However, HCCs discovered during the audit in subsequent years potentially may have a positive impact to both risk scores and payment transfers.

Addressing HCC Errors and Additional Medical Record Chart Requests

During comparison of HCCs abstracted during the IVA process to HCCs on the RADVDE Report, errors may be identified which indicate that additional records are required 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 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 and adjudicated claim on the RADVMCE Report or a Non-EDGE Claim from the issuer's source system for the 2015 Pilot year of 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 EDGE HCCs.

6 Inter-Rater Reliability

6.1 Purpose

This section provides the sampling approach, detailed procedures, and reporting requirements for IRR determinations over the diagnosis validation performed in Section 5.4.7. The purpose of IRR is to determine the accuracy of the abstraction of diagnostic codes by the primary coders when compared to the Senior Coders. This process measures the consistency between coders using the HCC through abstraction of ICD-9/ICD-10-CM by two or more coders evaluating the same Medical Records.

The coders consist of a Primary Coder and a Senior Coder as listed in Section 1.3.6, Coders. The Senior Coders will re-perform the Primary Coders' diagnosis validation as a quality control to ensure consistency and agreement in the application of medical coding requirements. IRR determinations provide confidence to HHS and issuers that the IVA and SVA Entity coders accurately performed the diagnosis validation. This process is completed by selecting a sample of Medical Records reviewed by the Primary Coder and having those files re-reviewed by a Senior Coder and then comparing the results of the reviews.

For additional information on the IRR submission process, please refer to the IVA Comprehensive User Guide. The IRR Report Template is located within the Audit Tool File Library.

6.2 IRR Sampling Methodology Analysis and Sample Selection

IVA Entities are not required to have all Medical Records reviewed by a Senior Coder and can use the sampling methodology below to meet the IRR requirement. This section outlines the methodology for the approach and the process for the selection of the sample for IRR by the IVA Entity. The sample sizes, as seen in Tables 10 and 11, were determined based on estimates of the size of the population of HCCs reviewed across issuers by a single Primary Coder.

6.2.1 Confidence Level

The confidence level is a threshold that is used to measure the reliability of a result. It also refers to the percentage of all possible samples that can be expected to include the true population parameters. The sample sizes calculated must use at least a 63 percent confidence level. Issuers may elect to have their IVA Entities apply a higher confidence level. It is important to note that the sample sizes outlined in Tables 10 and 11 are based on a 63 percent confidence level. Larger sample sizes could be used if issuers elect to apply a higher confidence level or a higher accuracy rate.

6.2.2 Required Accuracy Rate

The required accuracy rate is the rate at which a Senior Coder's results of HCCs match the results of a Primary Coder. The Primary Coder is required to reach an accuracy rate of 85 percent (without rounding) for benefit year 2015 HHS-RADV and 95 percent for Benefit Year 2016 and beyond. If the accuracy rate falls below these required targets, either additional Medical Records must be sampled until the required accuracy rate is met or all Medical Records need to be reviewed by a Senior Coder if the required sample size exceeds the remaining un-

sampled records in the population (i.e., a census, or 100 percent review must be performed).

6.2.3 Sampled Population

The sampled population is made up of Medical Records and their associated HCCs that were reviewed by a Primary Coder where no errors were found by the Primary Coder in the diagnosis validation in Section 5.3.7. Medical Records and their associated HCCs that were noted as having errors when compared to the EDGE server by the Primary Coder during testing in Section 5.3.7 will not be used for the Primary Coder's population of Medical Records eligible for IRR. These will still require Senior Coder review as outlined in Section 5.3.7. Any Medical Records that were submitted to the EDGE where there was not a diagnosis will not be included in the population for IRR. The final step after selecting Medical Records for the IRR pool for each Primary Coder is counting the number of HCCs on each Medical Record by the IVA Entity for use in sample selection.

Note: 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.

6.2.4 Sample Selection

This section outlines the definition of the population, the sample size, and adjustments to the sample size to meet the required accuracy rate. Sample sizes must be defined for each Primary Coder and may potentially increase based on the number of differences identified in the diagnosis coding by the Senior Coder. A deviation occurs when the Senior Coder identifies:

- No HCC when a Primary Coder identified an HCC;
- An HCC that was not identified by the Primary Coder; or
- An HCC that was different than the HCC identified by a Primary Coder.

The IVA and SVA Entities obtain the Medical Records for all enrollees that matched the EDGE for each Primary Coder, i.e., clean files. The IVA and SVA Entities then determine the initial sample size of HCCs across issuers for each Primary Coder depending on the benefit year, since benefit year 2015 has lower accuracy rate thresholds, and is expected to have smaller initial sample sizes than benefit years 2016 and beyond.

The various sample sizes for IRR validation allow the auditor to determine the number of acceptable deviations at each given sample size. For example, under the 63 percent confidence/85 percent required accuracy rate scenario, a sample size of 28 HCCs would allow for 3 acceptable deviations to conclude that the required accuracy rate is at least 85 percent, with 63 percent confidence.

To select the sample, the IVA and SVA Entities:

- Compile a list of the clean files/completed Medical Records by Primary Coder across all issuers;
- Perform a count function for the number of HCCs that are present on each Medical Record;

- Count all of the HCCs identified by the coder, as this count helps determine which sampling table to use;

- Use a random number generator to assign random numbers to each Medical Record subject to sample selection;

- Sort the Medical Records by the random number from smallest to largest; and

- Select the necessary number of Medical Records from smallest to largest random number and selects the necessary number of Medical Records with HCCs until the sample size is obtained; if the number of HCCs in the last Medical Record selected is greater than the number of HCCs left to be reviewed, the Senior Coder uses that Medical Record and abstracts all the HCCs from the last Medical Record; conversely, if the number of HCCs required for the sample size is larger than the remaining number of HCCs on the Medical Records for the Primary Coder, the IVA Entity selects all Medical Records for the Primary Reviewer for sampling.

The IVA and SVA Entities should ensure that the person selecting the sample is not the primary or Senior Coder. The Primary Coder cannot select the sample since their work is being validated. The Senior Coder cannot select the sample because the IRR review is a blind review and, therefore, the Senior Coder cannot know the results of the Primary Coder until after the review of the sample is complete.

If three or less deviations between the Senior Coder and Primary Coder are found on the initial 28 HCC IRR sample, the Primary Coder has met the required accuracy rate and no additional files need to be reviewed (see Tables 10 and 11). However, if the Senior Coder noted four deviations in the sample of 28 HCCs, the Senior Coder would select additional Medical Record files including 7 HCCs, resulting in a new sample total of 35 HCCs. If additional deviations are noted, the Senior Coder continues to select larger samples based upon the number of deviations until the Primary Coder meets the required accuracy rate (that is, by obtaining less than or equal to the acceptable number of deviations for the sample size, or until the Senior Coder has reviewed all Medical Records of the Primary Coder if the acceptable number of deviations has not been met).

Tables 10 and 11 detail the acceptable number of deviations for each sample size. **The table to be used when determining an IVA Entity coder's IRR sample size is dependent upon the number of HCCs identified by the Primary Coder across issuers.** The Senior Coder should start with the smallest sample size and increase the sample based upon the number of deviations noted within the Primary Coder's results. Table 10 includes the sample sizes of HCCs and acceptable number of deviations for coders with **less than 1,000 HCCs** identified in benefit year 2015.

Table 11 includes the sample sizes of HCCs and acceptable number of deviations for coders with **1,000 or more HCCs** identified in benefit year 2015. As the sample sizes increase, the sample is inclusive of the sample taken before it. For example, the sample of 35 includes the initial sample of 28 that was already sampled, thus the Senior Coder will select medical files accounting for an additional 7 HCCs if four deviations are noted. The same process applies for additional deviations noted as outlined in Tables 10 and 11.

Table 10: IRR Sample Sizes and Acceptable Number of Errors (Benefit Year 2015) for Coders with Less Than 1,000 HCCs Identified

Confidence Level – 63% Required Accuracy Rate – 85%			
Sample Size (# HCCs)	**Acceptable Number of Deviations**	**Sample Size**	**Acceptable Number of Deviations**
28	3	130	18
35	4	136	19
42	5	143	20
49	6	149	21
56	7	156	22
63	8	163	23
69	9	169	24
76	10	176	25
83	11	182	26
90	12	188	27
96	13	195	28
103	14	201	29
110	15	208	30
116	16	214	31
123	17		

Table 11: IRR Sample Sizes and Acceptable Number of Errors (Benefit Year 2015) for Coders with 1,000 or More HCCs Identified

Confidence Level – 63% Required Accuracy Rate – 85%			
Sample Size (# HCCs)	**Acceptable Number of Deviations**	**Sample Size**	**Acceptable Number of Deviations**
28	3	133	18
35	4	140	19
43	5	146	20
50	6	153	21
57	7	160	22
64	8	167	23
71	9	174	24
77	10	181	25
84	11	187	26
91	12	194	27
98	13	201	28
105	14	208	29
112	15	215	30
119	16	222	31
126	17		

6.3 IRR Process Steps

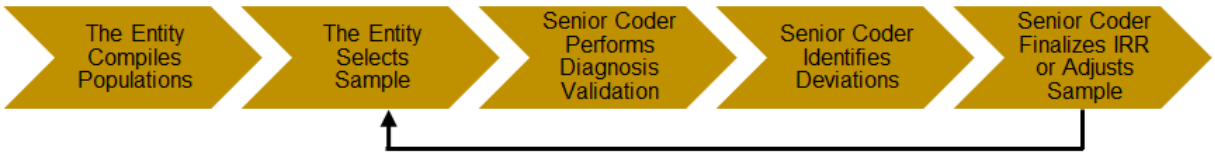


Figure 6: IRR Process Steps

Figure 6 contains the five main steps of the IRR process, which are described below. The steps are linear with a feedback loop based on the number of deviations.

1. **The IVA and SVA Entities Compile Populations:** The IVA and SVA Entities compile all Medical Records for each Primary Coder separately as outlined in section 6.2.4. The IVA and SVA Entities use the population of HCCs for each Primary Coder to determine the samples for each Primary Coder in Step 2.

2. **The IVA and SVA Entities Select Sample:** The IVA and SVA Entities take an initial sample of Medical Records, totaling 28 HCCs for Benefit Year 2015. If the total pool of HCCs for a Primary Coder is less than the initial minimum sample size required, the IVA and SVA Entities select all of the Primary Coder's records for Senior Coder review. The IVA and SVA Entities randomly select the 28 HHC sample for each Primary Coder based upon their populations as outlined in section 6.2.4. The IVA and SVA Entities record the Medical Records, HIOS ID, and count of associated HCCs sampled for IRR in the IRR Results Template.

3. **Senior Coder Performs Diagnosis Validation:** The Senior Coder performs the diagnosis coding for each Medical Record in the sample as outlined in Section 5.4.7. This includes abstracting ICD 9/ICD 10 code(s) and mapping to HCC(s) (as outlined in Section 5.4.7, Diagnosis Validation). The Senior Coder reports the diagnosis codes and HCCs on the IRR Results Template. Once the Senior Coder performs the diagnosis validation for IRR, any deviations from the Primary Coder's results are identified and additional sample taken as needed in the next step.

4. **Senior Coder Identifies Deviations:** The Senior Coder identifies and documents all deviations between the Senior Coder's HCCs and the Primary Coder's HCCs in the IRR Results Template. The number of deviations is used to determine if the IRR threshold is met or if an additional sample is needed.

5. **Senior Coder Finalizes IRR or Adjusts Sample:** If three or less deviations are noted, the Senior Coder has completed the review and records the results in the IRR Results Template. If four or more deviations are noted, the Senior Coder reviews either Table 10 or 11 to adjust the sample size based upon the number of deviations identified and the total number of HCCs identified by the Primary Coder, and then performs steps 2 through 5 for the adjusted sample size. In the event the sample size is larger than the remaining population, the Senior Coder reviews all remaining Medical Records and claims.

6.4 IRR Scenarios

This section outlines example scenarios for a Senior Coder's determination of populations, deviations, and adjusted sample sizes. The scenarios are based on the following assumptions:

1. The scenarios apply to a cover with under 1,000 total HCCs identified in the 2015 benefit year (Table 10).

2. Each Medical Record only has one HCC associated with it (in practice, a Medical Record can have more than one HCC).

3. The number of deviations found is only shown for the initial random sample of 28. The column titled "Additional Senior Level Review Sample Due to Deviations" in Table 12 below contains only the files to be selected in addition to the initial 28 that were already re-reviewed by the Senior Reviewer.

4. No additional deviations were noted during the additional sample review (Table 13); therefore, the sample sizes did not need to be increased further.

Table 12: Initial IRR Sample

Primary Coder's Results	Senior Coder's Results							
Scenario	HCCs Correctly Matched to EDGE	Initial Sample Size (# HCCs)	HCCs Identified	HCCs Correctly Matched to Primary Coder	New HCCs Identified	Total Deviations	Additional Senior Level Review Sample Due to Deviations	Total Sample Based Upon Initial Sample Deviations
1	45	28	28	28	0	0	0	28
2	45	28	30	27	3	4	7	35
3	32	28	29	26	3	5	4	32

Table 13: Additional IRR Sample

Senior Coder's Result for Additional Sample							
Scenario	Additional Sample Size	HCCs Identified	HCCs Correctly Matched to Primary Coder	New HCCs Identified	Total Deviations for Additional Sample	Additional Senior Level Review Sample Due to Deviations	Total Sample Based upon Additional Sample Deviations
1	0	0	0	0	0	0	28
2	7	7	7	0	0	0	35
3	4	4	4	0	0	0	32

Scenario 1 – This scenario assumes that Medical Records accounting for 45 HCCs matched the EDGE. The Senior Coder selects an initial sample size representing 28 HCCs out of the 45. The initial sample is selected randomly from the population of Medical Records until 28 HCCs are found. The Senior Coder abstracts ICD-9/ICD-10-CM codes from the Medical Records and matches them to HCCs. In this scenario, the Senior Coder matched all 28 HCCs to the Primary Coders HCCs with no deviations or new HCCs found; therefore, the Senior Coder would not have to increase the sample size and would document the results in the *IRR Results Template*.

Scenario 2 – This scenario assumes that Medical Records accounting for 45 HCCs matched the EDGE. The Senior Coder selects an initial sample size of Medical Records accounting for 28 HCCs. The initial sample is selected randomly from the population of Medical Records accounting for 45 HCCs. The Senior Coder abstracts ICD-9/ICD-10-CM codes from the Medical Records and matches them to HCCs. In this scenario, the Senior Coder only matched 27 of the HCCs and found three (3) additional HCCs that were not identified by the Primary Coder. Therefore, the Senior Coder would document a total of four (4) deviations between the Primary Coder and Senior Coder. Next, the Senior Coder increases their sample size by seven (7) HCCs for a total of 35 HCCs to test, which includes the initial 28 HCCs. The Senior Coder performs the same review on the additional seven (7) HCCs. If additional deviations are found, the sample size would continue to be increased until no additional deviations are noted. However, in this scenario, for the additional seven (7) HCCs sampled, the Senior Coder found no additional deviations. So the final sample size was 35 HCCs. The Senior Coder would document all results in the *IRR Results Template*.

Scenario 3 – This scenario assumes that Medical Records accounting for 32 HCCs matched the EDGE. The Senior Coder selects an initial sample size of 28 out of the 32 HCCs that matched the EDGE. The initial sample is selected randomly from the population of Medical Records representing 32 HCCs. The Senior Coder abstracts ICD-9/ICD-10-CM codes from the Medical Records and matches them to the HCCs. In this scenario, the Senior Coder only matched 26 of the HCCs found by the Primary Coder and found three (3) additional HCCs that were not identified by the Primary Coder. Therefore, the Senior Coder would document a total of five (5) deviations between the Primary Coder and Senior Coder. Since the Senior Coder found more than three (3) deviations in HCCs, the Senior Coder will need to increase the sample size. However, since the total number of HCCs in the population is less than the sample size required for the number of deviations, the Senior Coder must review the balance of the records in the population. In, in this case, the Senior Coder would have to increase the sample size by four (4) HCCs for a total of 32 HCCs to test, which includes the initial 28 HCCs. The Senior Coder performs the same review on the additional four (4) HCCs, and if additional deviations are identified, the deviations would be documented and the review would be completed. At the end, the Senior Coder found five (5) deviations in total, which would normally trigger the review of 14 additional HCCs; however, since the Primary Coder had a total population of only 32 HCCs, the Senior Coder's review is limited to the 32 HCCs. The Senior Coder would document all results in the *IRR Results Template*.

7 Appendices

7.1 CEO IVA Attestation Form

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

HHS-RADV Initial Validation Audit (IVA) Entity Attestation

I certify that my organization's Initial Validation Audit (IVA) entity(ies) for the 2015 benefit year, to the best of my knowledge and belief, is in compliance with the requirements set forth in 45 CFR 153.630(b). If my organization becomes aware of any compliance issues, CMS will be promptly informed via email at: ACA-HHS-RADV-Support@acumenllc.com.

I have reviewed the IVA Entity requirements and I certify that our organization is in compliance with the following:

1. **Ensure IVA Entity is Reasonably Capable of Performing Risk Adjustment Data Validation and has Certified Medical Coders 45 CFR 153.630(b)(2), and (b)(5)-(8):**

   i. The designated IVA Entity is reasonably capable of the performing risk adjustment data validation in accordance with HHS defined audit standards under 45 CFR 153.630(b)(2) and (b)(5)-(8), and in accordance with HHS-RADV data validation audit protocols.

   ii. 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 American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (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.

   iii. 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,[1] IVA Entity is not excluded from Medicare or Medicaid and IVA Entity is not the Issuer's Third-Party Administrator (TPA):[2]

i. The designated IVA Entity 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 conflict of interest and they have obtained equivalent representation from the IVA Entity regarding conflicts of interest.

ii. 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 Office of the Inspector General (OIG) exclusion list, or are under investigation with respect to any HHS program.

iii. 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 serve in any capacity as an advisor to our issuer organization regarding the initial validation audit. Additionally, the nominated IVA Entity is not this issuer's third party administrator (TPA).

[1] Criteria for assessing conflicts of interest between the issuer and the Initial Validation Audit (IVA) Entity consist of the following standards as published in the HHS Notice of Benefit and Payment Parameters for 2015 (79 FR 13758).

- 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 initial validation auditor, such that the financial success of the initial validation auditor 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 initial validation auditor;
- Neither the initial validation auditor 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 initial validation auditor or management team or audit 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 initial validation auditor 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;
- Members of the data validation audit team of the initial validation auditor may not be married to, in a domestic partnership with, or otherwise be in the same immediate family as an owner, director, officer, or employee of the issuer; and
- The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a State, or serve in any capacity as an advisor to the

issuer regarding the initial validation audit.

[2] A TPA may not also be the issuer's designated IVA Entity for purposes of the HHS-RADV process. The TPA, with respect a self-insured group health plan, an entity that is not under common ownership or control with the self- insured group health plan or its plan sponsor that provides the specified core administrate services (i.e. claims processing or adjudication, including the management or internal appeals, or plan enrollment).

3. Ensure Performance of HHS-RADV Audit [45 CFR 153.630(b)(1), (2), and (4)]

i. The issuer of a risk adjustment covered plan engages one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS.

ii. The issuer ensures that the IVA Entity auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit and ensures that the audit is so performed.

iii. The issuer ensures validation of the accuracy of the risk adjustment data for a sample of enrollees selected by HHS.

iv. The issuer ensures that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

RETIRED

My attestation is on behalf of Insurance Company Name **for the following HIOS ID(s):**

HIOS ID NO.	IVA ENTITY NAME	IVA ENTITY TIN	DATE MODIFIED

I further certify that I am authorized to legally and financially bind my organization.

Signature

Name

Title

Phone Number

Email

Date

7.2 ICD-9 Official Guidelines for Coding and Reporting

See CDC.org for the latest ICD-9 guidelines:
https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf

7.3 ICD-10 Official Guidelines for Coding and Reporting

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

7.4 EDGE Example Reports

See Regtap.info for latest EDGE outbound reports:
https://www.regtap.info/uploads/library/DDC_XMLXSD_OutboundFiles_5CR_062816.zip