



**Centers for Medicare & Medicaid Services**

**U.S. Department of Health and Human Services**

**Center for Consumer Information and Insurance Oversight**

**2018 Benefit Year Protocols  
PPACA HHS Risk Adjustment  
Data Validation**

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# Preface

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

- EDGE Server Business Rules (ESBR) Version 12.0 (3/25/19)
- EDGE Server XML and XSD Zip File Contents Job Aid (2/21/19)
- Risk Adjustment and Reinsurance (RARI) - Interface Control Document Addendum Version 05.00.23 (3/1/19)
- Job Aid for Validation of RADVPS Reports (5/23/19)
- Job Aid for Validation of RADVPSF Report (5/23/19)
- Job Aid for Validation of RADVIVAS Reports (5/23/19)

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<sup>1</sup> For the 2018 benefit year, no state elected to operate its own RA program. Therefore, HHS operates RA in all states and the District of Columbia.

**Section 1**  
**HHS Risk Adjustment Data Validation Protocols**  
**Overview**

# 1. Overview

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## 1.1 Purpose

The Risk Adjustment (RA) program is a premium stabilization program established by the Patient Protection and Affordable Care Act (PPACA). The overall goal of RA is to eliminate premium differences among plans based solely on favorable or unfavorable risk selection in the individual and Small Group Markets, both inside and outside of the Exchange(s). RA accomplishes this by transferring funds from issuers with lower risk enrollees to issuers with higher risk enrollees.

To ensure the integrity of the RA program and to validate the accuracy of data submitted by issuers to the EDGE servers for use in RA calculations, the Centers for Medicare & Medicaid Services (CMS) will perform HHS-RADV for each benefit year on behalf of any state that chooses not to implement its own state-operated RA program. HHS-RADV also ensures that issuers' actual actuarial risk is reflected in transfers and that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuer with plans with higher-than-average actuarial risk.

HHS-RADV is a six (6) step process:

1. CMS selects a sample of an issuer's enrollee records for audit.
2. Each issuer selects an IVA Entity to validate the demographic and enrollment (D&E) data, Prescription Drug Categories (RXC) data, and health status data submitted on the issuer's EDGE server for the selected sample enrollees.
3. A Second Validation Audit (SVA) is performed on a subsample of IVA Entity submission data to verify the accuracy of the IVA findings.
4. CMS performs Error Estimation and calculates issuer risk score error rates using the failure rate for each HCC across all issuers' IVA samples (or SVA samples, as applicable).
5. CMS administers the SVA Findings Attestation and Discrepancy Reporting Process, the Error Rate Attestation and Discrepancy Reporting Process, and an Administrative Appeals Process.
6. Final results are used to adjust RA risk scores and the transfers.

The six (6) step process of HHS-RADV is discussed in the following sections.

This document defines Protocols and guidance for the HHS-RADV process, outlines participant roles and responsibilities, and defines activity timelines. Issuers, IVA and SVA Entities are required to be familiar with, and adhere to, all statutes, regulations and guidance governing the HHS-RADV process, including these Protocols.

CMS will also offer guidance and information through HHS-RADV webinars and published materials. To view HHS-RADV webinars and other guidance information, issuers and IVA Entities are encouraged to sign up for access to the REGTAP Library at:

[https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php).

CMS will communicate all updates and amendments to these Protocols as they become available. Issuers and IVA Entities with inquiries related to the HHS-RADV program can email CMS at: [CCIIOACARADDataValidation@cms.hhs.gov](mailto:CCIIOACARADDataValidation@cms.hhs.gov). This e-mail address will be utilized for all HHS-RADV communications regarding HHS-RADV policies and operations (excluding charges and payments). Users who submit inquiries to this email address will receive an auto-generated confirmation message upon submission with an assigned case number.

This guidance is effective as of the publication date and is specific to 2018 benefit year HHS-RADV.

## 1.2 Regulatory Requirements

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

- *Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Final Rule*, 77 FR 17220 (March 23, 2012);
- *HHS Notice of Benefit and Payment Parameters for 2014 Final Rule*, 78 FR 15410 (March 11, 2013);
- *HHS PPACA Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 Part II, Final Rule*, 78 FR 65046 (October 30, 2013);
- *HHS Notice of Benefit and Payment Parameters for 2015 Final Rule (2015 Payment Notice)*, 79 FR 13744 (March 11, 2014);
- *HHS Notice of Benefit and Payment Parameters for 2016 Final Rule*, 80 FR 10749 (Feb. 27, 2015);
- *HHS Notice of Benefit and Payment Parameters for 2017 Final Rule*, 81 FR 12203 (March 8, 2016);
- *HHS Notice of Benefit and Payment Parameters for 2018 Final Rule*, 81 FR 94056 (Dec. 22, 2016);
- *HHS Notice of Benefit and Payment Parameters for 2019 Final Rule (2019 Payment Notice)*, 83 FR 16930 (April 17, 2018); and
- *HHS Notice of Benefit and Payment Parameters for 2020 Final Rule (2020 Payment Notice)*, 84 FR 17454 (April 25, 2019).

To ensure compliance with all regulatory requirements, issuers should be familiar with the regulations found in 45 C.F.R. Part 153 Subparts A, D, G and H.

The regulations governing the process by which an issuer may appeal the findings of the SVA or risk score error rate calculation, can be found at 45 C.F.R. § 156.1220.<sup>2</sup>

## 1.3 External Data Gathering Environment

It is important for issuers and their IVA Entities to understand the ESBR and to understand the data in the HHS-RADV sampling reports. The following resource documents are available in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)):

- EDGE Server Business Rules (ESBR) Version 12.0 (3/25/19)
- EDGE Server XML and XSD Zip File Contents Job Aid (2/21/19)
- Risk Adjustment and Reinsurance (RARI) - Interface Control Document Addendum Version 05.00.23 (3/1/19)
- Job Aid for Validation of RADVPS Reports (5/23/19)
- Job Aid for Validation of RADVPSF Report (5/23/19)
- Job Aid for Validation of RADVIVAS Reports (5/23/19)

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<sup>2</sup> Issuers cannot appeal the results of the IVA as the IVA entity is under contract with the issuer and HHS does not produce the IVA results. See 81 FR 94056 at 94106.

## 1.4 Record Retention Policy

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

## 1.5 Securing Protected Health Information

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

CMS will delete any and all PHI or PII information that is transmitted directly to CMS by issuers, IVA Entities, or providers outside of the secure IVA submission process within the HHS-RADV Audit Tool, including any PHI or PII communicated via email or regarding sampling reports.

## 1.6 HHS-RADV Participation

An RA covered plan is defined as any health insurance coverage offered in the individual or Small Group Markets, both inside and outside the Exchanges, with the exception of:

- Grandfathered health plans,
- Excepted benefit health insurance coverage described in 45 C.F.R. § 146.145(b)<sup>3</sup> and § 148.220, and
- Any plan determined not to be a RA covered plan under the applicable federally certified RA methodology.

Issuers of RA covered plans, as defined in 45 C.F.R. § 153.20, must submit all required RA data in accordance with procedures as outlined in this document.

### 1.6.1 Exemption from HHS-RADV

Issuers that do not meet one of the exemptions set forth below are required to comply with the 2018 benefit year HHS-RADV requirements.

Starting with 2018 benefit year HHS-RADV, CMS created a new HHS-RADV Issuer Exemption and DDVC Web Form which must be completed by all issuers meeting one of the exemptions set forth below or who wish to request a default data validation charge (DDVC). CMS will identify issuers meeting certain exemptions and will communicate that exemption status to issuers for the benefit year. Issuers are required to review the CMS-identified exemption reason(s) and confirm exemption from participation in the 2018 benefit year HHS-RADV audit for the specified Health Insurance Oversight System Identification (HIOS ID)(s) within the HHS-RADV Issuer Exemption

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<sup>3</sup> The 2020 Payment Notice updated this citation (from § 146.145(c)) in the definition of RA covered plan under 45 C.F.R. § 153.20. The amendment is effective June 24, 2019. See 80 FR 17454.

and DDVC Web Form. CMS will provide directions and the web form location to issuers following the determination of exemption status at the start of each HHS-RADV cycle (in May, around the receipt of IVA samples). Issuers can also request an exemption based on liquidation status or request a DDVC through this web form.

An issuer of a RA covered plan will be exempted from HHS-RADV requirements set forth in 45 C.F.R. § 153.630(b) for a given benefit year if the issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a statewide basis. These issuers **are not** subject to annual random (and targeted) sampling. The determination of whether an issuer has 500 or fewer billable member months statewide is calculated by combining the issuer's enrollment in all risk pools in a state in a benefit year. (See 45 C.F.R. § 153.630(g)(1)<sup>4</sup>).

An issuer of a RA covered plan will be exempted from the HHS-RADV requirements set forth in 45 C.F.R. § 153.630(b) for a given benefit year if the issuer is at or below the materiality threshold as defined by HHS and is not selected by HHS to participate in HHS-RADV in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits). Until otherwise amended through rulemaking, HHS defined the materiality threshold as total annual premiums at or below \$15 million, based on the premiums of benefit year being validated, calculated on a statewide basis. The determination of whether an issuer has \$15 million or fewer in total annual statewide premiums is calculated by combining the issuer's total premiums in all applicable risk pools (individual, small group or merged markets) in a state in a benefit year. (See 45 C.F.R. § 153.630(g)(2)<sup>5</sup>).

An issuer of a RA covered plan will be exempted from the HHS-RADV requirements set forth in 45 C.F.R. § 153.630(b) for a given benefit year if the issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that the issuer provides to HHS an attestation to that effect that is signed by an individual with the authority to legally and financially bind the issuer. This exemption will not apply to an issuer that was a positive error rate outlier under the Error Estimation methodology in HHS-RADV for the prior benefit year of HHS-RADV. For purposes of this exemption, "liquidation" means that a state court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest. Therefore, to qualify for this exemption for the 2018 benefit year, the issuer must enter liquidation by April 30, 2020 and must not have been a positive error rate outlier in 2017 benefit year HHS-RADV. (See 45 C.F.R. § 153.630(g)(3)<sup>6</sup>).

An issuer receiving a default risk adjustment charge (RADDC) pursuant to 45 C.F.R. § 153.740(b) as a result of insufficient EDGE data is exempt for the applicable benefit year from the requirements of HHS-RADV in the state market risk pools for which the issuer is receiving a RADDC.

A sole issuer in a state market risk pool in a benefit year is not required to conduct HHS-RADV for that state market risk pool because there are no RA transfers; however, if the sole issuer participates in multiple risk pools in the state during that benefit year where it is not the sole issuer, it would be subject to HHS-RADV for those risk pools where RA transfers are occurring with other issuers.

Lastly, as finalized in the 2020 Payment Notice<sup>7</sup>, a small group market issuer with off-calendar year coverage who exits the market in a state but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run-out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold) would be considered an exiting issuer and would also be exempt from HHS-RADV for the benefit year with the carry-over coverage. That is, small

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<sup>4</sup> This regulation is effective June 24, 2019. See the 2020 Payment Notice, 84 FR 17454.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

<sup>7</sup> See 84 FR at 17503.

group only issuers with off-calendar coverage years beginning in the 2017 benefit year with no new coverage being offered in the 2018 benefit year would not be subject to 2018 benefit year HHS-RADV requirements. Individual market issuers offering or selling any new individual market coverage in the subsequent benefit year would be subject to HHS-RADV, unless another exemption applied.

An issuer who qualifies for one (1) of the above exemptions, receives a RADC, is the sole issuer in a state market risk pool, or is a small group existing issuer with non-calendar year coverage is not subject to enforcement action for noncompliance with HHS-RADV requirements, nor will the issuer be assessed a DDVC under 45 C.F.R. §153.630(b)(10) for the applicable benefit year.

**Section 2**  
**HHS Risk Adjustment Data Validation Protocols**  
**Noncompliance Activities and Penalties**

## **2. Noncompliance Activities and Penalties**

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### **2.1 Noncompliance Activities**

Consistent with 45 C.F.R. § 153.630(a), issuers of RA covered plans in states where HHS operates RA must comply with HHS-RADV requirements. Issuers, IVA Entities, and the SVA Entity are required to conform to the criteria set forth in the applicable regulations and HHS-RADV operational guidance. The failure of an issuer to adhere to these criteria may result in enforcement actions related to noncompliance with HHS-RADV requirements. CMS will provide oversight over the HHS-RADV process and may take enforcement actions in cases where issuers and/or their IVA Entity are not following these requirements.

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

- Issuer Did Not Register for the Audit Tool – (Section 2.1.1); 45 C.F.R. § 153.630(a)
- Issuer Did Not Engage an IVA Entity or the Designated IVA Entity is Not Capable of Performing the Audit – (Section 2.1.2); 45 C.F.R. § 153.630(b)(2)
- IVA Entity Not Free of Conflict of Interest, or Not in Good Standing – (Section 2.1.3); 45 C.F.R. § 153.630(b)(3) and (5)
- Incomplete Audit Results Submissions – (Section 2.1.4); 45 C.F.R. § 153.630(f)
- Supporting Documentation Not Provided to IVA Entity or SVA Entity – (Section 2.1.5); 45 C.F.R. § 153.630(b)(6)
- Suspected Fraud in Submitted Data, and Follow-Up Actions – (Section 2.1.6); 45 C.F.R. § 156.630(b)(4)

#### **2.1.1 Issuer Did Not Register for the Audit Tool**

Issuers are required to register in the Audit Tool to perform HHS-RADV required activities. If an issuer does not register, the issuer is non-compliant with HHS-RADV. For additional Audit Tool guidance, refer to Section 5 (Audit Tool Overview).

#### **2.1.2 Issuer Did Not Engage an IVA Entity or the Designated IVA Entity is Not Capable of Performing the Audit**

According to 45 C.F.R. § 153.630(b)(2), the issuer must ensure that the IVA Entity is reasonably capable of performing an IVA audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed. The issuer is required to engage and designate an IVA Entity to perform the IVA for each HIOS ID for which it offers RA covered plans (barring any applicable exemptions). If an issuer does not engage and designate an IVA Entity, the issuer will be unable to perform the IVA as required by HHS-RADV.

#### **2.1.3 IVA Entity Not Free of Conflict of Interest, or Not in Good Standing**

As described in 45 C.F.R. § 153.630(b)(3), the issuer must ensure that each IVA Entity is reasonably free of conflicts of interest (COI), such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. Consistent with 45 C.F.R. § 153.630(b)(5), an IVA must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

Issuers are responsible for performing due diligence to determine the status of an IVA Entity during the selection process. During this process, issuers are to make every reasonable effort to determine if an IVA Entity has any existing legal issue that has either resulted in the IVA Entity being placed on the OIG exclusion list, HHS exclusion list, or a state exclusion list. Before engaging an IVA Entity, the issuer is expected to verify and document that any key

individuals involved in supervising or performing the IVA have not been excluded from working with either the Medicare or Medicaid program. Issuers must also confirm that the IVA Entity is reasonably free of any COI. CMS may elect to review the IVA Entity's qualifications and confirm that there are no COI. This could include using external sources to assess potential COI and confirm that the IVA Entity has the knowledge, skills, and abilities to conduct a high-quality IVA.

**Note:** CMS does not comment on COI or determine permissibility of IVA Entity selection outside of the parameters stated within this document. Please refer to Section 6.5 (Criteria for Assessing IVA Entity Capabilities) for additional guidance.

### **2.1.4 Incomplete Audit Results Submission**

Consistent with 45 C.F.R. § 153.630(f)(1), the issuer must ensure that the IVA and SVA source documentation are submitted to HHS in a manner and timeframe specified by HHS.

Issuers are required to confirm the completion and submission of their IVA results in the Audit Tool through completion of all required fields and confirmation that all required supporting documentation has been submitted. If an issuer does not confirm submission of their IVA results, the SVA Entity will be unable to perform the SVA, and CMS will reject the IVA submission as incomplete.

### **2.1.5 Supporting Documentation Not Provided to IVA Entity or SVA Entity**

According to 45 C.F.R § 153.630(b)(6), the issuer must provide the IVA Entity and SVA Entity with all relevant source enrollment documentation, all applicable Non-EDGE Claim (NEC) and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample.

Issuers are required to provide their IVA Entity and SVA Entity with the appropriate enrollee demographic, enrollment, applicable NEC, pharmacy and medical claims, and medical record documentation as needed to validate RXCs and HCCs. The IVA Entity should submit this documentation to the SVA Entity through the Audit Tool in a timely manner to support the issuer's compliance with HHS-RADV requirements.

### **2.1.6 Suspected Fraud in Submitted Data, and Follow-Up Actions**

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

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

## **2.2 Noncompliance Penalties**

CMS may take enforcement action, including the imposition of civil money penalties (CMPs), in the event of noncompliance by an issuer of a RA covered plan or the issuer's IVA Entity. Section 2.2.1 (Civil Monetary Penalties) and Section 2.2.2 (Default Data Validation Charge) provide information on two (2) penalties that can be imposed for noncompliance with HHS-RADV requirements and standards.

## 2.2.1 Civil Money Penalties

A CMP is a monetary penalty assessed to an issuer in the event of noncompliance. For example, if an issuer does not engage an IVA Entity or submit the results of an IVA to CMS, CMPs may be imposed, as appropriate, under 45 C.F.R. § 153.630(b)(9)(i) or (ii). Additionally, CMPs may be assessed if an issuer engages in misconduct or substantial noncompliance with the HHS-RADV standards and requirements or intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS, under 45 C.F.R. § 153.630(b)(9)(iii) or (iv).

## 2.2.2 Default Data Validation Charge (DDVC)

A DDVC is a charge assessed to an issuer that is noncompliant with certain HHS-RADV requirements. Under 45 C.F.R. § 153.630(b)(10), if an issuer of a RA covered plan fails to engage an IVA Entity, or to submit the results of an IVA to CMS, CMS will impose a DDVC, which is generally calculated in the same manner as the risk adjustment default charge (RADC) but is based on the data of the benefit year being audited.<sup>8</sup> CMS will determine the amount of the DDVC by using the enrollment data from the benefit year for which the issuer fails to engage an IVA Entity or does not submit the results of an IVA.

As stated in the 2020 Payment Notice<sup>9</sup>, CMS will allocate any DDVC collected from noncompliant issuers among the compliant and exempt issuers in the same benefit year risk pool(s) for the applicable benefit year in proportion to their respective market shares and RA transfer amounts for the benefit year being audited for HHS-RADV. CMS will not allocate any DDVC to any other noncompliant issuers in the same benefit year risk pool(s). However, as noted above, issuers in the same benefit year risk pool(s) that are exempt from the HHS-RADV requirement would be eligible to receive an allocation of any DDVC.

**Note:** 2018 Benefit Year DDVC data will be published in the Summary Report of 2018 Benefit Year Risk Adjustment Data Validation Adjustments to 2019 Benefit Year Risk Adjustment Transfers. The DDVC calculation generally uses the same methodology and benefit year data as the RADC. DDVC calculation details can be found within the 2020 Payment Notice.

The DDVC is separate from the RA transfer amount for the benefit year. Thus, an issuer may owe **both** a **RA charge** and a **DDVC** (for example, an issuer could owe an RA charge for the 2019 benefit year and a DDVC for the 2018 benefit year HHS-RADV). We note that receiving a DDVC for a benefit year of HHS-RADV does not preclude an issuer's subsequent benefit year RA transfers from being affected by other issuers' HHS-RADV results.

Similarly, an issuer may owe a RADC for a given benefit year, alongside a DDVC for the benefit year being audited (for example, an issuer could owe a RADC for the 2019 benefit year, as well as a DDVC for the 2018 benefit year HHS-RADV).

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<sup>8</sup> As finalized in the 2020 Payment Notice, the DDVC is calculated based on the enrollment in the benefit year being audited rather than the benefit year during which transfers would be adjusted as a result of RADV. See 84 FR at 14796.

<sup>9</sup> See 84 FR at 17496.

**Section 3**  
**HHS Risk Adjustment Data Validation Protocols**  
**Process Timeline**

## 3. Process Timeline

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### 3.1 Introduction

The HHS-RADV timeline for the 2018 benefit year process is posted in the REGTAP library. Note that this timeline is subject to change. Refer to the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)) for additional information on the timeline of HHS-RADV activities and corresponding deadlines for the applicable benefit year, including any updates.

Package 1 submissions are due January 9, 2020. Package 1 submissions should include the IVA Entity Audit Results Submission XML, RXC data for all sampled enrollees, and all D&E data for enrollees selected by CMS in the D&E Subsample Report. After the Issuer Senior Official (SO) signs off on Package 1 in the Audit Tool, CMS will release the SVA subsample to IVA Entities. Package 1 submission must be successfully completed, including review and sign-off by the Issuer SO, on or before January 9, 2020.

Package 2 submissions must be successfully completed, including review and issuer sign-off, by January 16, 2020. Package 2 submissions should include all medical records and NEC information for enrollees selected in the HHS-RADV SVA subsample. CMS is not requiring Package 2 be submitted immediately after issuer sign-off of Package 1, but strongly encourages IVA Entities to submit Package 2 well before January 16, 2020, to allow time for resolution of any issues that may arise in the submission process.

If CMS requests the submission of Package 3, the IVA Entity and issuer will have seven (7) calendar days to submit the remaining medical records. Note the seven (7) calendar day submission window includes Issuer SO sign-off on the Package 3 submission.

<p><b>Note:</b> Medical records submitted in both Package 2 and Package 3 must align with the medical records captured in the <i>IVA Entity Audit Results Submission XML</i>. Additional medical records not captured on the IVA Entity Audit Results XML are not allowed to be submitted.</p>
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### 3.2 Definitions

- Package 1 – refers to the submission of IVA audit findings, which includes workpapers, screenshots, D&E, RXC, and an IVA Entity Audit Results Submission XML.
- Package 2 – refers to the submission of the medical records for enrollees in the SVA subsample for SVA review.
- Package 3 – (as requested by CMS) refers to the submission of all medical records for the remaining enrollees in the IVA Sample that were not submitted during Package 2 submission. Package 3 is requested after executing a pairwise means test when **insufficient agreement** between IVA and SVA findings is determined. Not all issuers will have a Package 3 submission.

**Section 4**  
**HHS Risk Adjustment Data Validation Protocols**  
**Roles and Responsibilities**

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## 4. Roles and Responsibilities

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### 4.1 CMS Roles and Responsibilities

CMS is responsible for the implementation and oversight of HHS-RADV for issuers of RA covered plans in any state that does not implement its own state-operated RA program. CMS develops, implements, and approves actions associated with the EDGE server and Audit Tool in support of HHS-RADV.

CMS monitors and reviews issuer registration, issuer IVA Entity designation, IVA Entity registration, IVA Entity election to participate in HHS-RADV, and notifies the issuer of acceptance or rejection of the designated IVA Entity. See Section 6 (IVA Entity Selection) for detailed guidance on the IVA Entity selection process.

Additionally, CMS is responsible for selecting the SVA Entity and overseeing the completion of the SVA. CMS also evaluates each year's HHS-RADV process and makes updates for future benefit years where applicable.

CMS will also offer guidance and information through HHS-RADV webinars and published materials. CMS monitors and responds to feedback and inquiries related to HHS-RADV submitted through [CCIIOACARADDataValidation@cms.hhs.gov](mailto:CCIIOACARADDataValidation@cms.hhs.gov).

### 4.2 Issuer Roles and Responsibilities

Issuers are insurance companies that are required to be licensed to engage in the business of insurance in a state and are subject to the state's regulatory authority. Issuers are identified by a HIOS ID, which is unique to the issuer and a state. Issuers of RA covered plans in states where HHS operates the RA program are subject to HHS-RADV.

#### Issuer's Programmatic Responsibilities

- Be familiar with, and abide by, regulations regarding HHS-RADV found at 45 C.F.R. Part 153 Subparts A, D, G and H;
- Review and attest to RADV sampling reports, or submit a sampling discrepancy in the manner and timeframe established by CMS;
- Engage an independent auditor (IVA Entity) that is reasonably capable of performing the IVA;
- Attest that the selected IVA Entity is reasonably free of conflicts of interest and able to conduct the IVA in an impartial manner;
- Provide the IVA Entity access to applicable systems, processes, and source documentation for enrollment, premiums, claims and/or medical records, and any required attestations for sampled enrollees;
- Ensure the IVA results and requested supporting source documentation are submitted to CMS in the manner and time frame established by CMS;
- Substantiate results of the IVA;
- Complete necessary actions within the Audit Tool by the applicable deadline(s);
- Review and attest to SVA Findings or attest and submit SVA Findings Discrepancies, as applicable in the manner and timeframe established by CMS;
- Review and attest to RADV Final Results, inclusive of the RADV error rate, or attest and submit RADV error rate discrepancies in the manner and timeframe established by CMS; and
- Read and abide by guidance provided in the HHS-RADV Protocols, Interface Control Document (ICD), Job Aids, and all HHS-RADV related published documents.

Issuers are encouraged to sign up at <https://www.regtap.info> for access to HHS-RADV webinars and other guidance information.

**Note:** If an issuer of a RA covered plan fails to engage an IVA Entity or fails to submit IVA results within the designated time, CMS will impose a DDVC, may impose CMPs, or take other action (as appropriate). See 45 C.F.R. §§ 153.630(b)(9) and (10), and 153.740(a). Also see Section 2.2.2 (Default Data Validation Charge) for additional detail.

## Audit Tool

After registering for and obtaining access to the Audit Tool, issuers must designate and maintain an Issuer Senior Official (SO) and Back-up Issuer SO via the Audit Tool. Issuers also have the ability to select an Issuer RADV Coordinator in the Audit Tool. For additional details on designating Issuer SOs, Back-up SOs, RADV Coordinators and performing Audit Tool responsibilities, see the HHS-RADV IVA Submission Issuer User Manual.

Issuers must also complete the following RADV actions in the Audit Tool by the applicable deadline(s):

- Designate the IVA Entity through the IVA Designation Form in the Audit Tool;
- Review and approve the RADV Population Summary Statistics (RADVPS) Report and submit discrepancies to CMS, as necessary, through the RA EDGE discrepancy process;
- Review and approve the RADV Population Summary Statistics Final (RADVPSF) Report and RADV sampling reports (RADV Initial Validation Sample (RADVIVAS), RADV Medical Claim Extract (RADVMCE), RADV Supplemental Extract (RADVSE), RADV Detail Enrollee (RADVDE), and RADV Pharmacy Extract (RADVPCE)), and submit discrepancies to CMS, as necessary, during the RADV Sampling Report discrepancy window; and
- Confer with the IVA Entity regarding IVA findings prior to submission and complete sign-off, including confirmation of submission of IVA results and all required supporting documentation.

It is the issuers' and IVA Entities' responsibilities to maintain access to and activity in the Audit Tool during the benefit year.

## 4.3 Initial Validation Audit (IVA) Entities – Roles and Responsibilities

An IVA Entity is an independent organization contracted by an issuer to perform a validation audit of D&E data, RXC data, and health status information derived from the diagnoses data submitted to the Issuer's EDGE server for use in RA calculations. Enrollee health status is validated through review of all relevant medical record documentation for sampled enrollees.

Any IVA Entity electing to participate in the HHS-RADV process must complete the HHS-RADV IVA Entity Election Web Form and be registered for the applicable benefit year with CMS in order to be listed as an available IVA Entity in the Audit Tool. Detailed information related to IVA Entity Selection is outlined in Section 6 (IVA Entity Selection) of these Protocols.

**Note:** CMS is not imposing a deadline for completing the HHS-RADV IVA Entity Designation and Maintenance Form. However, the IVA Entity will not have access to the issuer's sample reports until the IVA Entity is designated by the issuer and accepted by CMS. For additional guidance regarding the HHS-RADV IVA Entity Election Web Form, refer to the corresponding HHS-RADV webinar available in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)). CMS encourages issuers and IVA Entities to register on REGTAP for HHS-RADV notifications and to periodically check REGTAP for information on deadlines and updates regarding the 2018 benefit year.

The IVA Entity shall perform an independent audit of the issuer's submitted documentation. Once completed, the IVA Entity shall upload the results of the audit, along with any supporting documentation into the Audit Tool. Guidance for submitting the results of the audit and supporting documentation are provided within Section 9 (Audit Procedures and Reporting Requirements) of these Protocols.

### **IVA Entity's Programmatic Responsibilities:**

- Ensure and certify that there is an absence of a COI between the issuer and IVA Entity;
- Engage with the issuer to facilitate timeliness with findings and submission of the audit results;
- Ensure that the validation audit is performed independent of the issuer;
- Ensure that personnel are be capable of performing an IVA according to applicable requirements, these Protocols and industry coding standards;
- Ensure that its personnel attend all recommended training related to the HHS-RADV specified by CMS, and review all published HHS-RADV documents, including regulations, Protocols, and guidelines;
- Perform assessment of enrollee health status for all enrollees, review of D&E information for enrollees in the D&E subsample, and review of RXC data for adult enrollees;
- Perform medical Inter-rater Reliability (IRR) quality assurance assessments in accordance with the requirements described within these Protocols;
- Register for and obtain access to the Audit Tool; and
- Designate employees who will act as the IVA Entity SO and a backup SO in the Audit Tool.

### **IVA Entity Personnel:**

The IVA Entity personnel consists of medical coders, D&E/RXC reviewers, an IVA Entity SO, and an IVA Entity Back-up SO.

#### **Medical Coders:**

- The IVA audit must be conducted by medical coders who are certified and in good standing by a nationally recognized accrediting agency (e.g., American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC)).
- The IVA Entity must ensure that one (1) or more Primary Coders are available to perform health status data validation activities, who are certified and in good standing by a nationally recognized accrediting agency.
- The IVA Entity must ensure that one (1) or more Senior Coders are available to perform medical records review, with at least 5 years of experience, who are certified and in good standing by a nationally recognized accrediting agency.
- The IVA Entity must ensure that a Senior Coder reviews any enrollee RA error discovered during the IVA.

#### D&E/RXC Reviewers:

- The IVA Entity must ensure that Primary and Senior Reviewers are available to perform D&E and RXC data validation and conduct medical record intake.
- Errors identified by Primary Reviewers must be confirmed by a Senior Reviewer.

#### IVA Entity SO and IVA Entity Back-up SO:

- The IVA Entity SO is responsible for ensuring that the IVA findings are signed off properly and completely uploaded into the Audit Tool in a timely manner.
- The IVA Entity SO should engage with the issuer prior to the IVA findings submission signoff deadline.
- The IVA Entity SO must sign-off on discrepancy and attestation processes.
- The IVA Entity SO may designate a Back-up SO to assist with performing these responsibilities.

## **4.4 Second Validation Audit Entity – Roles and Responsibilities**

CMS will select a subsample of the RA data validated by the IVA for a SVA. The SVA Entity validates the issuer's D&E data, RXC data, and health status information on a subsample of the IVA sampled enrollees for all IVA submissions as directed by CMS. The SVA validation of health status information for the subsamples follows the steps and requirements outlined in these Protocols.

#### **SVA Entity's Programmatic Responsibilities:**

- Validate and approve RADV Sample Reports;
- Conduct the SVA independently and in accordance with these Protocols; and
- Perform IRR assessments between medical coders as part of quality assurance.

#### **SVA Entity Personnel:**

The SVA Entity personnel consists of medical coders, D&E/RXC reviewers, and administrative staff.

#### Medical Coders:

- The SVA must be conducted by medical coders who are certified and in good standing by a nationally recognized accrediting agency, e.g., AHIMA or AAPC.
- The SVA Entity must ensure that one (1) or more Primary Coders are available to perform health status data validation activities, who are certified and in good standing by a nationally recognized accrediting agency.
- The SVA Entity must ensure that a Senior Coder is available to perform medical records review, with at least 5 years of experience, who is certified and in good standing by a nationally recognized accrediting agency.
- The SVA Entity must ensure that a Senior Coder reviews any enrollee RA error discovered by the Primary Coder.

#### D&E/RXC Reviewers:

- The SVA Entity must ensure that Primary and Senior Reviewers are available to perform D&E and RXC data validation and conduct medical record intake.
- The errors identified by Primary Reviewers must be confirmed by a Senior Reviewer.

**Section 5**  
**HHS Risk Adjustment Data Validation Protocols**  
**Audit Tool Overview**

## 5. Audit Tool Overview

### 5.1 Purpose

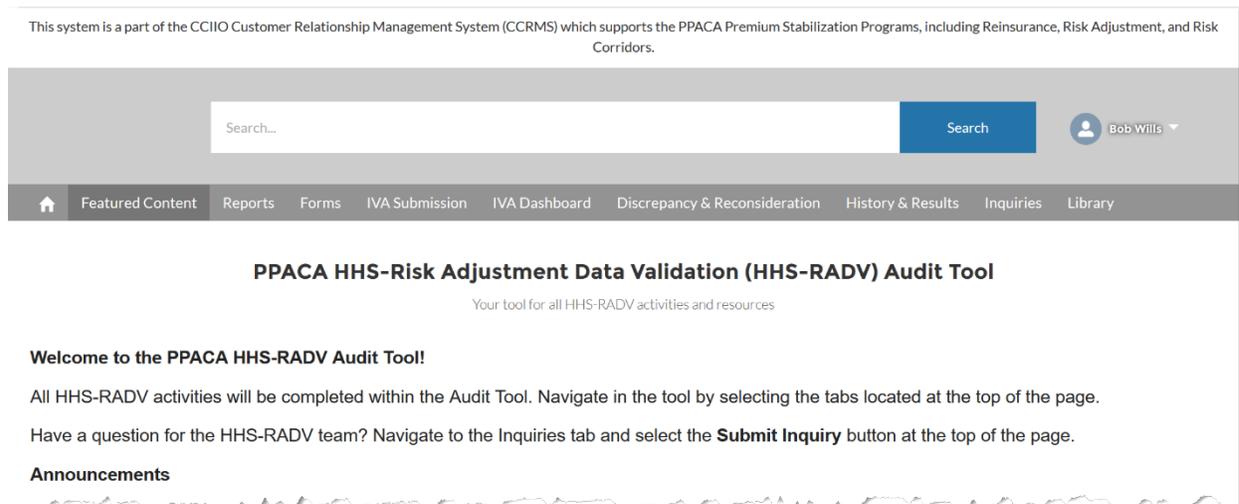
The HHS-RADV Audit Tool is built on the Salesforce platform in accordance with CMS Technical Reference Architecture and CMS Information Security (IS) Acceptable Risk Safeguards (ARS)<sup>10</sup> to maintain and protect PHI and PII. The Audit Tool is comprised of externally facing web-based forms (or “Visualforce” pages) and a Salesforce Community area accessed with login credentials.

The Visualforce pages will allow IVA Entities to submit initial registration information related to participation, including identifying IVA Entity SOs, as necessary.

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

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

#### Featured Content Tab in the Audit Tool



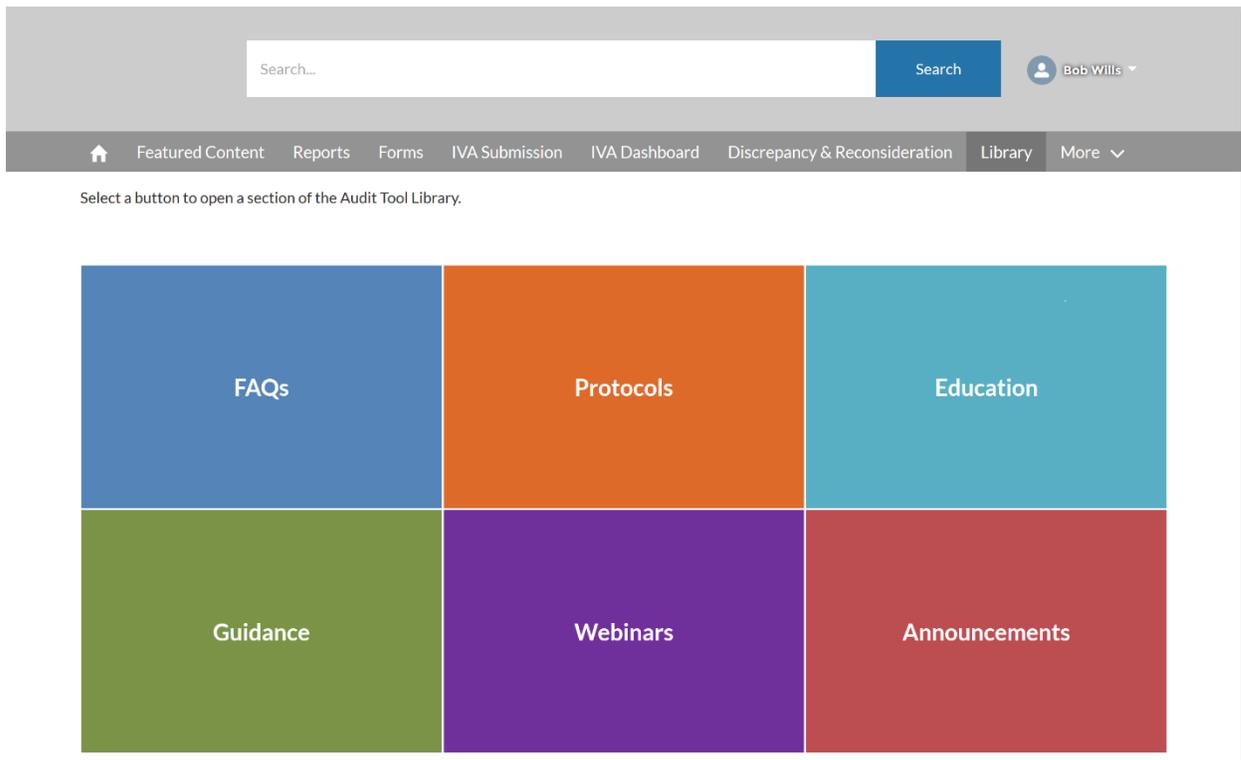
<sup>10</sup> CMS' Information Security and Privacy Library can be found at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html>

The Audit Tool contains a Library tab that includes six (6) sections where various HHS-RADV program materials are available. These sections include Announcements, Education, FAQs, Guidance, Protocols, and HHS-RADV-specific webinars. HHS-RADV webinars are also available on REGTAP (<https://www.regtap.info/>).

### Library Tab in the Audit Tool

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

Specific instructions on the functionality of the Audit Tool are provided in user guides located within the library of the Audit Tool.



**Section 6**  
**HHS Risk Adjustment Data Validation Protocols**  
**IVA Entity Selection**

## 6. IVA Entity Selection

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### 6.1 Purpose

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

### 6.2 IVA Entity Selection Participants

#### 6.2.1 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. As stated in Section 2.1.2 (Issuer Did Not Engage an IVA Entity or the Designated IVA Entity is Not Capable of Performing the Audit) and in accordance with 45 C.F.R. § 153.630(b)(2), the issuer must ensure that the IVA Entity is reasonably capable of performing an IVA audit according to the standards established by CMS for such audit, and must ensure that the audit is so performed. Furthermore, as stated in Section 2.1.3 (IVA Entity Not Free of Conflict of Interest or Not in Good Standing) and as described in 45 C.F.R. § 153.630(b)(3), the issuer must ensure that each IVA Entity is reasonably free of conflicts of interest (COI), such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. CMS has defined COI standards between an issuer and IVA Entity in Section 6.5 (Criteria for Assessing IVA Entity Capabilities). CMS also details the protocols the IVA Entity must follow for purposes of performing the IVA under Section 9. These protocols can be used by the issuer to assess a potential IVA Entity's capability to conduct an IVA.

The issuer must register in the Audit Tool and complete the IVA Entity Designation process within the Audit Tool before the applicable deadline. CMS will review and provide a final decision based on § 153.630(b)(1). See Section 6.2.3 (CMS Oversight) for further information regarding CMS's oversight methods and review of the IVA Entity selection.

**Note:** CMS does not publish a list of approved IVA Entities for HHS-RADV. Issuers should solicit an IVA Entity based on their business needs and advise the IVA Entity to complete the IVA Entity election process to be reviewed by CMS.

#### 6.2.2 IVA Entity

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

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

#### 6.2.3 CMS Oversight

CMS monitors and reviews IVA Entity registration and election to participate within the Audit Tool by verifying their information against the OIG exclusions list.<sup>11</sup> CMS reviews the issuer's

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<sup>11</sup> This CMS check does not in any way reduce the issuer's separate obligation to confirm as part of the required COI review that no key individuals involved in supervising or performing the IVA have been excluded from working with either the Medicare or Medicaid program, are on the OIG exclusion list or, to its knowledge, are under investigation with

designation of an IVA Entity, along with the issuer's attestation verifying the IVA Entity and issuer are free of COI. CMS will either accept or reject the issuer's IVA Entity designation within the Audit Tool.

### 6.3 IVA Entity Requirements

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

- Is reasonably capable of performing the IVA and validating the accuracy of the RA data in accordance with CMS defined audit standards;
- Is reasonably free of COI for the entity and the individuals working on the IVA, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question; and
- Employs medical coders to conduct the IVA who are certified and in good standing by a nationally recognized accrediting agency such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC).

### 6.4 Timeline of IVA Entity Selection

For each benefit year, CMS instructs issuers and IVA Entities to begin preparing for the selection process, and communicates timing requirements via the HHS-RADV Process Timeline available on REGTAP (<https://www.regtap.info/>). Refer to REGTAP for any updates to the HHS-RADV Timeline and corresponding deadlines for the applicable benefit year, and to Section 3 (Process Timeline).

**Note:** CMS is not imposing a deadline for completing the HHS-RADV IVA Entity Designation and Maintenance Form. However, the IVA Entity will not have access to the issuer's sample reports until the IVA Entity is designated by the issuer and accepted by CMS. For additional guidance regarding the HHS-RADV IVA Entity Election Web Form, refer to the corresponding HHS-RADV webinar available in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)). CMS encourages issuers and IVA Entities to register on REGTAP for HHS-RADV notifications and to periodically check REGTAP for information on deadlines and updates regarding the 2018 benefit year.

### 6.5 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, medical and pharmacy claims, and enrollment data. The issuer must retain documentation from the selection and review process that demonstrates the IVA Entity meets regulatory requirements. CMS may request documentation regarding the issuer's IVA Entity selection process and the IVA Entity's compliance with applicable requirements.

Each year, the issuer will complete and provide CMS with an attestation stating that they have used a documented process to ensure that there is no COI between the issuer (or its owners, directors, officers, or employees) and the IVA Entity (or the members of its audit team, owners, directors, officers, or employees). This attestation can be downloaded from the Audit Tool by the

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respect to any HHS programs.

Issuer SO and must be signed by the issuer's chief executive officer (CEO), chief financial officer (CFO), or a person who is authorized to legally and financially bind the organization, for the current benefit year HHS-RADV.

**Note:** The issuer's CEO does not need to be the individual to submit the attestation into the Audit Tool; however, the attester must be an individual who can legally and financially bind the company, such as the CEO/CFO. The IVA Entity Designation process is not complete until the COI Attestation is signed and submitted through the Audit Tool.

The Issuer's SO must then upload the signed COI Attestation to the Audit Tool. The IVA Entity must certify that there is an absence of COI, at both the organization and staff levels, and must provide signed documentation to the issuer. For additional information on the COI Attestation process, refer to the corresponding HHS-RADV webinar available in the REGTAP Library (<https://www.regtap.info/>).

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

**Note:** CMS does not comment on COI or determine permissibility of IVA Entity selection. Issuers are responsible for performing due diligence to know the status of an IVA Entity during the selection process and to conduct its own COI review. Issuers can also refer to the corresponding HHS-RADV webinar available in the REGTAP Library (<https://www.regtap.info/>).

The following section outlines requirements which should be used by issuers to evaluate the IVA Entity's potential COI as stated in the 2015 Payment Notice.<sup>12</sup>

### **Conflict of Interest (COI) Requirements:**

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

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<sup>12</sup> See 79 FR at 13758.

IVA Entity, and vice versa.

- Members of the data validation team of the IVA Entity may not be married to, in a domestic partnership with, or otherwise in the same immediate family as an owner, director, officer, or employee of the issuer.
- The IVA Entity may not have a role in establishing any relevant internal controls for the issuer related to RA or the IVA process or serve in any capacity as an advisor to the issuer regarding the RA process or IVA.
- The IVA Entity may not perform any SVA activities on behalf of CMS.
- Third Party Administrators (TPAs) or any organization/company/entity responsible for reviewing, analyzing, submitting claims or supplemental diagnosis records on behalf of an issuer via their EDGE server for RA calculation is considered to have a COI and may not be designated as an IVA Entity.

## 6.6 Additional Reasons for IVA Entity Exclusion

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

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

## 6.7 Required Documentation for IVA Entity Selection by an Issuer

Issuers are required to select and designate their IVA Entity by completing the HHS-RADV IVA Entity Designation and Maintenance Form within the Audit Tool. For additional Audit Tool guidance, refer to the BY18 HHS-RADV Issuer Participation Requirement and IVA Entity Designation Webinar available in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)). If the IVA Entity cannot be located in the Audit Tool, issuers should contact the IVA Entity directly to ensure they have completed the HHS-RADV IVA Entity Election Web Form for the current benefit year.

By completing this form in the Audit Tool, the issuer will also confirm compliance with the following criteria, listed in Table 2.

**Table 2: Criteria Categories for IVA Entity Selection**

<p>1. Ensure IVA Entity is Reasonably Capable of Performing Risk Adjustment Data Validation and has Certified Medical Coders [45 C.F.R. § 153.630(b)(2) and (b)(5)-(8)]:</p>	<p>a) The designated IVA Entity is reasonably capable of performing HHS-RADV in accordance with CMS defined audit standards under [45 C.F.R. § 153.630(b)(2) and (b)(5)-(8)], and in accordance with HHS-RADV audit Protocols.</p>
	<p>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. The IVA Entity cannot utilize coders who are only certified through Practice Management Institute (PMI) or a similar certifying entity.</p>
	<p>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.</p>
<p>2. Ensure IVA Entity is Free of COI, IVA Entity is not excluded from Medicare or Medicaid, and IVA Entity is not the Issuer's Third-Party Administrator (TPA) [45 C.F.R. § 153.630(b)(3)]</p>	<p>a) The designated IVA Entity is reasonably free of COI, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question (refer to HHS-RADV Conflict of Interest Guidelines). The issuer attests they have performed a reasonable investigation into COI and they have obtained equivalent representation from the IVA Entity regarding conflicts of interest.</p>
	<p>b) No key individuals involved in supervising or performing the initial validation audit have been excluded from working with either the Medicare program or the Medicaid program, are on the Federal OIG exclusion list, or are under investigation with respect to any CMS program.</p>
	<p>c) The IVA Entity designated did not have a role in establishing any relevant internal controls for the issuer organization related to the HHS-RADV process or serves in any capacity as an advisor to the issuer organization regarding the IVA. Additionally, the nominated IVA Entity is not the issuer's TPA or an organization/company/entity, responsible for reviewing, analyzing, submitting claims or supplemental diagnosis records on behalf of an issuer via their EDGE server for RA calculations.</p>
<p>3. Ensure Performance of HHS-RADV Audit [45 C.F.R. § 153.630(b)(1), (2), and (4)]</p>	<p>a) The issuer of a RA covered plan engages one (1) or more independent auditors to perform the IVA of a sample of its RA data selected by CMS.</p>
	<p>b) The issuer ensures that the IVA Entity auditors are reasonably capable of performing the IVA according to the standards established by CMS and ensures that the audit is performed according to those standards.</p>
	<p>c) The issuer ensures validation of the accuracy of the RA data for a sample of enrollees selected by CMS.</p>
	<p>d) The issuer ensures that the IVA findings are submitted to CMS in a manner and timeframe specified by CMS.</p>

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

CMS will review the issuer's IVA Entity designation in the Audit Tool and either accept or reject the designation within the Audit Tool. CMS may reject a designation or exclude an IVA Entity based on the criteria above. In the event that CMS has rejected an issuer's designation or excluded an IVA Entity, the issuer must procure the services of a different IVA Entity that meets all applicable requirements. CMS will communicate to the issuer the outcome of the review in order to assist the issuer in selecting an eligible IVA Entity. Refer to the HHS-RADV Process Timeline located on REGTAP (<https://www.regtap.info/>) for a timeline of activities and corresponding deadlines for the applicable benefit year, and to Section 3 (Process Timeline).

## **6.8 Implications of Failure to Engage an IVA Entity**

If an issuer of an RA covered plan fails to engage an IVA Entity in accordance with the requirement stated within this section by the applicable deadline, CMS will impose a DDVC under 45 C.F.R. § 153.630(b)(10) and may take other action (as appropriate). This DDVC is generally calculated based on the same methodology as the RADC (see Section 2.2.2 (Default Data Validation Charge)).

**Section 7**  
**HHS Risk Adjustment Data Validation Protocols**  
**Enrollee Sampling Process**

# 7. Enrollee Sampling Process

## 7.1 Purpose

CMS will select a sample of 200 enrollees for each issuer<sup>13</sup> participating in the applicable benefit year of HHS-RADV. The enrollee sampling process will help ensure that the HHS-RADV process reviews an adequate sample of enrollees for each issuer so that estimated risk score errors will be statistically sound and the sample will adequately cover applicable subpopulations.

## 7.2 Sample Design

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

- Stratification – discusses how and why CMS stratified the sample;
- Proxy Issuer Population – discusses how CMS initially created an assumed average issuer population;
- Actual Population – discusses what assumptions will change as CMS gathers actual issuer populations and RADV payment years’ data.

### 7.2.1 Stratification

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

Each issuer’s enrollee population will be grouped into 10 strata based on presence of HCCs (or RXCs for adults), RA age model, and risk level. Table 3 provides a listing of assigned strata by risk level for each age group with the presence of at least one (1) HCC (or RXC for adults). Note that stratum 10 (no HCCs (or RXCs for adults)) is not stratified by age or risk level because it is assumed to have a uniformly low error rate. Beginning in the 2018 benefit year, note that the adult strata (strata one (1) through three (3)) include enrollees with at least one HCC or RXC. Only the adult RA model includes RXCs so the child and infant strata (strata four (4) through six (6) and seven (7) through nine (9), respectively) will not include RXCs.

**Table 3: Stratification Mapping**

HCC Stratum	Age	Risk Level	Stratum
1 or More HCC(s) (or RXCs for adults)	Adult	Low	1
		Medium	2
		High	3
	Child	Low	4
		Medium	5
		High	6

<sup>13</sup> Lower sample sizes may be calculated for issuers with a small number of enrollees. See Section 7.3.2 (Alternate Sample Sizes)

HCC Stratum	Age	Risk Level	Stratum
	Infant	Low	7
		Medium	8
		High	9
No HCCs (or RXCs for adults)	All	N/A	10

### 7.2.2 Proxy Issuer Population

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

CMS originally used 2014 summary data from the EDGE server as a proxy population for the sample design. The EDGE server summary data included the stratified populations of each issuer. CMS performed subsequent sample size analyses using the 2015, 2016, and 2017 benefit years' EDGE data to assess precision for small, medium, and large issuers. The sample sizes were approximately in-line with the original proxy populations. For additional detail on how CMS determines an acceptable sample size for issuer populations see Section 7.3 (Sample Size).

### 7.2.3 No-HCC (or RXC for Adults) Assumptions

CMS will use the lowest error rate and variance across all HCC (or RXC) strata as the error rate and variance assumption for the No-HCC (or RXC) 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 (or RXC) population, the risk score errors will likely be under-statements, meaning the No-HCC (or RXC) risk scores should be adjusted upward, as any identification of any new conditions for enrollees in the No-HCC population would reflect under-reported risk.

Given that the No-HCC population will make up the vast majority of the expected enrollee population (79% of the total population for the 2017 benefit year), there is potential sampling risk in this population if enrollees in this stratum are misclassified as being No-HCC (or RXC) when they should have been included in the HCC strata (as determined after the HHS-RADV process).

Consequently, there is some risk that CMS may be understating the error rate, variance, and risk score assumptions for the No-HCC stratum.

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

### 7.2.4 Sampling Assumptions

The sampling assumptions used for the 2018 benefit year HHS-RADV are held constant from the 2017 benefit year and are expected to approximate the average issuer size and the issuer population distributions for the HCC versus No-HCC groups, and achieve the targeted precision levels.

CMS continues to evaluate the sampling methodology used for each benefit year and measure the precision of Error Estimation results. Findings of the 2017 benefit year HHS-RADV process were consistent with assumptions and precision targets established for the 2017 benefit year. CMS will continue to evaluate sampling assumptions for subsequent benefit years.

## 7.3 Sample Size

45 C.F.R. §§ 153.350(a) and 153.630 require that a statistically valid sample of enrollees from each issuer be validated every year. For the initial years of HHS-RADV, as well as the 2018 benefit year, the enrollee sample selected for the IVA will include 200 enrollees from each issuer to estimate a risk score error rate related to RA. The assumptions discussed above in Section 7.2 (Sample Design) support the sample size of 200 enrollees per issuer. Note that a lower sample size may be calculated for issuers with a small number of enrollees by using a Finite Population Correction (FPC) factor described in Section 7.3.2 (Alternate Sample Sizes).

The sample of 200 enrollees is selected from all state risk pool markets in which the issuer had enrollment in RA covered plans for the applicable benefit year. However, as finalized in the 2019 Payment Notice<sup>14</sup>, the IVA sample will only include enrollees from state risk pool markets in which there was more than one (1) issuer.

### 7.3.1 Precision and Confidence Level

CMS utilizes an enrollee sample size to target a 10 percent relative sampling precision (or margin of error) at a two (2)-sided 95 percent confidence level (CL). The use of a 10 percent targeted precision was selected based on a survey of guidance from the Office of Management and Budget (OMB), the Internal Revenue Service (IRS), and the CMS-developed Payment Error Rate Measurement (PERM) program.<sup>15</sup> This target will be re-evaluated in subsequent years based on actual results.

### Neyman Allocation

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

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

The sample size for each stratum is calculated from:

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

On average, two-thirds of the total sample size will be allocated to the HCC (or RXC for adults) strata [strata one (1) through nine (9)] using the Neyman optimal allocation method, with the remaining one-third assigned to the “No-HCC or RXC” stratum ten (10).

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<sup>14</sup> See 83 FR at 16967.

<sup>15</sup> For additional information on the sampling guidance surveyed by CMS for this purpose, see Section 4.3.1 of the 2016 Benefit Year Protocols PPACA HHS-Operated Risk Adjustment Data Validation Version 14.00.00 (October 20, 2017), available at: [https://www.regtap.info/reg\\_library.php?i=2104](https://www.regtap.info/reg_library.php?i=2104).

Based on population characteristics for some issuers, there could be instances in which the original HCC target sample size for a stratum - determined using the Neyman optimal allocation method - is larger than the actual sample size allocated to that stratum. This situation could occur if an issuer has a stratum with a small number of enrollees with highly variable risk scores. In these cases, the Neyman allocation weight for that stratum could be relatively high, leading to a Neyman allocation-calculated sample size that exceeds the total number of enrollees in that stratum. If this occurs, the actual sample size must be used in place of the target sample size for that stratum, but as a result, the total sample size may not meet the minimum number of enrollees required to achieve the target precision threshold referenced above. In these instances, an incremental factor equal to one (1) will be added to the total target HCC sample size and the Neyman allocation for strata one (1) through nine (9) will be re-executed. This will allow for an increase in the target sample size of all the strata, making it possible to meet the minimum total sample size required, even if the actual sample size for a particular stratum is used instead of the target sample size. This process continues until the target sample size is reached or exceeded across strata one (1) through nine (9), or until the number of iterations reaches 100. If a sample size equal to or larger than the original HCC target sample size is not generated after 100 iterations, then the selected sample will be used.

### 7.3.2 Alternate Sample Sizes

While a sample size of 200 is adequate, based on the assumptions presented above, a smaller

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

sample size will be calculated for issuers with a small enrollee population. In such cases, a Finite Population Correction (FPC) factor will be used to adjust the sample size:<sup>16</sup>

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

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

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

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 fewer than 50 enrollees in

<sup>16</sup> The Finite Population Correction formula can be found in Section 2.6: *Cochran, William G., Sampling Techniques, third edition, John Wiley & Sons, 1977.*

its population, all enrollees in the population will be reviewed.

### **7.3.3 SVA Subsample Sizes**

While the IVA sample size is 200, there will be multiple incremental samples used for the purposes of the SVA process. The SVA sample sizes will consist of an initial sample of 12 enrollees and expand, if necessary, to include 24, 50, 100, and up to the full IVA sample of 200 in the event of failure of pairwise means testing. Since pairwise means testing will be performed on all SVA initial subsamples, comparing them to their corresponding enrollees in the IVA sample of 100 during the sample review portion of the HHS-RADV process (discussed in Section 9 – Audit Procedures and Reporting Requirements), the SVA subsamples must be large enough to validate testing results. In cases where pairwise means testing of the SVA subsample of 12 enrollees fails, CMS will increase the SVA subsample by 12 enrollees for a total of 24 enrollees, then to a total of 50 enrollees, then to the full 100 SVA subsample.

If the pairwise means testing fails at 100, the SVA subsample may be expanded up to a total of 200 enrollees, so that the final SVA results would replace the IVA results based on a sample large enough to extrapolate. A sample size of 200 for SVA testing is approximated by the precision analysis mentioned above. Issuers that have to apply a FPC for the IVA sample size will use the initial subsample size of 12 and an expanded SVA subsample size that may be equivalent to the IVA sample size (depending on the results of the pairwise means testing).

## **7.4 Future Sample Size Refinement**

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

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

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

**Section 8**  
**HHS Risk Adjustment Data Validation Protocols**  
**Sampling Reports**

## 8. Sampling Reports

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### 8.1 Purpose

The following sections outline the suite of reports used to determine the issuer's RADV population. These reports include the RADV Population Summary Statistics (RADVPS) Report, which contains the population statistics of the issuer's total population, and the seven (7) RADV Sampling Reports described in Section 8.3 (RADV Sampling Reports). It is critical that issuers review their RA reports and RADV sampling reports to verify and attest to the accuracy of the data, as well as to report any discrepancies to CMS, which is discussed in greater detail in Section 8.5 (EDGE Report Discrepancy Reporting). See Section 8.3 (RADV Sampling Reports) for an overview of EDGE server RADV Report resources.

### 8.2 RA Report – RADV Population Summary Statistics (RADVPS) Report

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

The RADVPS Report contains population statistics for the issuer's total population separated into sub-categories, or "strata," based on enrollee age (infant, child, adult) and risk score (low, medium, high). The RADVPS Report provides issuer level data, including total enrollees and plans, number of enrollees in each risk pool market (individual, small group, merged or catastrophic), strata-level data (including number of enrollees in each of the specific stratum), and summary statistics for each of the specific strata, including mean (average), minimum (min), and maximum (max) risk scores for enrollees in the stratum. New for 2018, the RADVPS Report will also include RXC specific data elements. Issuers should review this report to ensure that the data contained in it is accurate, as compared to their knowledge of their enrolled populations, and that the stratification is representative of their total population.

If an issue is identified in the RADVPS Report generated by the RA final report command, issuers must communicate that issue to CMS through the RA formal discrepancy reporting process described in Section 8.5 (EDGE Report Discrepancy Reporting) for additional detail. However, issues related to data incorrectly submitted by an issuer to their EDGE server are not considered a discrepancy on the RADVPS Report (although an issuer can report such errors to CMS as part of the EDGE/RA Attestation and Discrepancy Reporting process).

**Note:** The EDGE/RA formal discrepancy window is different from the RADV Sampling Discrepancy Reporting Period.

It is essential that issuers review the RADVPS Report because the sample size will be applied to the entire population. For more detailed information about the RADVPS Report, refer to the ***Job Aid for Validation of RADVPS Reports (5/22/19)***, available in the REGTAP Library ([https://www.regtap.info/reg\\_librarye.php?i=2039](https://www.regtap.info/reg_librarye.php?i=2039)).

### 8.3 RADV Sampling Reports

After the final RA report run and RA transfer run related to the calculation of RA transfers for the applicable benefit year, CMS transmits the HHS-RADV command to the EDGE servers to generate the RADV sample reports, which are sent to CMS for validation. CMS reviews the

sample reports to determine if the sample is representative of the issuer's population by comparing the RADV IVA Statistics (RADVIVAS) Report to the RADV Population Summary Statistics Final (RADVPSF) Report. After CMS approves the samples, the final RADV report command is sent to the EDGE servers to generate the RADV sampling reports including the IVA sample, which are released to issuers via their EDGE servers and accessible to IVA Entities via the Audit Tool. Issuers should review their HHS-RADV sampling reports to ensure they are representative of the issuer's population in the risk pool markets included in HHS-RADV.

The HHS-RADV sampling reports consist of seven (7) reports generated by the issuer's EDGE server:

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

- Contains population statistics for an issuer's population included in RADV broken into sub-categories, known as "strata," which are based on enrollee age (infant, child, adult) and risk score (low, medium, high).
- Contains only enrollees in a risk pool market where a RA transfer occurs and excludes enrollees in a risk pool market if the issuer is the only issuer in that risk pool market.
- Generated by the RADV Report command after the final RA report run and the RA transfer calculation run.
- The RADVPSF Report has the same data elements as the RADVPS Report; however, the RADVPSF Report will include only enrollees in a risk pool market where a RA transfer occurs, and excludes enrollees in a risk pool market if the issuer is the sole issuer in that risk pool market.<sup>17</sup>

The RADVPSF Report should be utilized when reviewing the RADV population, as the RADVPS Report reflects statistics of the issuer's total population, prior to the removal of risk pool markets not subject to RADV.

- **RADV IVA Statistics (RADVIVAS) Report**

- Contains the sample statistics calculated at the strata-level for the enrollees selected for the RADV IVA sample.
- Similar in layout to the RADVPS and RADVPSF Reports, but limited to the enrollees selected for the IVA sample.

For more detailed information about the RADVIVAS Report, see the Job Aid for Validation of RADVIVAS Reports (5/22/19), available in the REGTAP Library ([https://www.regtap.info/reg\\_librarye.php?i=2552](https://www.regtap.info/reg_librarye.php?i=2552)).

The RADVIVAS Report contains only the information on the sampled enrollees, unlike RADVPS which contains information on the issuer's entire population or the RADVPSF Report that contains information on the issuer's population only in the risk pool markets included in RADV.

- **RADV Detailed Enrollee (RADVDE) Report**

- Identifies the issuer's enrollees selected for the RADV IVA sample.
- Contains enrollee-level data for each enrollee selected for the RADV IVA sample, such

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<sup>17</sup> As described in Section 1.6.1 (Exemption from HHS-RADV), in the event an issuer is the sole issuer in a state across all market risk pools in a state for a given benefit year, then that issuer will be excluded from RA payments and charges, and also excluded from HHS-RADV for that benefit year.

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

- **RADV Enrollee Extract (RADVEE) Report**
  - Contains all active enrollment data that was submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Medical Claims Extract (RADVMCE) Report**
  - Contains all active RA eligible and RXC eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.
- **RADV Pharmacy Claims Extract (RADVPCE) Report (new beginning in the 2018 benefit year)**
  - Contains all active RXC eligible pharmacy claims that were submitted by the issuer in the pharmacy claim XML for each adult enrollee with RXCs included in the RADV IVA sample.
- **RADV Supplemental Extract (RADVSE) Report**
  - Contains all active supplemental records for active RA eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample.

For further information about the RADV sampling reports, see the **Risk Adjustment and Reinsurance (RARI) - Interface Control Document Addendum Version 05.00.23 (3/1/19)** and the **EDGE Server XML and XSD Zip File Contents Job Aid (2/21/19)** available in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)). Additionally, the following Job Aids for validation of RA Reports and RADV Reports are located in the REGTAP Library:

- **Job Aid for Validation of RADVPS Reports (5/23/19),**
- **Job Aid for Validation of RADVPSF Report (5/23/19)**
- **Job Aid for Validation of RADVIVAS Reports (5/23/19)**

See **XML/XSD Outbound Files** in the REGTAP Library ([https://www.regtap.info/reg\\_library.php](https://www.regtap.info/reg_library.php)) for the latest EDGE server outbound report XML examples and XSDs.

## 8.4 Steps to Validate the IVA Sample Generated by CMS

Issuers are able to validate the IVA sample generated by CMS, based on the RADVPSF Report, by following the 10 steps outlined in the section below. With these steps, issuers can confirm that the HHS-RADV process has selected a statistically valid sample size of enrollees that is representative of the issuer's RADV population, including the expected number of enrollees assigned to each of the ten (10) strata. The calculation steps are as follows:

### Step 1: Calculate Risk Score for Each Enrollee

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

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

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

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

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

### Step 2: Determine IVA Sample Size

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

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

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

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

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

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

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

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

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

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

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 (or RXC) stratum.
- $S_h$  represents the standard deviation of risk score error for the  $h^{th}$  stratum. The standard deviation of risk score error is the square root of the variance of risk score error (Estimated variance for initial years of HHS-RADV). The risk score calculated for RADV is based on the demographic, CSR, enrollment duration, RXC (and interaction) and HCC (and interaction) factors.

**Note:** The calculated value should be rounded to the nearest whole number. For example, 133.1 will be rounded to 133 and 133.5 will be rounded to 134.

### Step 5: Calculate the Standard Deviation of Risk Score Error

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

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

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

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

Risk Stratum	Variance of Error
Low	0.095
Medium	0.201
High	0.654

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

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

$$S_{h_1} = \sqrt{9.5\%} \times 3 \times 4.500$$

$$S_{h_1} \approx 4.161$$

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

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

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

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

## Step 7: Calculate Total Actual Sample Size for Strata 1-9

The issuer should sum the sample size for each stratum (one (1) through nine (9)) to confirm if a large enough sample size was selected for the HCC (or RXC) strata (e.g., sample size in strata one (1) through nine (9) should be at least  $\frac{2}{3}$  x Target Sample Size).

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

**Table 4: Example of IVA Sample**

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

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

Decision Point: The issuer should determine if the actual sample selected is smaller, larger, or equal to the original HCC target sample size. If the original HCC target sample size is reached, skip Step 9 and go on to Step 10. If the actual HCC sample selected is smaller than the original HCC target sample, follow the instructions in Step 9 to re-execute the Neyman Allocation until the original HCC target sample size is reached, or you have completed 100 iterations.

## Step 9: Re-Execute Neyman Allocation for Strata 1-9 if Sample Selected is Smaller 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 strata one (1) through nine (9) if the actual sample size selected is smaller than the original HCC target sample size. If a sample size equal to or larger than the original HCC target sample size is not generated after 100 iterations, then the selected sample will be used.

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

The issuer should determine the number of enrollees to assign to stratum 10.

For stratum 10, the issuer should use the following formula to calculate how many enrollees should be assigned ( $n_{10}$ ):

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

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

$$n_{10} = 63$$

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

## 8.5 Sampling Report Discrepancy Reporting

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

More specifically, if an issuer identifies an issue with the RADVPS Report or any of the RADV sampling reports, they may file a discrepancy with CMS using the appropriate discrepancy reporting process as outlined in Table 5, which depicts the reports included in each report run (RA versus RADV) and the process for reporting discrepancies for each report. Both the RA Report discrepancies and RADV Sampling discrepancies must be reported within fifteen (15) calendar days. Once the fifteen (15) calendar day discrepancy window has closed, the population statistics are not subject to further dispute or appeals. **While these reporting windows may overlap, they are two (2) separate processes.** Refer to the HHS-RADV Activities Timeline located on REGTAP (<https://www.regtap.info/>) for a timeline of activities and corresponding deadlines for the applicable benefit year, and to Section 3 (Process Timeline).

**Table 5: HHS-RADV Reports and Discrepancy Reporting Processes**

Report Run	Report Name	Discrepancy Reporting Process
RA Reports	RADVPS	<p>If an issuer identifies an issue with the RADVPS Report, they may file a discrepancy with CMS using the formal EDGE/RA attestation and discrepancy reporting process. The discrepancy must be submitted using the EDGE Attestation and Discrepancy Reporting web form (a link will be sent when the submission window opens).</p> <p><b>Note:</b> The formal EDGE Attestation and discrepancy reporting period is 15 days and will generally open shortly after the April 30<sup>th</sup> data submission deadline, ahead of the RADV sampling discrepancy reporting period.</p> <p><b>Note:</b> Issuers should submit a workpaper to outline any data inaccuracies that occurred during EDGE server submission and reported as a RA discrepancy. For workpaper guidelines refer to Appendix A (2018 Benefit Year D&amp;E Documentation Examples)</p>
RADV Sampling Reports	RADVPSF RADVIVAS RADVDE RADVEE RADVMCE RADVPCE RADVSE	<p>If an issuer identifies an issue with any of the HHS-RADV sampling reports, they may file a discrepancy with CMS during the HHS-RADV discrepancy reporting window. The issuer may submit the discrepancy in the Audit Tool.</p> <p><b>Note:</b> The discrepancy reporting window is 15 days beginning the date the final RADV command is pushed to issuers' EDGE servers.</p>

## **Section 9**

# **HHS Risk Adjustment Data Validation Protocols Audit Procedures and Reporting Requirements**

# 9. Audit Procedures and Reporting Requirements

## 9.1 Purpose

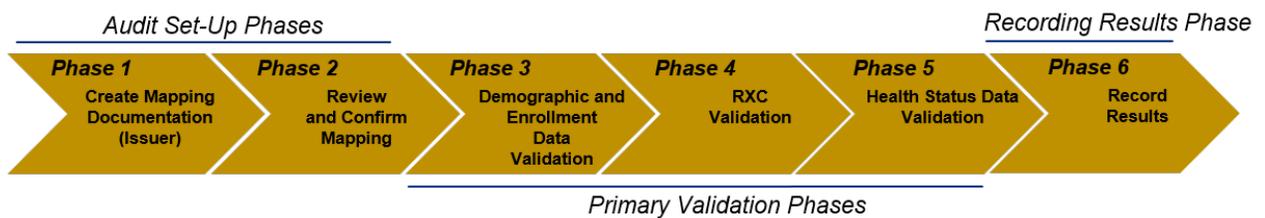
CMS has selected data elements required for IVA Entity and SVA Entity validation based on their impact on risk score calculations and RA transfer calculations.

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

In the following sections of this document, “*IVA Entity Audit Results Submission XML*” refers to the XML file that will be submitted containing the IVA findings.

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

## 9.2 Process Overview and Audit Execution



The initial step of the HHS-RADV audit process requires issuers to create documentation, or gather existing documentation, that maps issuer source system data to EDGE server data submissions (Section 9.4 – Phase 1 – Creating Mapping Documentation (Issuer)). Issuers are required to provide source system mapping documentation for D&E and RXC data elements (if subject to RXC validation). Issuers and IVA Entities must then review and confirm the accuracy of the mapping evidence (Section 9.5 – Phase 2 – Review and Confirm Mapping). This mapping documentation will be used in the review and validation of D&E data elements for a subsample of enrollees from the IVA Sample (Section 9.6 – Phase 3 – D&E Data Validation). See [Appendix A](#) (2018 Benefit Year D&E Documentation Examples)

RXC data is then validated (Section 9.7 – Phase 4 – RXC Validation), a new process beginning with the 2018 benefit year. Subsequently, in Section 9.8 (Phase 5 – Health Status Data Validation), medical records are matched to the enrollees in the IVA sample and valid diagnosis codes are abstracted. In the final audit phase described in Section 9.9 (Phase 6 – Record Validation Results), audit results are entered into the *IVA Entity Audit Results Submission XML* and submitted to CMS.

### 9.2.1 Audit Timing Considerations

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

- D&E data validation and RXC validation is **not** required to be completed prior to health status data validation.
- If a medical record linked to a NEC is provided as part of the IVA, the claim should be validated prior to review of the associated medical record utilizing a screenshot with mapping documentation. This will be discussed in Section 9.3 (HHS-RADV Documentation Requirements).

## 9.2.2 Issuer and IVA Entity Correspondence

During D&E Data Validation (Phase 3), RXC Validation (Phase 4), and Health Status Data Validation (Phase 5), IVA Entities will review and validate documentation provided by the issuer in order to validate the accuracy of issuer-submitted EDGE server data.

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

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

Additional documentation generated for these purposes must always be documented in workpapers and submitted along with the audit results. Refer to Section 9.3 (HHS-RADV Documentation Requirements) for additional detail on screenshot and workpaper requirements.

## 9.3 HHS-RADV Documentation Requirements

During the IVA process, the IVA Entity will review the supporting audit documentation for the sampled enrollees to validate the issuer's EDGE server data, as well as document their own audit validation methods and findings. The four (4) key documentation types are listed below. The key documentation types are:

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

An example of mapping documentation, screenshots, and workpapers, as well as tick-marking of evidence, is demonstrated within [Appendix A](#) (2018 Benefit Year D&E Documentation Examples).

### 9.3.1 Mapping Documentation

CMS requires issuers to provide IVA Entities with a set of documents that map to the issuer's or Pharmacy Benefit Manager's (PBM) source system data to EDGE server data submissions. Often, data from a source system is transformed to comply with EDGE server data submission business rules. This required mapping documentation allows both the IVA Entity and the SVA Entity to gain an understanding of the path of data from source systems into the EDGE server.

CMS requires that mapping documentation be captured for D&E Data Elements, RXC Data Elements, and NECs. Mapping documentation created by issuers for IVA Entities must be identified and recorded in the *IVA Entity Audit Results Submission XML* and submitted during the IVA Data Submission process. The mapping documents must be clear and legible for the SVA

Entity's comprehension or may result in a data element validation error.

CMS requirements for issuer source system mapping documentation and corresponding data validation activities are detailed within Section 9.3.2 (Source System Documentation - Screenshots), and Section 9.7.3 (RXC Documentation).

### 9.3.2 Source System Documentation (Screenshots)

IVA Entities must work with issuers to obtain evidence from the issuer's source systems that include D&E Data Elements and RXC Data Elements for selected enrollees in the issuer's sample, as well as any data necessary for NEC validation. This evidence is expected to be in the form of screenshots of the actual data in the issuer's source system(s). In order to validate the required D&E and RXC Data Elements, screenshots from various source systems may be necessary, including membership or enrollment, premium billing, claims adjudication, and Pharmacy Benefit Manager's (PBM) system(s).

Source documentation requirements are defined in Table 6.

**Table 6: Source Documentation**

Source documentation is expected to:
<ul style="list-style-type: none"> <li>• Capture all required HHS-RADV data elements.               <ul style="list-style-type: none"> <li>– <i>The eleven (11) required D&amp;E Data Elements are identified in Section 9.4.</i></li> <li>– <i>If required, the six (6) RXC RADVPCE data elements, and/or the four (4) RXC RADVMCE data elements identified in Section 9.7.3.1.</i></li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Be in the form of screenshots of the actual data in the issuer source system(s).               <ul style="list-style-type: none"> <li>– <i>Any data elements that exist in an issuer's source system must be documented from that source system using the screenshot requirements as stated.</i></li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Be understandable in the context of an audit.               <ul style="list-style-type: none"> <li>– <i>The screenshots should provide sufficient information to allow a reviewer the ability to confirm the accuracy of the data being validated with no additional inquiry required.</i></li> <li>– <i>Tick-marking screenshots is encouraged to achieve this requirement and is discussed further in Section 9.3.3.1.</i></li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Reflect the most recent enrollment file or claim data submission to the EDGE server for the 2018 benefit year.</li> </ul>
<ul style="list-style-type: none"> <li>• Be accompanied by workpapers in the event that a data element has been manipulated or differs from that which was submitted to EDGE.               <ul style="list-style-type: none"> <li>– <i>These workpapers should be based directly on supporting documentation provided by the issuer to substantiate the manipulation of the source data.</i></li> <li>– <i>Refer to Section 9.3.3 for additional information regarding workpaper documentation.</i></li> </ul> </li> </ul>
<p><b>NOTE: Source documentation shall not be in the form of a data extract or report query.</b></p>

The IVA Entity is not required to have physical or logical access to issuer systems or to oversee the screenshot process in real time. However, all screenshots taken, whether by the issuer or IVA Entity, must be understandable in the context of an audit and meet all criteria as specified in Table 6. Both IVA and SVA Entities will rely upon screenshot documentation to abstract data values and compare them to data submitted to the EDGE server.

### 9.3.2.1 Screenshot Automation

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

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

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

If the issuer and IVA Entity elect to utilize an automated screenshot process, the below listed guidelines are recommended but not required:

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

The IVA Entity should understand and validate script parameters, execution results, and log review, if these guidelines are used.

### 9.3.3 Audit Workpapers

To assist in a comprehensive and logical audit, issuers may provide workpapers to IVA Entities, and IVA Entities may submit workpapers to CMS and the SVA Entity. Workpapers provide a means to communicate HHS-RADV program-related matters that would not otherwise be documented in the *IVA Entity Audit Results Submission XML*, and play a critical role in allowing the SVA to evaluate and interpret the findings of the IVA Entity.

Workpapers will be drafted as required throughout the D&E validation, RXC validation, and health status validation phases of the HHS-RADV process by the IVA Entity. Workpapers should document the IVA Entity’s procedural steps taken to validate issuer data using the screenshot documentation and any accompanying mapping documentation. IVA Entities will validate the workpapers with the issuer to ensure the procedures align with the issuer’s systems and processes.

IVA Entities will combine workpaper documentation with source system documentation (screenshots), and/or medical records to capture evidence of their validation process. Documentation of validation procedures in workpapers is important and should be prepared so that an experienced auditor, having no previous connection to the audit, can re-perform the validation. Note that workpapers are not required, but are strongly encouraged by CMS in all phases of the Audit Process.

Additionally, issuers can use workpapers to outline any data inaccuracies that occurred during EDGE server submission and were reported as a RA discrepancy. For workpaper guidelines and

sample documentation refer to [Appendix A](#) (2018 Benefit Year D&E Documentation Examples).

### 9.3.3.1 Tick-Marking Source System Documentation

Tick-marking (adding numeric or symbol indicators to a document to assist in interpretation) is an effective method of improving the consistency and clarity of audit documentation. Tick-marking source system screenshot documentation, and explaining these tick-marks in mapping documents or accompanying workpaper documents, is strongly encouraged.

### 9.3.4 Medical Record Documentation

Issuers and IVA Entities are required to obtain medical record documentation for enrollees in the IVA sample.

For the purpose of HHS-RADV, medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers, observations, notes, therapies, assessment, clinical impression, diagnosis, tests, and services. “Medical record documentation” means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted RA services that occurred during a specified time period. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services within the state. See [Appendix E](#) (Guidance to Coders), for examples of acceptable and unacceptable provider signatures.

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

## 9.4 Phase 1 – Creating Mapping Documentation (Issuer)

Issuers are required to provide IVA Entities with a set of documents that map the issuer’s source system data to EDGE server data submissions. The mapping documents must be clear and legible for the SVA Entity’s comprehension or may result in a data element validation error. This section provides details specific to D&E mapping documentation requirements. Details specific to mapping documentation requirements for RXC validation are discussed in Section 9.7.3.1 (RXC Mapping Documentation).

The documentation provided from issuers must indicate:

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

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

- A detailed process narrative, which may include supporting documentation such as process flows, data mapping tables, screenshots, or other information that would allow a third party to understand the processes and to map the data without additional inquiry.
- Mapping documentation linking each data element (and their EDGE server acceptable values) to the corresponding element in the issuer's source systems via screenshots. The EDGE server data elements that must be mapped to source systems/processes are listed in Table 7.

Column one (1) outlines the data elements required to be mapped.

Column two (2) is the corresponding XML element in the HHS-RADV sampling reports.

Column three (3) indicates the EDGE Sampling Report where that data element is located.

**Table 7: EDGE Enrollment Data Elements**

<b>Enrollment Data Elements (ICD)</b>	<b>XML Element Reference</b>	<b>EDGE Sampling Report Reference</b>
Unique Enrollee Identification (UID)	insuredMemberIdentifier	RADVEE
Member ID	N/A	N/A - IVA Entity to Identify
Enrollee First Name	N/A	N/A - IVA Entity to Identify
Enrollee Last Name	N/A	N/A - IVA Entity to Identify
Enrollee Date of Birth (DOB)	insuredMemberBirthDate	RADVEE
Enrollee Gender	insuredMemberGenderCode	RADVEE
Plan ID, which includes: <ul style="list-style-type: none"> <li>• HIOS ID</li> <li>• CSR Factor</li> </ul>	insurancePlanIdentifier	RADVEE
Enrollment Start Date	coverageStartDate	RADVEE
Enrollment End Date	coverageEndDate	RADVEE
Premium Amount	insurancePlanPremiumAmount	RADVEE
Rating Area	ratingAreaIdentifier	RADVEE

CMS requires a specific mapping document to be created and uploaded, containing the data elements referenced in Table 7. For the 2018 benefit year, CMS requires that issuers create and IVA Entities submit at minimum of one (1) mapping document. If issuers and IVA Entities choose to submit only one (1) mapping document, this document should contain all data elements identified in Table 7 and their mapping information. IVA Entities may elect to submit additional “Other” mapping documents to provide additional information related to mapping of source system data to EDGE. Note that enrollee demographic information and EDGE server UIDs must be submitted, providing the IVA Entity and the SVA the ability to map UIDs to the corresponding enrollee. Additional detail regarding this mapping document can be found in Section 9.4.1 (Mapping EDGE Unique Enrollee ID to Source System Member ID & Demographic Information).

Content required for submission within the consolidated mapping documentation is specified below:

UID / Member ID / Name / DOB / Gender Mapping – Refer to Section 9.4.1 (Mapping EDGE Unique Enrollee ID to Source System Member ID & Demographic Information) for additional detail;

- Plan ID Mapping;
- Rating Area Mapping;
- Premium Mapping;
- Enrollment Period Mapping;
- Other Mapping (*Optional*).

Within the mapping documentation, issuers are required to define how source system data corresponds to submitted EDGE server data. In the event source system data does not exactly match an EDGE server field definition, the issuer must document any interim steps or transformations performed to change the data (e.g., DOB 1/1/40 changed to DOB 1940-01-01). The issuer must also document the process of creating and linking UIDs between their EDGE server and their source data systems.

Note that RXC mapping documentation may be consolidated with D&E mapping documentation content and submitted as a single document in the IVA submission process. RXC specific mapping documentation and the RXC required data elements to be included are detailed in Section 9.7.3.1 (RXC Mapping Documentation). Mapping documentation will be used in the analysis and validation of D&E and RXC data elements, and is essential for both the IVA and SVA Entities to complete audit activities.

#### **9.4.1 Mapping EDGE Unique Enrollee ID to Source System Member ID & Demographic Information**

The issuer and/or IVA Entity must include in their mapping documentation the details necessary to provide a crosswalk between the EDGE server UID and the issuer’s Member ID, DOB, Gender, and First Name and Last Name for each enrollee in the complete IVA Sample. **Each enrollee in the IVA Sample must be included in the document. This is an essential step required for all enrollees in the complete IVA sample.** This is required to link EDGE server data to key information not found in the EDGE server (Source system Member ID, Enrollee First Name, Enrollee Last Name).

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

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

#### **9.4.2 Mapping of Supplemental Diagnoses**

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

applicable business rules.

## 9.5 Phase 2 – Review and Confirm Mapping

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

Workpapers must be drafted by the IVA Entity as required throughout D&E data validation, RxC validation, and NEC data validation to supplement mapping documentation. Workpapers must combine issuer documentation (source system documentation and mapping documentation) with the IVA Entity's procedural steps taken to validate the issuer data. The IVA Entity will review the workpapers with the issuer to ensure the procedures align with the issuer's systems and processes.

## 9.6 Phase 3 – D&E Data Validation

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

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

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

As set forth in the 2019 Payment Notice<sup>18</sup>, CMS will use HHS-RADV as a method of discovering materially incorrect EDGE server data submissions and making adjustments pursuant to 45 C.F.R. § 153.630(e).<sup>19</sup> D&E errors discovered during HHS-RADV will be the basis for adjustments to the applicable benefit year transfer amount, rather than the subsequent benefit year risk score, as underlying errors in diagnoses contributing to risk scores are treated.

For example, in cases where there is a material impact on RA transfers for that particular market as a result of incorrect EDGE server premium data discovered through HHS-RADV or otherwise, CMS would calculate the dollar value of differences in RA transfers, and, where the difference is detrimental to one (1) or more issuers in the state market risk pool, adjust the other issuers' RA

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<sup>18</sup> 83 FR at 16970.

<sup>19</sup> This guidance is also included in the [Evaluation of EDGE Data Submissions for the 2018 Benefit Year](https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf), released on November 15, 2018, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf>.

transfer amounts by that calculation, and increase the RA charge (or decrease the RA payment) to the issuer that made the data error, in order to balance the market. CMS will evaluate all D&E Data Elements required for validation similarly.

Issuers identified as having D&E errors will receive outreach from CMS to evaluate the prevalence of these errors. These issuers may require EDGE data correction through the discrepancy process if material errors are identified.

### 9.6.1 Audit Steps

The steps that should be taken when performing D&E data validation for the enrollees in the IVA sample are described in this section and consist of the two (2) primary steps:

**Step 1:** Linking the enrollee in the IVA sample to the enrollee in the issuer’s source system (required for the full IVA sample);

**Step 2:** Validating enrollee data elements (required for D&E subsample only)

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

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

#### Step 1: Linking the Enrollee to the IVA Sample (required for the complete IVA sample)

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

It is important to note that, as stated in Section 9.4.1 (Mapping EDGE Unique Enrollee ID to Source System Member ID & Demographic Information) the linking of source system data to the enrollee in the IVA sample is done by linking the masked UID from the EDGE server to the actual enrollee Member ID within the issuer’s source system, and this is required for all enrollees in the IVA sample. Without this linkage, the IVA and SVA Entities will not have the ability to verify the enrollee in the IVA sample or verify that the medical records are linked to the correct enrollee.

**Step 2: Validating Enrollee D&E Data Elements (required for D&E subsample only)**

Sub-step	Description	Additional Details
1	IVA Entity gathers source system documentation <b>including screenshots</b> for the enrollees in the D&E subsample.	Reviewer gathers issuer mapping documentation and enrollment screenshots to perform D&E data review for the enrollees in the D&E subsample.
2	IVA Entity obtains EDGE server data element values and performs D&E data review.	<p>The reviewer performs D&amp;E data review for EDGE server data elements based on screenshot evidence. These data elements are:</p> <ul style="list-style-type: none"> <li>- DOB</li> <li>- Gender</li> <li>- Plan ID</li> <li>- Enrollment Start Date</li> <li>- Enrollment End Date</li> <li>- Premium Amount (for subscriber enrollees only)</li> <li>- Rating Area (for subscriber enrollees only)</li> </ul> <p>Reviewers identify the corresponding data element in the source system screenshot documentation and consult with the issuer to determine an accurate value (i.e., what should have been submitted to the EDGE server, based on the source system).</p> <p>Once identified, this value is compared to the RADVEE Report data value.</p>
3	IVA Entity drafts workpaper documentation as needed.	<p>In the event that the source system data does not match the EDGE server data, or requires data transformation, the reviewer will document the correct value or data transformation in an accompanying workpaper.</p> <p><b>Note:</b> CMS review is constrained to EDGE data for the benefit year being audited, including the evaluation of enrollment coverage dates. In the event an enrollment coverage date extends past the end of the benefit year, CMS evaluates if the dates indicated are consistent with coverage through the last day of the benefit year being audited. CMS encourages the IVA Entity and issuer to coordinate on the findings and any discrepancy identified.</p>
4	IVA Entity records results.	The reviewer records the results found from the issuer's source system for the enrollee in the <i>IVA Entity Audit Results Submission XML</i> .
5	IVA Entity repeats for the next enrollee in the D&E subsample.	The reviewer repeats the steps for the next enrollee in the D&E subsample.

An example of mapping documentation, screenshots, and workpapers, is demonstrated within

[Appendix A](#) (2018 Benefit Year D&E Documentation Examples).

Refer to [Appendix B](#) (D&E Subsample Data Elements), for detailed validation guidance regarding the 2018 benefit year HHS-RADV D&E subsample data elements.

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

For the purposes of D&E review specific to enrollees with system-generated enrollment records associated with cross-year claims, IVA Entities should validate the 2017 benefit year enrollment period which led to the creation of the 2018 benefit year system-generated enrollment period.

For these enrollees, the IVA Entity or issuer should substantiate the latest enrollment information from the prior year via screenshots and workpapers and document that the enrollee was appropriately enrolled prior to creation of the system-generated enrollment period. Issuers should provide IVA Entities with the applicable 2017 benefit year plan enrollment screenshots to confirm that the system-generated enrollment period was appropriately created for the individual. IVA Entity workpapers should indicate how the source system enrollment period corresponds to the system-generated enrollment record. IVA Entities should submit this documentation as part of their IVA Entity Audit Results Submission (XML) and Package 1 Submission for CMS and SVA review.

**Note:** Premium Amount and Rating Area are only required to be validated for Subscriber enrollees.

### **Newborn Verifications with No Source System Support**

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

IVA Entities should only evaluate medical record documentation for enrollees in the IVA Sample. In the event the newborn information was not separated and unbundled from the mother, in accordance with the ESBR, the newborn information should not be evaluated as part of the mother's health status. Detailed information related to unbundling of newborn and mother data is captured in the **ESBR Version 12.0**, which can be found in the REGTAP Library (<https://www.regtap.info/>).

The IVA Entity must confirm that the guidance contained in **ESBR Version 12.0** was followed appropriately for handling newborn coverage. The issuer must provide evidence of newborn coverage through workpaper documentation, if there are no screenshots.

### **Changes to Enrollment Records Following RA Data Submission**

In certain circumstances, it is possible that enrollee information is updated following final data submission for RA (e.g., gender changes from Male to Female). In the event issuers can adequately support these situations with documentation from source systems, IVA Entity

reviewers will document the post-submission updated enrollment data value as stored in the issuer's source system, along with workpaper documentation providing a clear explanation of the steps taken to validate the issuer's information.

### **Documentation of Enrollment Periods**

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

## **9.7 Phase 4 – RXC Validation**

Beginning with the 2018 benefit year, CMS will incorporate the validation of RXCs into the HHS-RADV IVA and SVA processes to validate the prescription drug component of adult enrollees' risk scores. All issuers are required to participate in the HHS-RADV RXC validation for the 2018 benefit year.

As finalized in the 2020 Payment Notice<sup>20</sup>, the 2018 benefit year HHS-RADV RXC validation will be treated as a pilot year, in that CMS will not use RXC validation results to adjust enrollee risk scores as a result of findings from the claim-based validation. Rather, CMS will use the findings from the RXC data element validation as a data quality control measure and will evaluate the findings of the 2018 benefit year to inform future decisions specific to error application, sampling, and reporting for RXC data. In order to have an informative pilot year, CMS will implement all aspects of the RXC validation process in 2018 benefit year HHS-RADV, including outreach to issuers with identified errors; however, CMS will not use RXC validation results to adjust enrollee risk scores or transfers as a result of findings from the claim-based validation.

The three (3) primary objectives of RXC validation are as follows:

- Validate that the prescription was filled (RXC Source: Pharmacy Claim);
- Validate that the RXC eligible Product/Service ID is on a pharmacy claim paid by the issuer;
- Validate that the RXC eligible Service Code is on a medical claim paid by the issuer.

RXC validation will be conducted as a claim-based review process. For each enrollee's RXC, an RXC-eligible<sup>21</sup> claim on the RADVPCE or RADVMCE Report must be identified and validated. Issuers and IVA Entities must validate that the claim in the issuer source system supports the claim submitted to the EDGE server.

### **9.7.1 RXC Sample Size**

The total population of issuers' enrollees with RXCs is expected to be relatively low compared to the population of enrollees with HCCs. Only adult enrollees (a subset of IVA sampled enrollees) can have an RXC, and the observed frequency of RXCs among adult enrollees is relatively low.

All adult enrollees with at least one (1) RXC in the IVA sample constitute the RXC sample for an issuer. CMS **will not** separately communicate an RXC sample to the issuer. The issuer's HHS-

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<sup>20</sup> 84 FR at 17501.

<sup>21</sup> RXC eligible medical claims are identified in the RADVMCE Report by the 'RXC Eligible Flag' data element, where 'Y' indicates that the RADVMCE claim is RXC eligible. RXC eligible pharmacy claims are listed in the RADVPCE Report.

RADV sampling reports must be used to determine the applicable RXC sample.

**Note:** If an issuer has no adult enrollees in the IVA sample with an RXC, the issuer is not subject to any of the RXC validation requirements.

To determine the enrollees in the RXC sample, IVA Entities should review the RADVDE Report to identify all enrollees with at least one (1) RXC. All RXCs for the RXC sample enrollees must be validated by the IVA Entity. As a result, CMS encourages issuers and IVA Entities to communicate to identify the unique RXCs for each sampled adult enrollee with RXCs which are required for validation.<sup>22</sup>

### 9.7.2 Identifying RXC Source

To support the validation of sampled adult enrollees' RXCs, issuers and IVA Entities must first determine the source of the RXC. The RXC source includes the following:

- The National Drug Code (NDC), submitted on a pharmacy claim, and
- The Healthcare Common Procedure Coding System (HCPCS)/Service Code submitted on a medical claim.

To identify the source of each enrollee's RXC, issuers and IVA Entities should use 'Table 10a' and 'Table 10b' of the 2018 Benefit Year HHS-Developed RA Model Algorithm "Do It Yourself (DIY)" Software (4/4/2019).

**Note:** The 2018 Benefit Year HHS-Developed RA Model Algorithm "Do It Yourself (DIY)" Software (4/4/2019) and instructions can be found on the CCIO website or by using the following links:

- **Instructions:** <https://www.cms.gov/CCIO/Resources/Regulations-and-Guidance/Downloads/Updated-CY2018-DIY-instructions.pdf>
- **Technical Details (tables):** <https://www.cms.gov/CCIO/Resources/Regulations-and-Guidance/Downloads/Updated-DIY-Tables-2018.xlsx>

DIY Table 10a provides a crosswalk for NDCs to RXCs and DIY Table 10b provides a crosswalk for HCPCS service codes to RXCs. Issuers and IVA Entities can use these tables to identify the RXC source for each unique RXC for an enrollee in the RXC sample by crosswalking an enrollee's pharmacy claim NDCs from the RADVPCE Report to the RXCs identified in DIY Table 10a. Similarly, a HCPCS code from an RXC-eligible medical claim on the RADVMCE Report can be crosswalked to the RXCs identified in DIY Table 10b.

If an RXC can be linked to both a RADVPCE and a RADVMCE claim, the IVA Entity is only required to validate one (1) of the corresponding linked claims to substantiate the RXC for the enrollee. For example, when both a pharmacy claim NDC and a RXC-eligible medical claim HCPCS service code correspond to 'RXC 1' per DIY Tables 10a and 10b, then only one (1) claim is required to be validated. However, if the claim selected for validation cannot be validated by the IVA Entity, issuers and IVA Entities are encouraged to identify other claims on the RADVPCE or RADVMCE reports to substantiate the RXC.

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<sup>22</sup> RXCs are only associated with adult enrollees in the RA model. In HHS-RADV, enrollees in strata 1-3 (Adult: High, Adult: Medium, and Adult: Low) are the only enrollees who may be assigned an RXC.

Once the RXC source is determined (pharmacy claim NDC or RXC-eligible medical claim HCPCS service code), issuers must identify the corresponding source system claim to facilitate the IVA Entity (and SVA) review activities, as described in Section 9.7.3 (RXC Documentation).

### 9.7.3 RXC Documentation

The documentation requirement for the RXC validation process is similar to that of the D&E process, and includes:

- **Mapping Documentation** (Section 9.7.3.1) – Issuer documentation enabling the linking of source system data to EDGE data identified in the RADVPCE or RADVMCE Reports
- **Source System Documentation – Screenshots** (Section 9.7.3.2) – Source system documentation of positively adjudicated pharmacy or RXC-eligible medical claims. For the purposes of RXC validation, one (1) of the following source system submissions are acceptable:
  - Issuer system screenshot(s) containing the required validation data elements.
    - This includes screenshot(s) from the issuer’s system following the ingest of data files obtained from a Pharmacy Benefit Manager (PBM).
  - PBM system screenshot containing the required data elements.
- **Workpapers** (Section 9.7.3.3) – IVA Entity documentation explaining details of audit steps performed

**Note:** IVA Entities and issuers are **not** required to engage with or retrieve supporting documentation from dispensing providers or medical providers to validate RXCs.

#### 9.7.3.1 RXC Mapping Documentation

Issuers are required to provide IVA Entities with documentation which maps the issuer’s source system data to submitted EDGE server data. This mapping documentation must contain information specific to the RXC linked claims and must be sufficient to allow the IVA and SVA Entities to interpret claim source system screenshots and validate claims data.<sup>23</sup>

All RXC mapping documentation may be compiled into one (1) mapping document that contains all elements (inclusive of those in Tables 8 and 9), and may also be consolidated with D&E mapping documentation (see Section 9.4 – Phase 1 - Creating Mapping Documentation). Additional mapping document files may be submitted with the ‘Other Mapping’ file type in the XML Submission.

The data elements included in RXC mapping documentation must correspond to the claim type (RADVPCE or RADVMCE) being used to validate the RXCs.

- If pharmacy claims from the RADVPCE Report are utilized, RADVPCE data elements must be documented in the mapping documentation.
- If RXC-eligible medical claims from the RADVMCE Report are utilized, RADVMCE data elements must be documented in the mapping documentation.
- If both are used, RADVPCE and RADVMCE data elements must be documented within the

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<sup>23</sup> See Section 9.4 – Phase 1 – Creating Mapping Documentation for additional detail

mapping documentation.

Mapping documentation provided must enable the linking of each RADVPCE or RADVMCE data element to the corresponding element in the issuer's source systems.

### **RADVPCE Data Elements**

The RADVPCE Report data elements listed in Table 8 must be validated when an RXC is associated with a National Drug Class (NDC) 'Product/Service ID' on a pharmacy claim. If a RADVPCE claim is utilized, each data element below must be documented in mapping documentation.

Note the following for Table 8:

- The left column lists the data elements required to be mapped to the issuer's source system.
- The right column lists the corresponding XML element in the RADVPCE Report.

**Table 8: RADVPCE Data Elements**

<b>Claim Data Elements (ICD)</b>	<b>XML Element Reference<sup>24</sup></b>
Unique Enrollee Identification (UID)	insuredMemberIdentifier
Source System Claim ID <sup>25</sup>	N/A
Claim ID	claimIdentifier
Claim Processed Date Time	claimProcessedDateTime
Fill Date	prescriptionFillDate
Dispensing Provider ID	dispensingProviderIdentifier
Product/Service ID	nationalDrugCode

### **RADVMCE Data Elements**

The RADVMCE Report data elements listed in Table 9 must be validated when an RXC is associated with a Healthcare Common Procedure Coding System (HCPCS) service code on an RXC-eligible medical claim. If a RADVMCE claim is utilized, each data element below must be documented in mapping documentation.

Note the following for Table 9:

- The left column lists the data elements required to be mapped to the issuer's source system.
- The right column lists the corresponding XML element in the RADVMCE Report.

**Table 9: RADVMCE Data Elements**

<b>Claim Data Elements (ICD)</b>	<b>XML Element Reference</b>
Unique Enrollee Identification (UID)	insuredMemberIdentifier

<sup>24</sup> See the Interface Control Document – Risk Adjustment Data Validation (RADV) Addendum posted in the REGTAP Library

<sup>25</sup> The Source System Claim ID is not in the RADVPCE Report but rather the claim ID from the issuer's source system that maps to the claim submitted to the EDGE server which is represented by the Claim ID in the RADVPCE Report

Claim Data Elements (ICD)	XML Element Reference
Source System Claim ID <sup>26</sup>	N/A
Claim ID	claimIdentifier
Claim Processed Date Time	claimProcessedDateTime
Service Code	serviceCode

## Mapping Documentation – Mapping EDGE Claim IDs to Source System Claim IDs

To support the IVA Entity in determining the claim in the issuer’s source system to validate, issuers may choose to provide the IVA and SVA Entities with a crosswalk of RADVPCE or RADVMCE Claim ID and Source System Claim ID reference information. The crosswalk can be developed by establishing a table within the mapping documentation to include the RADVPCE or RADVMCE Claim ID and the corresponding Source System Claim ID. This information enables the IVA and SVA Entities to link the source system claim to the EDGE Claim ID on the RADVPCE or RADVMCE Report.

### 9.7.3.2 RXC Source System Documentation (Screenshots)

For the RXC claims-based review process, source system documentation (screenshots) must be provided to enable the audit steps defined in Section 9.7.4 (RXC Validation Steps) by IVA Entities and the SVA Entity. Source system screenshot documentation must be provided for all required RXC Data Elements found on the RADVMCE and RADVPCE Reports.

The source system screenshot provided for each RXC claim data element must be sufficient to allow the IVA and SVA Entities to determine the appropriate RADVPCE or RADVMCE data value when reviewed in conjunction with mapping and workpaper documentation. This documentation should enable an independent reviewer to reproduce validation activities and arrive at the same conclusion (i.e., the same determined data value).

### Documenting Enrollee Details for RXC Linked Claims

When obtaining source system documentation (screenshots) of Source System Claim IDs for each RXC linked claim, issuers and IVA Entities must include in these screenshots any associated enrollee identifying information for the claim, including DOB, Gender, First Name, and Last Name if available in the source system. The IVA and SVA Entities will utilize this information in conjunction with issuer provided mapping documentation to confirm that the source system claim data can be linked to sampled enrollee for which it is submitted. This activity is detailed in Section 9.7.4 (RXC Validation Steps), Step 3, Sub-step 2.

### 9.7.3.3 RXC Workpaper Documentation

CMS encourages IVA Entities to develop workpaper documentation to capture any details specific to the interpretation, calculation, or correlation of source system data to EDGE data. Additionally, workpaper documentation may be used to identify steps taken to reconcile source system documentation (screenshots) with mapping documentation in order to verify RADVPCE or RADVMCE data for RXC linked claims.

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<sup>26</sup> The Source System Claim ID is not in the RADVMCE Report but rather the claim ID from the issuer’s source system that maps to the claim submitted to the EDGE server which is represented by the Claim ID in the RADVMCE Report

## 9.7.4 RXC Validation Steps

The steps taken when performing RXC validation for the adult enrollees in the RXC sample consist of the following:

- **Step 1:** Use the RADVDE Report to determine the adult enrollees in the RXC sample and the list of unique RXCs to be validated for each enrollee;
- **Step 2:** Use DIY Tables 10a and 10b to determine the source for each RXC to be validated (NDC code from a pharmacy claim or HCPCS from an RXC-eligible medical claims);
- **Step 3:** Use issuer mapping documentation to identify the RXC linked claim on the RADVMCE or RADVPCE Report;
- **Step 4:** Use screenshots to validate issuer source system claim data and determine values for each RADVPCE or RADVMCE data element; and
- **Step 5:** Record results and assess if all adult enrollee RXCs have been validated by the IVA Entity.

**Step 1:** Use the RADVDE Report to determine adult enrollees in the RXC sample and the list of unique RXCs to be validated for each enrollee.

Sub-step	Description	Additional Details
1	Determine enrollees included in the RXC sample	Reviewer references the RADVDE Report to determine all adult enrollees with RXCs that require validation. Enrollees where RADVDE data element 'Total Payment RXCs' is one (1) or greater, indicates that RXCs were attributed to the enrollee.
2	Determine the RXCs for each enrollee to be validated	For each adult enrollee where RADVDE data element 'Total Payment RXCs' is one (1) or greater, reference the RADVDE data element 'RXC' to determine the unique RXCs requiring validation.

**Step 2:** Use DIY Table 10a or 10b to determine the source for each RXC to be validated (NDC code from a pharmacy claim or HCPCS from an RXC-eligible medical claim).

Sub-step	Description	Additional Details
1	Determine the source of the enrollee RXC	Reviewer determines the source of the unique RXC that requires validation. The source for a unique RXC can be from the following: <ul style="list-style-type: none"> <li>• NDC code submitted on a pharmacy claim (RADVPCE Report) or</li> <li>• HCPCS/Service Code submitted on an RXC-eligible medical claim (RADVMCE Report).</li> </ul>
2	IVA Entity references the 2018 DIY Tables 10a and 10b for RXC crosswalk	Reviewer references the 2018 DIY Tables 10a and 10b to determine the appropriate crosswalk for each enrollee RXC in the RXC sample. <ul style="list-style-type: none"> <li>• Crosswalking an enrollee's RXC identified in the RADVDE Report to an NDC identified in DIY Table 10a</li> <li>• Crosswalking an enrollee's RXC identified in the RADVDE Report to a HCPCS code identified in DIY Table 10b</li> </ul>

**Step 3:** Use issuer mapping documentation to identify the RXC linked claim on the RADVMCE or RADVPCE Report.

Sub-step	Description	Additional Details
1	For each unique enrollee RXC, the IVA Entity and issuer select a linked claim on the RADVPCE or RADVMCE Report which corresponds to the enrollee's RXC	<p>Once the RXC source is determined (NDC/pharmacy claim or HCPCS/RXC-eligible medical claim), reviewers must identify the corresponding source system claim within the issuer provided mapping documentation.</p> <p>Reviewers are only required to validate a unique RXC once, with the appropriate data elements corresponding to the report which they are using to substantiate the RXCs.</p> <p><i><b>Example:</b> The RADVDE Report identifies an enrollee has RXC 4. RXC 4 maps to NDC code '00024107501' from a pharmacy claim for the enrollee on the RADVPCE report. The same RXC 4 also maps to HCPCS 'J0881' code which is found on an RXC-eligible medical claim for the enrollee found on the RADVMCE Report.</i></p> <p>Selecting one (1) claim for validation (either the RADVPCE or RADVMCE claim) and submitting the appropriate data elements related to the claim will result in a successful validation of the RXC.</p>
2	IVA Entity confirms that the linked claim is for the sampled enrollee	<p>Reviewer confirms that the EDGE Unique Enrollee ID on the RADVDE report corresponds to the Unique Enrollee ID in the RADVPCE or RADVMCE report associated with the linked pharmacy or medical claim.</p> <p>Next, the Reviewer identifies the Source System Claim ID in the issuer's RXC mapping documentation that corresponds to the linked Claim ID from the RADVPCE or RADVMCE report.</p> <p>Next, the Reviewer confirms that in the claim source system, data elements including DOB, Gender, First Name, and Last Name correspond to the DOB and Gender for the enrollee as identified in the RADVEE report and the First Name and Last Name of the enrollee as documented in the UID mapping documentation referenced in Section 9.4.1 - Mapping EDGE Unique Enrollee ID to Source System Member ID &amp; Demographic Information).</p> <p>If, using professional judgement, the Reviewer determines that source system claim DOB, Gender, First Name, and Last Name corresponds to the DOB and Gender on the RADVEE report and the First Name and Last Name identified in the UID mapping documentation, the Reviewer may continue to Step 4.</p>

**Step 4:** Use screenshots to validate issuer’s source system claim data and determine values for each RADVPCE or RADVMCE data element.

Sub-step	Description	Additional Details
1	For each unique enrollee RXC linked claim, the IVA Entity gathers source system documentation <b>including screenshots</b> to support the data elements selected for review	Reviewer gathers issuer mapping documentation that contains claim specific data elements for the selected claim to be validated (RADVPCE and RADVMCE) and claim screenshots to perform the RXC validation for all enrollees’ RXCs in the RXC sample as determined in Step 1.
2	IVA Entity obtains EDGE server data element values and performs RXC data review	<p>The reviewer performs RXC data review for EDGE server data elements based on screenshot evidence. For each linked claim, the IVA Entity shall review and evaluate screenshot documentation to determine if source system data corresponds to EDGE server data for the linked claim.</p> <p>If the linked claim is a RADVPCE Report claim, the following data elements are required to be validated:</p> <ul style="list-style-type: none"> <li>- Source System Claim ID</li> <li>- Claim Processed Date/Time</li> <li>- Fill Date</li> <li>- Dispensing Provider ID</li> <li>- Product/Service ID</li> </ul> <p>If the linked claim is a RADVMCE Report claim, the following data elements are required to be validated:</p> <ul style="list-style-type: none"> <li>- Source System Claim ID</li> <li>- Claim Processed Date/Time</li> <li>- Service Code</li> </ul>
3	IVA Entity drafts workpaper documentation as needed	<p>In the event that the source system data does not match the EDGE server data on the RADVPCE or RADVMCE report and/or requires data transformation, the reviewer will document the correct value or data transformation in an accompanying workpaper.</p> <p>If the IVA Entity determines that the EDGE value for the data element under review is different than the EDGE value on the RADVPCE or RADVMCE report or is unable to substantiate the applicable data element, this information should be documented within the results submission documentation and workpapers.</p>

**Step 5:** Record results and assess if all enrollee RXCs have been validated by the IVA Entity

Sub-step	Description	Additional Details
1	IVA Entity records results	The reviewer records the results found from the issuer's source system for the enrollee in the <i>IVA Entity Audit Results Submission XML</i> .
2	IVA Entity repeats these steps for the next enrollee in the RXC sample	The reviewer repeats the steps for the next enrollee RXC in the RXC sample.  <b>Note:</b> Detailed Audit Tool procedures and guidance, including IVA Entity Audit Results Submission XML data elements, will be provided via webinar guidance, documented within the IVA Submission XML ICD, and subsequently retained within REGTAP.

Refer to [Appendix C](#) (Final Drug Diagnosis (RXC-HCC) Pairs for the 2018 Adult Models) for additional details regarding the final drug diagnosis pairs for the 2018 Adult Model.

## 9.8 Phase 5 – Health Status Data Validation

Health status data validation will be performed on all enrollees in the IVA Sample in order to substantiate diagnoses in accordance with the International Classification of Diseases (ICD) Clinical Modification (CM) Tenth edition coding guidelines, hereafter referred to as ICD-10-CM. See [Appendix D](#) (ICD-10-CM Official Guidelines for Coding and Reporting) for additional resources and guidance.

**Figure 1: Health Status Data Validation**



Figure 1 illustrates the IVA and SVA Entity health status data validation process.

The issuer or IVA Entity will link medical records for the enrollee with at least one (1) RA eligible claim per medical record, and the issuer will provide the medical records to the IVA Entity to evaluate. The linked claim for each medical record must be a claim on the RADVMCE report where the claims statement covers from/through date aligns to at least one (1) of the dates of service found on the medical record. Alternatively, if applicable, the medical record can be linked to a RA eligible paid/positively adjudicated NEC submitted via the NEC section of the *IVA Entity Audit Results Submission XML*. If this criterion is met, the medical record is permissible for review for the purposes of the 2018 benefit year HHS-RADV audit program. All diagnoses within the benefit year from a permissible medical record may be abstracted, independent of the enrollee's plan enrollment.

For 2018 benefit year HHS-RADV, CMS has revised HHS-RADV specific guidance for the abstraction of lifelong permanent health conditions. The 'Chronic Condition HCC' list of the 2017 benefit year HHS-RADV protocols is no longer valid. CMS has revised the 2018 Protocols document to include a simplified list of health conditions which share similar characteristics of being lifelong, permanent conditions. Conditions selected by CMS for inclusion in the 'Lifelong Permanent Conditions' list may be abstracted if documented in any of the documentation provided for an enrollee's medical history. Refer to [Appendix E](#) (Lifelong Permanent Conditions) for

additional information.

CMS encourages the utilization of the ICD-10-CM Official Guidelines for Coding and Reporting, the American Hospital Association (AHA) Coding Clinic, and the HHS-RADV 2018 benefit year Protocols, along with professional judgment to make final determinations when abstracting diagnoses related to all conditions not contained within this list.

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

CMS will allow medical records to be submitted that do not have an associated EDGE server claim, but for which the issuer did bear a financial risk. The IVA Entity should ensure that all required EDGE server data elements for these NECs are documented in the *IVA Entity Audit Results Submission XML* and that evidence of the source systems, including adjudication, is provided with the results.

Additionally, screenshot documentation of NECs must be provided along with the medical record for the purposes of health status validation.

### 9.8.1 Medical Record and Chart Retrieval

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

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

If the provided medical record does not contain sufficient medical documentation to abstract the intended diagnosis, the issuer and IVA Entity should work with the provider to obtain sufficient documentation. If the SVA Entity is not provided with sufficient medical documentation needed to support the diagnosis, the SVA Entity may not be able to abstract the diagnosis.

A HHS-RADV Provider Medical Record Request Memo, on CMS letterhead, will be provided via the Audit Tool for issuers and/or IVA Entities to send to relevant providers to support a medical record request. The memo will identify the purpose of the request and underscore the necessity that providers respond to the medical record request in a timely manner and at minimum submit all progress notes and discharge summary, if applicable, for the enrollee under review **to the issuer**. This memo shall not be altered in any way and shall not be used by the issuer or IVA Entity for any purpose other than retrieval of documentation to support HHS-RADV. Please note that the Provider Medical Record Request Memo should not be submitted with the accompanying medical record as part of the IVA results submission.

It is the issuer's responsibility to assist its IVA Entity in the retrieval of medical records and documentation sufficient to provide evidence of HCCs from providers; CMS cannot provide assistance. It is the issuer's responsibility to ensure all medical record requests contain the necessary information for the provider to fulfill the request, including the sampled patients' names, information about the date(s) of service being audited, and the corresponding address for medical record submission, so that providers can provide the relevant medical record documentation. The

HHS-RADV Provider Medical Record Request Memo can be accessed in the Audit Tool by selecting the "Library" tab and then clicking the "Guidance" section.

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

### **9.8.2 Medical Record Review and Diagnosis Abstraction – Overview**

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

Enrollee medical record review consists of the following steps:

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

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

Medical record review and diagnosis abstraction involves linking the medical record to one (1) of the enrollee's claims identified in the EDGE server RADVMCE Report, or as documented in the source system evidence.

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

IVA Entity Senior Coders shall also perform IRR on a sample of records for all Primary Coders and record the results of any revalidation. This process is detailed in Section 10 (IVA Inter-Rater Reliability).

### **9.8.3 Medical Record Intake**

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

Medical record intake can be completed by the Primary or Senior Reviewer, or by certified

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

- **Primary Reviewer:** The Primary Reviewer verifies that the enrollee name, DOB, and gender documented on the medical record matches the enrollee data on the UID mapping documentation provided by the issuer and confirmed by the IVA Entity. If there is a discrepancy, the issuer or IVA Entity may engage providers to verify that the correct medical record was provided, or to obtain the correct record if the provider supplied an incorrect record. If no provider errors are identified and discrepancies persist between the medical record and the enrollee, the Primary Reviewer will flag the medical record as an error. After review, files marked as errors will be sent to a Senior Reviewer.
- **Senior Reviewer:** The Senior Reviewer revalidates the steps for medical records that did not link to enrollee data on the UID mapping documentation provided by the issuer and confirmed by the IVA Entity. If the Senior Reviewer is unable to link the medical record to an enrollee in the IVA Sample, the Senior Reviewer will reject the record.

The Medical Record Intake Testing process consists of the following three (3) steps further described in Table 10.

- Step 1:** Gather medical record documentation;
- Step 2:** Primary Reviewer compares medical record data to the Unique Enrollee ID content in the mapping document;
- Step 3:** Senior Reviewer compares medical record data to the Unique Enrollee ID content in the mapping document.

**Table 10: Medical Record Intake Testing**

Step	Description	Additional Details
1	Gather medical record documentation.	Primary Reviewer gathers enrollee medical record documentation from the issuer to identify linking data element values on the medical record (First Name, Last Name, DOB, Gender).
2 (a-c)	Primary Reviewer – Compare medical record data to the Unique Enrollee ID mapping document.	The Primary Reviewer compares the demographic data from the medical record to the UID mapping documentation provided by the issuer and confirmed by the IVA Entity to determine, using professional judgment, that the fields recorded reasonably match.
		a) If there is agreement or the Primary Reviewer determines, using professional judgment, that the fields reasonably match, then the Primary Reviewer records the results as final in the <i>IVA Entity Audit Results Submission XML</i> . No additional review is necessary.
		b) If there are differences, the Primary Reviewer marks the inconsistent findings and submits the record to the Senior Reviewer for confirmation.

Step	Description	Additional Details
		<p>c) Chart Request Feedback Loop. For enrollee medical records for which inconsistent findings are initially identified, the IVA Entity reviewer should confirm with the issuer that the appropriate medical record requested was provided. This step may be performed either by the Primary Reviewer, prior to Senior Reviewer review, or by the Senior Reviewer once the files marked as containing errors are allocated for senior review. If performed by the Senior Reviewer, this process step would relocate within the table.</p>
3 (a-b)	Senior Reviewer – Compare medical record data to the Unique Enrollee ID mapping document.	The Senior Reviewer compares the results from the medical record to the UID mapping documentation provided by the issuer and confirmed by the IVA Entity 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, then the medical record should be passed along for diagnosis abstraction.
		b) If there is a difference and if the <i>Chart Request Feedback Loop</i> has been completed, the Senior Reviewer should reject the medical record.

### 9.8.4 Key Considerations of Medical Record Intake

#### Evaluating Match Between Medical Record and Demographics and Enrollment Data

In this process, the enrollee’s first name, last name, DOB, and gender should reasonably match between the medical record and the issuer provided UID mapping documentation. If a complete match between the medical record and the UID mapping documentation is not found, the IVA Entity may use professional judgment to support the verification of the step. If professional judgment is used, the IVA Entity should submit a medical record workpaper detailing why and how professional judgment was employed. The medical record workpaper should provide sufficient information for the SVA Entity to arrive at the same conclusion, as determined by the IVA Entity.

**Note:** The reasonability of a match is based upon the IVA Entity reviewer’s professional judgment. For example, one (1) source may show the enrollee’s name as Michael Smith, whereas the second source may show Mike Smith – based on a reviewer’s professional judgment, this scenario may be determined to be acceptable. In the event that the enrollee name, DOB, and gender cannot be corroborated between the UID mapping documentation and the data on the medical record, the IVA Entity must perform necessary due diligence to contact

issuers or providers and determine if the correct medical record was provided.

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

### **9.8.5 Documentation of Claims Not Accepted in EDGE**

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

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

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

#### **Cross-Year Claims**

For 2018 benefit year HHS-RADV, CMS has updated the RADVMCE Report claim logic to be inclusive of “cross-year claims” or claims with dates of service spanning across two (2) benefit years. “Cross-year claims” should not be submitted as NECs.

### **9.8.6 Acceptable Date of Medical Record or Claim**

The medical record date of service (DOS) defines when an enrollee received medical treatment from a physician, permitted provider, medical facility, or telehealth visit (as described in Section 9.3.4 Medical Record Documentation). For medical records to be permissible for HHS-RADV, the criteria listed below must be confirmed by IVA Entities. If the below criteria are met, then those medical records are permissible for review for the 2018 benefit year HHS-RADV audit:

1. All authenticated medical records from inpatient hospital, outpatient, and professional sources must match the demographic data for the sampled enrollee on the UID mapping documentation.
2. The medical record must be linked to either one (1) EDGE server accepted RA eligible claim from the RADVMCE Report where the claims statement covers from/through date aligns to at least one (1) of the dates of service found on the medical record. Alternatively, the medical record can be linked to a RA eligible paid/positively adjudicated NEC for the specified sampled enrollee, if applicable.

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

### 9.8.6.1 Inpatient Considerations

For inpatient records, when linking the medical record to a claim, the dates of service or admission and discharge dates on a medical record should align with the statement covers from/through dates on the claim. The statement covers through date and the discharge date MUST fall within the benefit year being audited. For example, if an enrollee is admitted to a hospital in December 2018 and is discharged in January 2019, the services performed that occurred in both December 2018 and January 2019 are considered in the 2019 benefit year for calculation of enrollee risk scores, and therefore are not eligible for the 2018 benefit year HHS-RADV.

#### Professional Service Claims Documented within Inpatient Stays

If an inpatient medical record spans multiple benefit years, the reviewer should ensure the discharge date is within the benefit year being audited. An inpatient medical record with an admission date in the benefit year being reviewed and the inpatient status extending into the next benefit year, is not considered valid in the benefit year being audited. An exception to this restriction is noted below.

If an inpatient medical record spanning multiple benefit years contains professional services that were paid/positively adjudicated separately as professional claims within the benefit year, CMS is providing amended guidance to allow issuers and IVA Entities to abstract diagnoses from the dates of service for these professional claims.

In this situation, a workpaper may be submitted to allow the abstraction of diagnoses associated with the professional service claims that were paid and positively adjudicated within the benefit year. IVA Entities should submit a medical record workpaper documenting the professional services claims evidenced within the inpatient record but claimed separately. This workpaper will enable the SVA to evaluate the professional services claims independently, despite the discharge date on the inpatient medical record being in the subsequent benefit year. Note that the SVA will only evaluate those professional claims identified within this workpaper document.

Additionally, for the purposes of linking the medical record to a RA accepted claim for submission of IVA Entity audit results, the medical record must be linked to a professional claim on the RADVMCE report or to a NEC professional claim. If the medical record is only linked to an inpatient hospital claim that crosses into the subsequent benefit year, then the professional services may not be abstracted separately.

For example: An enrollee is admitted to a hospital in December 2018 and the inpatient medical record indicates a discharge date in January 2019. However, there is a paid/positively adjudicated claim for professional services provided in December 2018. The IVA Entity should submit a medical record workpaper with the following information captured for the professional service claim:

- RADVMCE linked claim identifier
- RADVMCE statement covers from/through dates
- Professional or institutional indicator

If this workpaper is submitted, the SVA Entity will only abstract the diagnoses associated with the RADVMCE claims noted in the medical record workpaper (i.e., the professional service claims).

**Note:** If a medical record workpaper is not submitted and the medical record contains a discharge date outside of the benefit year under review, the SVA Entity will not abstract diagnoses from the medical record.

### 9.8.6.2 Outpatient and Physician/Professional Services

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

The medical record intake portion of the health status validation process may be performed by Primary or Senior Reviewers. Detailed steps for reviewing acceptable dates in a medical record are defined in Table 11:

**Table 11: Acceptable Date of Medical Record Testing**

Step	Description	Additional Details
1 (a-b)	Primary Reviewer – Record medical record dates of service	The Primary Reviewer identifies that the “statement covers from” (for inpatient claims, this is the admission date) and “statement covers through” (for inpatient claims, this is the discharge date) from the medical record links to a claim in the RADVMCE Report where the claims statement covers from/through date aligns to at least one (1) of the dates of service found on the medical record. Alternatively, the medical record can be linked to a RA eligible, paid/positively adjudicated NEC, if applicable.
		a) The Primary Reviewer determines if the “statement covers from” (admission date) “and through” (discharge date) from the medical records are linked to a claim in the RADVMCE Report and documents the associated RADVMCE claim number in the <i>IVA Entity Audit Results Submission XML</i> .
		b) The Primary Reviewer reviews the NEC (if applicable) to determine if valid RA services were provided within the “statement covers from/through” dates on the claim.

Step	Description	Additional Details
2(a-b)	Primary Reviewer – Compare medical record dates of service to linked claim on the RADVMCE Report or to a RA eligible, paid/positively adjudicated NEC to identify inconsistent findings	The Primary Reviewer compares the results of the medical record to the RADVMCE Report or a RA eligible, paid/positively adjudicated NEC to ensure that all fields recorded match using professional judgment. If the IVA Entity determines, based on its professional judgment, that the service or treatment is eligible for review for the benefit year being audited, the IVA Entity must explain this determination in a workpaper accompanying the medical record.
		a. If there is agreement, document results in the IVA Entity Audit Results Submission XML, and no additional review is necessary.
		b. If there is a difference, the Primary Reviewer marks the enrollee file as an inconsistent finding and forwards the record to the Senior Reviewer to review.
3	Senior Reviewer – Record medical record dates of service	The Senior Reviewer identifies that the “statement covers from” (for inpatient claims, this is the admission date) and “statement covers through” (for inpatient claims, this is the discharge date) from the medical record links to a claim on the RADVMCE Report where the claims statement covers from/through date aligns to at least one (1) of the date of service found on the medical record. Alternatively, the medical record can be linked to a RA eligible, paid/positively adjudicated NEC, if applicable.
4 (a-b)	Senior Reviewer – Compare medical record dates of service to linked claim on the RADVMCE report to identify final inconsistent findings	The Senior Reviewer compares the results of the medical record to the EDGE server RADVMCE Report or the NEC to ensure that all fields recorded match, using professional judgment.
		a) If there is agreement, document results in the <i>IVA Entity Audit Results Submission XML</i> , and no additional review is necessary.

Step	Description	Additional Details
		<p>a. If there is a difference, the Senior Reviewer should use professional judgment to determine if the difference is a result of a claims submission error from the provider and the IVA entity may need to reach out to the issuer for clarification. However, a claim with dates prior to the medical record dates of service should be carefully scrutinized before consideration.</p> <p>If the reviewer <u>is able</u> to reasonably determine that a date discrepancy exists only as a result of a billing error, then the Senior Reviewer <i>IVA Entity Audit Results Submission XML</i> should record the correct date, but should NOT note a final inconsistent finding.</p> <p>If the reviewer <u>is not able</u> to reasonably determine that a date discrepancy exists only as a result of a billing error, then the Senior Reviewer will reject the record. This may result in the medical record not being coded.</p>

### 9.8.6.3 Key Considerations for Professional Judgment in Evaluating Dates of Service

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

For the purposes of HHS-RADV, a provider attestation is not required when professional judgment is used to determine date of service issues. However, the IVA Entity and its reviewers must perform necessary due diligence before making such a determination. **The IVA Entity must also explain this determination in workpapers.**

### 9.8.7 Documentation of Capitated Encounter Data

Issuer capitated encounter data may need to be used during the IVA process for medical records linked to RA eligible, paid/positively adjudicated NECs. In Section 9.5 (Phase 2 – Review and Confirm Mapping), the IVA Entity must document the path of capitated encounter data to the EDGE server. The issuer must provide a clear description of how the issuer determined if claims/encounter data submitted was covered by a capitated arrangement. Capitated encounter data may require the documentation of additional workpapers to demonstrate the mapping between EDGE server claims data elements and the encounter data in the issuer system(s). These workpapers should document how the EDGE data was populated for the encounter and how the encounter was allowable within RA criteria.

The issuer must provide documentation as to how the issuer converted encounter data into EDGE claims and if any of the validated fields were derived. This documentation should be

documented in a workpaper and identified within the *IVA Entity Audit Results Submission XML*.

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

### 9.8.8 Acceptable Medical Record Source

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

For institutional claims, IVA Entities and the SVA Entity review the bill type code to determine if the claim is allowable. For professional claims, IVA Entities and the SVA Entity note that the claim is a professional claim and **no additional review is necessary**. See Tables 12 and 13 for the allowable and non-allowable bill type codes for RA data submission specific to institutional. Note that issuers should follow the ESBR when submitting bill type codes to their respective the EDGE servers. Refer to the **ESBR Version 12.0** located in the REGTAP Library (<https://www.regtap.info/>).

**Table 12: Allowable Bill Type Codes for Institutional Claims**

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

**Table 13: Not Allowable Bill Type Codes for Institutional Claims**

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

**Note for HHS-RADV and Mental Health or Behavioral Health Records:** As set forth in 45 C.F.R. § 153.630(b)(6), as amended by the 2019 Payment Notice, a qualified provider that is licensed to diagnose mental illness by the state and that is prohibited from furnishing a complete medical record by applicable state privacy laws concerning any enrollee’s treatment for one (1) or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable federal and state privacy laws, should contain: (1) the enrollee’s name; (2) sex; (3) DOB; (4) current status of all mental or behavioral health diagnoses; **and** (5) dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable state privacy laws. Psychotherapy notes are not required for RADV.<sup>27</sup>

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

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

<sup>27</sup> “Psychotherapy notes” is defined as notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual’s medical record. The term excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. See 45 C.F.R. § 164.501.

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

### **9.8.9 Recommended Documents for Medical Record Abstraction Submission**

It is imperative that all medical records necessary to substantiate an enrollee’s diagnoses be submitted into the Audit Tool during the IVA Submission Process. The submitted medical records must be able to independently substantiate the diagnoses found on the RADVMCE Report or NEC. CMS recommends providing the complete medical record of an inpatient stay. If a history and physical and/or discharge summary is the only submission for an inpatient stay, diagnoses may not be able to be substantiated if they are listed in a summary list or bullet point style without including the entire inpatient stay (progress notes and consults).

As with any diagnosis validation, it is incumbent upon the issuer and IVA Entity to provide sufficient medical record documentation for demonstrating the disease process and/or treatment plan of care. If the provided medical record does not contain sufficient medical documentation to abstract the intended diagnosis, the issuer and IVA Entity should work with the provider to obtain sufficient documentation. RADV stakeholders should reference the ICD-10-CM Official Coding Guidelines for Coding and Reporting, the AHA Coding Clinic, and the 2018 benefit year HHS-RADV Protocols for coding guidance.

Certain medical records on their own **cannot** be used to substantiate a diagnosis. However, the following may be used in conjunction with a valid medical record to help substantiate a diagnosis:

- Pathology Reports;
- Physician Orders;
- Radiology Reports;
- List of Current Medications

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

- Nurse notes;
- Flow sheets;
- Photos (including photos of wounds or infants);
- Labs;
- Discharge instructions;
- Medication Administration Records (MAR).

### **9.8.10 Acceptable Service Code Validation (Outpatient and Professional Medical Records Only)**

The purpose of Service Code Validation is to determine if the Service Code assigned is RA Acceptable. The service code is validated from the medical record to ensure that the service code is acceptable per the ESR. The service code qualifier, found on the RADVMCE Report, identifies if the code is Current Procedural Code/Healthcare Common Procedure Coding System (CPT/HCPCS).

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

No other validation of the service code is required to be performed (i.e., if the correct management level code was appropriately assigned).

**Table 14: Acceptable Service Code Validation Steps**

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

### 9.8.11 Acceptable Medical Record Signature

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

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

All medical records must have an acceptable provider signature and credentials displayed on the medical record within 180 days of the date of service. Signatures dated greater than 180 calendar days from the date of service or absent from the medical record, must include a valid attestation in

order for medical record review to continue. For example, an unsigned medical record, a signed medical record signature dated greater than 180 days without a valid attestation, a stamped signature, or a signed medical record missing credentials is considered incomplete and may result in a RA error.

Refer to [Appendix F](#) (Guidance to Coders) for specific criteria and examples of acceptable and unacceptable provider signatures.

### 9.8.11.1 Medical Record Attestations

CMS will also accept attestations to authenticate medical documentation that was not authenticated at the date of service. Signature attestation forms can be sent to providers and electronically populated, signed, and returned to the IVA Entity, issuer, or other party requesting the record on behalf of the issuer.

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

IVA Entities may still abstract diagnoses from the medical record with signature or credential issues while attestations are being sought.

**Note:** If an attestation **cannot be sent** to validate the medical record, the medical record and abstracted diagnoses remain invalid, and therefore should not be submitted via the *IVA Entity Audit Results Submission XML* for use in the enrollee’s risk score calculation.

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

CMS will allow for the attestation document to be submitted as a separate file or consolidated with the medical record PDF. At a minimum, the attestation statement must contain the signature and date. DO NOT include the issuer name. See [Appendix F](#) (Guidance to Coders) for guidance regarding attestations.

### 9.8.11.2 Key Considerations for Telehealth

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

Step	Description
1	Confirm that the applicable state insurance law regarding telehealth services requires or permits issuer reimbursement for telehealth services. The applicable state insurance law would be the law of the state of licensure of the issuer.

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

## 9.8.12 Abstraction Coding

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

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

ICD-10-CM diagnosis codes are used to describe the clinical reason for a patient’s treatment. ICD-10-CM codes do not describe the service performed, only the patient’s medical condition. Coders will first code all medical records for the applicable enrollee per the applicable ICD-10-CM code set. Once the ICD-10-CM codes are abstracted from all the enrollee’s medical records, the codes need to be mapped to HHS-HCCs using the 2018 Benefit Year HHS-Developed RA Model Algorithm “Do It Yourself (DIY)” Software to allow for error identification versus EDGE server data. As a reference, the HHS DIY Software instructions, and Technical Details, which includes the ICD-10 to HHS-HCC mappings, can be found on the CCIIO homepage.<sup>28</sup>

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

- Diagnoses mapping to supported HCCs;
- Newly identified diagnoses that map to new HCCs;
- Diagnoses mapping to unsupported HCCs.

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

**Note:** CMS cannot provide specific coding guidance beyond what has been released in these Protocols. CMS encourages the utilization of the ICD-10-CM Official Guidelines for Coding and

<sup>28</sup> 2018 Benefit Year DIY Software Instructions <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-RA-Model-DIY-Instructions.pdf> and 2018 Benefit Year DIY Software Technical Details <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-RA-Model-DIY-Tables.xlsx>

Reporting (See [Appendix D](#)), the AHA Coding Clinic, and the HHS-RADV 2018 benefit year Protocols 'Lifelong Permanent Conditions' list (See [Appendix E](#)) along with professional judgment to make final determinations when abstracting diagnoses.

Historical best practice utilizes inpatient guidelines for an inpatient record and outpatient guidelines for an outpatient record.

CMS is only requiring final IVA Entity diagnoses be recorded in the *IVA Entity Audit Results Submission XML*. If an enrollee's medical records are reviewed by both a Primary and Senior Coder, only the final diagnoses are required to be submitted to CMS. The RADV XML Data Elements Job Aid<sup>29</sup> located in the Audit Tool library provides further detail on the technical requirements for submission.

**Table 15: Diagnosis Validation**

Step	Description	Additional Details
1	Primary Coder – Abstract diagnoses.	The Primary Coder identifies the ICD-10-CM diagnoses from the medical record, for all of the enrollee's medical records, and records the diagnoses in the <i>IVA Entity Audit Results Submission XML</i> *.
2	Primary Coder – Map diagnoses to HCCs.	The Primary Coder maps the identified ICD-10-CM diagnoses from the medical records to their assigned HCCs.
3	Primary Coder – Collate enrollee HCCs across medical records.	The Primary Coder collates HCCs for each enrollee and removes duplicate HCCs identified. IVA Entities should use these identified HCCs as the basis of comparison to EDGE HCCs, as outlined in Step 4 (a-c).
4 (a-c)	Primary Coder – Compare IVA abstracted HCCs to EDGE server HCCs and identify errors and document results.	The Primary Coder compares the HCCs determined from medical record diagnosis abstraction to the enrollee's HCCs identified in the EDGE server RADVDE Report.
		a. The Primary Coder identifies supported HCCs (HCCs in the RADVDE Report which are supported by abstracted diagnoses from the medical record assigned to HCCs). A supported HCC is considered an agreement.
		b. The Primary Coder identifies newly identified HCCs (diagnoses assigned to HCCs following medical record abstraction, but which are not present in the EDGE server RADVDE Report). Newly identified HCCs are considered a New Finding.
		c. The Primary Coder identifies unsupported HCCs (HCCs which are present in the EDGE server RADVDE Report but were not assigned to abstracted diagnoses identified during the review of the enrollee's medical records). Unsupported HCCs are considered an error.

<sup>29</sup> The RADV XML Data Elements Job Aid for the 2018 benefit year is anticipated to be released in June 2019.

Step	Description	Additional Details
5 (a-c)	Primary Coder – Determine requirement of Senior Coder review.	The Primary Coder determines next steps based on the results in Step 4.
		a. If there is agreement between the HCCs identified by the Primary Coder and the EDGE server RADVDE Report, no additional review of the enrollee’s medical records is necessary.
		b. If a newly identified diagnosis that maps to a HCC is found, the IVA Entity has the option to have the Primary Coder escalate either the individual medical record that contains the newly identified diagnosis that maps to a HCC or all medical records for the enrollee to Senior Coders for re-review.
		c. If, after all medical records have been reviewed for the enrollee, and an HCC found on the RADVDE Report has not been substantiated, then all the medical records for the enrollee must be escalated to Senior Coders for re-review.  <b>Note:</b> If the Primary Coder abstracts all supported diagnoses that are assigned HCCs, and there is no difference between the RADVDE Report and the Primary Coder’s findings, then the Primary Coder may record the final medical record diagnoses in the <i>IVA Entity Audit Results Submission XML</i> .
6	Senior Coder – Abstract diagnoses	For those enrollees for which an unsupported or newly identified HCC were noted: The Senior Coder identifies the ICD-10-CM diagnoses for all of the enrollee’s medical records and records all final diagnoses in the <i>IVA Entity Audit Results Submission XML</i> .  <b>Note:</b> Only final medical record diagnoses, regardless of Primary or Senior Coder review, are required to be recorded in the <i>IVA Entity Audit Results Submission XML</i> .
7	Senior Coder – Map diagnoses to	The Senior Coder maps the identified ICD-10-CM diagnoses from the medical records to their assigned HCCs.
8	Senior Coder – Collate enrollee HCCs across medical records	The Senior Coder collates HCCs for each enrollee, removes duplicate HCCs identified. IVA Entities should use these identified HCCs as the basis of comparison to EDGE HCCs.
9 (a-d)	Senior Coder – Compare IVA abstracted HCCs to EDGE server HCCs and identify final errors	The Senior Coder compares the HCCs to the EDGE server RADVDE Report.
		a. The Senior Coder identifies supported HCCs (HCCs in the RADVDE Report that are supported by HCCs assigned to diagnoses abstracted from the medical record). A supported HCC is considered an agreement.

Step	Description	Additional Details
		<p>b. The Senior Coder identifies newly identified HCCs (HCCs that are determined as valid based on identified diagnosis codes, but which are not present in the EDGE server RADVDE Report). Newly identified HCCs are considered a New Finding.</p>
		<p>c. The Senior Coder identifies unsupported HCCs (HCCs that are present in the EDGE server RADVDE Report, but were not identified during the review of the enrollee's medical records through a diagnosis).</p>
		<p><b>Note:</b> Only final diagnoses, regardless of Primary or Senior Coder review, are required to be submitted via the <i>IVA Entity Audit Results Submission XML</i>. No additional indicators regarding errors identified, new HCCs, or unsupported HCCs are required. CMS and the SVA will utilize diagnoses to determine enrollee HCCs and compare to EDGE server HCCs from the RADVDE Report.</p>

For all health status and diagnosis validations performed over sampled enrollees, Primary and Senior Coders are required to work in tandem to identify, validate, and review errors, and to complete IRR (Section 10). While a Senior Coder may act as a Primary Coder, the results of this Senior Coder's review must be reviewed by another Senior Coder so that all errors are always given a second review by a Senior Coder. Additionally, any Senior Coder who acts as the Primary Coder will be subject to IRR testing to ensure that they are meeting IRR consistency measure requirements, as required for all Primary Coders.

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

### 9.8.13 Key Considerations for Medical Record Abstraction

#### Blind Coding

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

#### New HCC Findings with Positive Risk Score Impact

To more effectively assist CMS in assessing an issuer's outlier status related to validation of diagnoses and their assigned HCCs used in enrollees' risk scores, IVA Entities are encouraged to prioritize the validation of diagnoses attributable to HCCs submitted to EDGE and used in RA risk score calculations.

Under the HCC Failure Rate Methodology for Error Estimation which CMS implemented beginning with benefit year 2017 HHS-RADV, the addition of a new diagnosis from medical record documentation that maps to an HCC not previously identified on the RADVDE Report (a non-EDGE HCC) may impact an issuer's failure rate calculation within an HCC group and thus, the issuer's determination of outlier status.

The impact of new diagnosis codes is dependent upon the underlying enrollee EDGE HCCs and how any new diagnosis code interacts with other abstracted diagnoses. For example, if a diagnosis abstracted during the IVA process results in an additional enrollee HCC, and all EDGE HCCs are substantiated by the IVA Entity's final HCC results, this will have a favorable impact on the calculation of the issuer's HCC group failure rate in the HCC group in which the new HCC was found.

However, if a diagnosis is abstracted which results in a final IVA HCC that does not correspond to an existing EDGE HCC, and the EDGE HCC is not otherwise substantiated by the IVA Entity's final HCC results, two (2) outcomes occur: the failure rate of the unsubstantiated EDGE HCC would increase, and the failure rate for the newly found IVA HCC would decrease. This process is illustrated below:

- The issuer enrollee has HCC 21 (Diabetes without complications) in EDGE.
- IVA Entity abstracts both Dx E8021 (Diabetes mellitus due to underlying condition with diabetic nephropathy) and E119 (Type 2 diabetes mellitus without complications) which in isolation would map to HCCs 21 and 20 in isolation. Because these HCCs are within a HHS-HCC Hierarchy, the final IVA HCC for the enrollee would be reflected as HCC 20 (Diabetes with Chronic Complications).
- HCC group failure rates would then be calculated using only the final IVA HCC of HCC 20. All other results held constant, the failure rate for HCC 21 would increase, and the failure rate for HCC 20 would decrease.

Refer to Section 11 (Error Estimation) for additional details regarding the HCC Failure Rate Methodology. IVA Entities are encouraged to prioritize the validation of diagnoses that map to HCCs identified on the RADVDE Report rather than searching for newly identified diagnoses. However, it is at the discretion of the issuer and IVA Entity to determine practices and policies related to validation of non-EDGE HCCs and targeting of HCCs identified in the RADVDE Report to validate.

### **Addressing HCC Errors and Additional Medical Record Chart Requests**

When the diagnoses that are abstracted during the IVA process are compared to corresponding HCCs on the RADVDE Report, the IVA Entity may determine that an enrollee's EDGE HCCs have not been validated. In these situations, additional records may need to be retrieved in order to fully validate all RADVDE Report HCCs.

In the event the comparison to the EDGE server RADVDE Report HCCs reveals HCCs not substantiated, the issuer or IVA Entity is permitted to coordinate with the issuer to request additional medical records to substantiate these HCCs, as long as the records are associated with a paid/positively adjudicated claim on the RADVMCE Report, or a RA eligible claim, or a paid/positively adjudicated NEC from the issuer's source system or 2018 benefit year HHS-RADV.

Additional medical records provided in these situations are still subject to all validation requirements in the HHS-RADV process, including medical record intake, abstraction, and collation of results for comparison to the enrollee's HCCs listed in the RADVDE Report.

## SOAP Notes Acceptability

For the purposes of HHS-RADV, Subjective, Objective, Assessment, and Plan (SOAP) notes are acceptable as a stand-alone medical record **only** if they meet all criteria of an acceptable medical record for RA, as defined in 45 C.F.R. § 153.630.

## Discharge/Death Summaries

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

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

## 9.9 Phase 6 – Record Validation Results

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

Medical record documentation utilized during the Health Status Data Validation process is part of Package 2 submission process and will not be submitted with Package 1 submission. After IVA results submission of Package 1, CMS will identify specific enrollees for whom medical records are to be submitted for the SVA subsample.

As described in Section 11 (Error Estimation), CMS may require the submission of medical records for all additional enrollees in the event significant differences are identified between IVA submitted findings and SVA findings for enrollees in the SVA subsample. In these situations, CMS will request Package 3 submission of the medical records for the balance of enrollees in the IVA sample that were not submitted during Package 2 submission. If CMS requests the submission of Package 3, IVA Entities and issuers will have seven (7) calendar days to complete the submission of medical records, inclusive of Issuer SO sign-off.

### 9.9.1 Key Considerations for Recording Validation Results

#### Diagnosis Validation Submission

IVA Entities are required to follow all audit steps as indicated in Section 9.8.12 (Abstraction Coding) but only final Coder diagnoses are required to be submitted in the *IVA Entity Audit Results Submission XML*. CMS is not requiring that both Primary Coder and Senior Coder diagnosis codes be submitted in the *IVA Entity Audit Results Submission XML*. Instead, IVA Entities are to determine the final diagnosis codes and submit those final diagnosis codes in the *IVA Entity Audit Results Submission XML*.

## File Naming and Submission Considerations

All files submitted during the IVA submission process must be uniquely named. The Audit Tool does not distinguish case sensitivity in the file name. For example, “RADV123.pdf” and “radv123.pdf” would be recognized as the same file name. CMS recommends naming files with a comprehensible link to each IVA submission package (for example, a HIOS ID in the file name for all files submitted for a single HIOS ID), but this is not required. **File names should not contain PHI/PII or the issuer name.**

## Medical Record Documentation Submission

Issuers and IVA Entities should submit only the medical records needed to substantiate each diagnosis and assigned HCC reported in the RADVDE Report for the enrollees in the IVA Sample. Issuers and IVA Entities should not submit duplicate medical records for an enrollee multiple times in the *IVA Entity Audit Results Submission XML*. Only unique medical records for an enrollee should be captured in the *IVA Entity Audit Results Submission XML*. Refer to the HHS-RADV IVA Submission Process User Manual located in the Audit Tool file library for information regarding acceptable file sizes.

## Documenting Strata 1-9 Enrollees without Medical Records

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

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

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

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

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

**Section 10**  
**HHS Risk Adjustment Data Validation Protocols**  
**Inter-Rater Reliability**

## 10. IVA Inter-Rater Reliability

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### 10.1 Purpose

IRR is a quality control measure to determine the accuracy of the abstraction diagnoses by Primary Coders when compared to Senior Coders. Medical records reviewed by the Primary Coder and sampled for IRR are then re-reviewed by a Senior Coder. The comparison of HCCs assigned to diagnoses found between the Primary Coder and the Senior Coder are then used to determine the Primary Coder's IRR consistency measure. CMS requires that IVA Entities achieve a consistency measure of at least 95% for all Primary Coder review outcomes.

IRR determinations provide assurance to CMS and issuers that certified medical coders are consistent in their performance of the Health Status Data Validation process. IRR results are calculated and submitted for an IVA Entity and are not specific to a HIOS ID. IRR results are submitted independent from issuer IVA findings.

### 10.2 IRR Submission and Documentation

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

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

IVA Entities who elect to use the CMS recommended IRR methodology, documented in Sections 10.3 (IRR Process), 10.4 (Sample Population), and 10.5 (Sample Selection and Review), will not be required to submit a summarization of their IRR procedural processes to CMS during IRR submission.

### 10.3 IRR Process

Independent of the IRR methodology used, IVA Entities will be required to submit Primary Coder results to CMS, including final consistency measures, at the conclusion of the IVA process. CMS will require that the IVA Entity indicate the IRR methodology used ('CMS recommended' or 'Other'), along with a written summarization of the IVA Entity's IRR process if the 'Other' option is chosen. This written summarization must be included with the IRR submission to the Audit Tool. IVA Entities will be required to attest to the methods used as well as to the consistency measures communicated for Primary Coders in their results to CMS, independent of the IRR methodology

utilized ('CMS recommended' or 'Other'). All IVA Entities must also attest that Primary Coders who are unable to meet IRR consistency measure requirements had all medical records re-reviewed by a Senior Coder.

The five (5) steps of the CMS recommended IRR process are described in Table 16.

**Table 16: CMS Recommended IRR Process Steps**

Step	Description	Additional Details
1	Primary Coder Performs Health Status Data Validation	Primary Coders perform health status data validations, and the number of medical records evaluated by each Primary Coder is monitored. The IRR sample selection process is initiated once 25 medical records have been evaluated by the Primary Coder.
2	IRR Sample Selection	Once 25 medical records have been evaluated by the Primary Coder, the initial sample of 25 medical records are evaluated by the Senior Coder.
3	Senior Coder Performs Health Status Data Validation	<p>The Senior Coder performs health status data validations, including diagnosis coding and abstraction for each medical record in the sample. Once Senior Coders complete the health status data validation for all 25 sampled medical records, the consistency measure for the Primary Coder is calculated, as seen in Step Four (4).</p> <p><b>Note:</b> CMS does not require one (1) senior coder to review all primary coder records for IRR purposes. Multiple senior coders can be utilized to review a primary coder's IRR eligible records.</p>
4	Calculate Primary Coder Consistency Measure	<p>Following Primary Coder and Senior Coder review, HCCs are assigned to abstracted ICD-10-CM diagnoses to enable calculation of the Primary Coder consistency measure. The Primary Coder consistency measure (<math>CM_{PC}</math>) for the sample of 25 medical records is calculated using the following formula:</p> $CM_{PC} = \frac{\text{Count of Primary Coder and Senior Coder HCC Matches}}{\text{Count of Unique HCCs (Primary Coder \& Senior Coder)}}$ <p>The numerator term 'Count of Primary Coder and Senior Coder HCC Matches' indicates the instances of HCC agreement between the Primary and Senior Coders as they perform medical record abstraction. An HCC match is counted when both coders record diagnoses that result in identical HCCs for the same enrollee. Note that each Primary Coder and Senior Coder HCC match for a unique HCC will be counted as a single match for each enrollee.</p> <p>The denominator term 'Count of Unique HCCs (Primary Coder &amp; Senior Coder)' indicates the total universe of unique enrollee HCCs identified by both Primary and Senior Coders as they perform medical record abstraction. This value is calculated by totaling the number of unique enrollee HCCs identified within the 25 medical record sample by both the Primary Coder and Senior Coder. Note that the same HCC for a single enrollee should not be counted more than once; however, the same HCC identified for different enrollees should be considered unique for each enrollee for the purposes of calculating the denominator.</p> <p>For example, if one (1) enrollee has 25 medical records and HCC 8 is identified on all medical records, HCC 8 would be counted once in the denominator value of the calculated consistency measure. Assuming the Senior Coder also identified only HCC 8 on the medical records, both terms 'Count of Primary Coder and Senior Coder HCC Matches' and 'Count of Unique HCCs (Primary &amp; Senior Coder)' would be one (1). That is, HCC 8 would be counted once in the numerator and once in the denominator.</p>

Step	Description	Additional Details
		<p>Alternatively, if one (1) enrollee has 10 medical records and a second enrollee has 15 medical records and HCC 8 was identified on both enrollee's medical records, HCC 8 would be counted once in both the numerator and denominator <u>for each enrollee</u>, assuming no other HCCs were identified. That is, HCC 8 would be counted twice in both the numerator and the denominator (if recorded by the primary and senior coder)</p> <p>The Count of Primary Coder and Senior Coder HCC Matches is calculated across all 25 medical records, along with the count of unique HCCs identified by both the Primary Coder and Senior Coder(s). The calculated Primary Coder consistency measure is used to determine if the IRR threshold of 95% is met or if an additional sample of medical records is needed.</p>
5 (a-b)	Finalize IRR or Adjust Sample	<p>The last step in the IRR process is to either finalize IRR results or adjust the sample size.</p> <p>a) If the Primary Coder's calculated consistency measure meets or exceeds the required 95%, the Primary Coder has completed the requirements for IRR evaluation.</p> <p>b) If the Primary Coder's calculated consistency measure fails to meet the required 95%, the Primary Coder has not completed the requirements for IRR evaluation, and the IVA is required to re-perform the IRR assessment of the Primary Coder, re-performing steps 1 – 5. This process must be re-performed until the acceptable consistency measure is achieved or until no additional medical records reviewed by the Primary Coder remain.</p>

## 10.4 Sample Population

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

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

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

**Section 11**  
**HHS Risk Adjustment Data Validation Protocols**  
**Error Estimation**

# 11. Error Estimation

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## 11.1 Overview

The objectives of the pairwise and Error Estimation processes are to verify the accuracy of the IVA results, calculate HCC failure rates, identify issuers with EDGE data validation rates that are statistically different than national validation rates, determine if risk score adjustments are required, and calculate risk score error rates to be applied to issuers' PLRS.

Without viewing the actual IVA results, the SVA Entity re-performs the validation steps executed by the IVA Entity on a sample of enrollees validated by the IVA Entity to verify the accuracy of the IVA results. The initial SVA sample must be sufficiently large enough to determine sufficient similarity between the IVA and SVA results by pairwise means testing.<sup>30</sup> At the conclusion of the SVA review, CMS identifies the issuers that are statistical outliers in their health status submission inaccuracies and applies an adjustment to those issuers' risk scores.

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

## 11.2 Pairwise Test and IVA Sample Adjustment

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

### 11.2.1 Pairwise Test between SVA and IVA

During the pairwise means test, the SVA Entity will compare the SVA results to the IVA results to determine if the results are sufficiently similar. The SVA sample sizes consist of an initial subsample of 12 enrollees and expands, if necessary, based on insufficient pairwise agreement to IVA results, to 24, 50, then 100 enrollees. If sufficient agreement is not found after reviewing all 100 enrollees in the SVA subsample, the SVA Entity requests the medical records for the remaining enrollees in the IVA sample. All enrollees in the IVA sample that were not initially selected as part of the SVA subsample of 100 are included as part of Package 3. CMS will conduct a precision analysis on error rates calculated at the conclusion of the SVA process to determine whether to use a HIOS ID's SVA 100 level findings for the 100 SVA subsample enrollees<sup>31</sup> (a result of acceptable precision) or expand to the full SVA 200 level inclusive of all enrollees in the IVA sample (a result of unacceptable precision) for the HIOS ID. If unacceptable precision is found at the SVA 100 level, the medical records for Package 3 enrollees will be reviewed by the SVA.

CMS will prioritize enrollees with medical records in the initial subsample groups, such that enrollees with medical records are reviewed prior to those without medical records.

If the results from the initial pairwise means test or the pairwise means test from any of the incremental SVA subsample expansions are found to demonstrate sufficient agreement to the IVA findings, then the IVA results will be used for the calculation of HCC failure rates, the calculation of HCC Group Failure Rates, and any applicable adjustments.

If there is insufficient agreement between the IVA results and the results of the expanded SVA sample, the SVA results will be used in the calculation of HCC failure rates, the calculation of HCC Group Failure Rates, and any applicable adjustments.

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<sup>30</sup>Pairwise Means Test: A statistical means test, which is a hypothesis-testing procedure to determine if two (2) population means are different when there is a one-to-one (1:1) correspondence between the values in the two (2) samples.

<sup>31</sup> In the event the SVA subsample is expanded to the full IVA sample of 200, we will still refer to the SVA sampled enrollees as the SVA subsample to distinguish the SVA sample from the IVA sample.

For the 2018 benefit year HHS-RADV, CMS will use the demographic data from the EDGE server reports for risk score calculations used in the pairwise means test rather than the demographic results of the IVA or SVA D&E data validation. Additionally, for the 2018 benefit year HHS-RADV, CMS will use EDGE server enrollee RXCs for risk score calculations used in the pairwise means test rather than the RXC results of the IVA or SVA RXC data validation. Therefore, any pairwise differences will be the result of health status variance between the IVA and SVA.

To illustrate the pairwise means statistical test, consider the following notations where  $i$  stands for sampled enrollee  $i$ :

$\tilde{x}_i$	is the $i$ th IVA risk score observation in the SVA subsample of $n$ observations
$\tilde{y}_i$	is the $i$ th SVA risk score observation in the SVA subsample of $n$ observations
$d_i$	is the difference between $\tilde{y}_i$ and $\tilde{x}_i$ within the SVA subsample $d_i = \tilde{y}_i - \tilde{x}_i$
$S_d$	is the standard deviation of $d_i$
$\bar{d}$	is the mean of $d_i$ in all $n$ observations within the SVA subsample $\bar{d} \pm t_{1-\alpha, \gamma} \left( \frac{S_d}{\sqrt{n}} \right)$
$N$	is the number of IVA sampled enrollee records.
$n$	is the number of observations in the SVA subsample
$t_{1-\alpha, \gamma}$	is the critical t-value associated with a two-sided 95% confidence level

From the  $N$  IVA records ( $N=200$ ), CMS will select a small subsample of  $n$  SVA records ( $n=12$ ). For each SVA selected record, CMS will calculate the difference, as shown by the formula for  $d_i$ . CMS will then conduct a pairwise means test to determine whether the mean difference is statistically different than zero (0) at a 95% confidence level [two (2)-sided]. Specifically, CMS will test if zero (0) is contained within the bound,  $\bar{d} \pm t_{1-\alpha, \gamma} \left( \frac{S_d}{\sqrt{n}} \right)$  where  $t_{1-\alpha, \gamma}$  is the critical t-value associated with a two (2)-sided 95% confidence level.<sup>32</sup>

If zero (0) is contained, CMS will conclude that there is no statistically significant difference between the IVA and SVA results for the sampled enrollees and accept the results of the IVA review.

However, if zero (0) is not contained within this bound (i.e., the difference is statistically significant), CMS will incrementally expand the SVA subsample from 12, to 24, to 50, and finally 100, reviewing the enrollee files and conducting an alternate pairwise means test using the larger SVA subsample at each expansion. This difference may be positive or negative depending on the direction and magnitude of each difference found between the IVA and SVA results. If the pairwise means test shows no statistically significant difference, CMS will accept the results of the IVA review. If the pairwise means test shows that there is a statistically significant difference between the IVA and SVA results, after expanding the SVA subsample to 100, CMS will conduct a precision analysis for evaluating the SVA findings to determine if selecting a larger subset of the 200 total IVA sampled enrollees can be justified.

CMS uses a nonparametric bootstrap technique for estimating properties of the error estimate

<sup>32</sup> The critical t-value  $1-\alpha = 1.96$ , when the sample is large enough, approaching infinity  $\alpha$  represents the significance level and  $\gamma$  represents the degrees of freedom of the critical t-value associated with a two (2)-sided 95 percent confidence level. CMS assumes that  $\alpha = 0.05$  for 95% confidence and  $\gamma = n-1$ .

because the approach requires no assumptions to be made about the parent distribution.<sup>33</sup> This approach is used to determine standard errors and confidence intervals when the underlying distribution is unknown, when sample sizes may be too small, and/or when no formula may exist for the complex calculation. Due to the complexity of the Error Estimation method, the mathematical derivation of standard errors and confidence intervals cannot otherwise be derived as a formula.

The bootstrap resampling technique will allow CMS to derive precision metrics such as standard error and confidence intervals for the point estimate of the error rate of each issuer when the IVA failed pairwise at SVA 100 review (n=100). If the confidence interval or standard error of the error rate for any of these issuers is large enough to lose confidence in the quality of results (e.g. using CMS established precision targets of 10% and in comparison to other issuers with 200 samples), then CMS will conclude that the precision for the estimated error rate is poor and the SVA will expand and use the full SVA reviewed sample of 200 enrollees (n=200). However, if these metrics (standard error or confidence interval) fall in a similar range compared to other issuers, then the SVA subsample will not be expanded to 200.<sup>34</sup>

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

1. For issuer i, draw N (or n) enrollees from the list of all sampled enrollees with replacement (i.e., select a random enrollee from the sample and return the enrollee back into the sample prior to the next enrollee being selected), where N (or n) is the number of IVA or SVA sampled enrollees.
2. Calculate the issuer's error rate using the method, described above, by assuming the resampled enrollees create a bootstrap sample. The estimated error rate for issuer i and the bootstrap sample is recorded as  $\widehat{ErrorRate}_{i,1}$ .
3. Repeat Step 1 and 2 at minimum 1,000 times.<sup>35</sup> Each time, a new error rate is estimated based on a resampled data set. At the end of the resampling experiment, a set of error rate estimates are collected as

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

where B is the times the resampling experiment repeats.

4. Calculate the sample standard deviation of all the B re-sampled error rates. This standard deviation is an approximation of the bootstrapped standard error (SE) of the error rate estimate for issuer i.
5. Obtain the 2.5<sup>th</sup>, and 97.5<sup>th</sup> percentiles of all the B re-sampled error rates. This is the bootstrapped two (2)-sided 95% confidence interval boundary for the error rate estimate for issuer i.

The standard error is one (1) way to indicate how precise the estimate of an issuer's error rate is. If an issuer's standard error is large enough to lose confidence in the quality of results, the issuer's SVA Findings will be assessed as having poor precision. The precision test and the calculated precision values are used to resolve the following scenarios:

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<sup>33</sup> Bootstrap Resampling: A non-parametric resampling procedure used to estimate the sampling distribution based on independent observations.

<sup>34</sup> A standard IVA Sample Size is 200 enrollees. For additional information regarding alternate sample sizes, refer to Section 7.3.2 Alternative Sample Size and Section 7.3.3 SVA Subsample Sizes.

<sup>35</sup> Statistical standards note that 1,000 iterations of bootstrap resampling adequately captures the range of variability produced as a results of random sampling.

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

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

Note that CMS intends to use bootstrap resampling techniques to measure the precision of the finalized error rate estimates and inform future sampling methods.

### 11.3 Error Estimation

Under § 153.350, HHS may adjust RA payments and charges to all issuers of RA covered plans based on adjustments to the average actuarial risk of a RA plan due to errors discovered during HHS-RADV.<sup>36</sup> Under the original HHS-RADV Error Estimation approach, all issuers of RA covered plans would have received risk score adjustments impacting payment transfers in the subsequent benefit year based on HHS-RADV audit results and using the audit-confirmed, issuer-specific risk score error rate. However, as recognized in the 2019 Payment Notice,<sup>37</sup> CMS believes that some variation and error should be expected in the compilation of data for risk scores.

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

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

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

- invalid documentation (as described in Section 9.8 – Phase 5 - Health Status Data Validation);
- missing or insufficient medical record documentation; or

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<sup>36</sup> Consistent with 45 C.F.R. §153.630(e), HHS also may adjust payments and charges for issuers that do not comply with HHS-RADV requirements and standards.

<sup>37</sup> 83 FR 16961.

- incorrect diagnosis coding.

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

CMS will apply HCC hierarchies to all submitted diagnoses on the IVA Entity Audit Results Submission XML to determine final IVA HCCs for each audited enrollee. HCC hierarchies are similarly applied to SVA results to determine final SVA HCCs for an enrollee. HCCs for an enrollee are determined only after the hierarchies are applied to documented diagnoses, and HCC failure rates are calculated using only these final HCCs. See Section 11.3.1.1 (Applying HCC Hierarchies) as well as [Appendix G](#) (Examples of Applying HCC Hierarchies) for additional guidance and examples associated with applying HCC hierarchies.

Upon completion of the IVA and SVA audits, CMS will calculate an issuer-level risk score error rate for identified outliers. This risk score error rate will generally be applied to an issuer's RA plan-level risk scores in the subsequent benefit year to the benefit year being audited.<sup>38</sup> The risk score error rate represents the percent of an issuer's EDGE risk scores that are estimated to be in error after applying risk score adjustments to sampled enrollees identified as outliers in the HCC Groups and extrapolating the impact of those adjustments to the issuer's RA population. For issuers that are not outliers, they will have no error rate ( $ErrorRate_i = 0$ ). A positive error rate means an issuer's EDGE risk scores are higher than the adjusted risk scores found during the audit ( $ErrorRate_i = Positive Value$  (e.g., 10%). A negative error rate indicates that an issuer's EDGE risk scores are lower than the adjusted risk scores found during the audit ( $ErrorRate_i = Negative Value$  (e.g., -10%).

The one (1) exception to this general rule is for issuers who are determined to have had a positive error rate<sup>39</sup> and exit the market; for these issuers, risk score error rates will be applied to the RA risk scores for the issuer's final benefit year in which they participated (i.e., issuer had membership) in the state market risk pool, which is the same RA benefit year as the benefit year being audited. By "exit," CMS means that the issuer is claiming that no new coverage is being offered in any state market risk pools in the benefit year they "exit". If an issuer only exits some of the markets or risk pools in the state, but continues to sell or offer new plans in other states, then it would not be considered an exiting issuer. Small Group Market Issuers with off-calendar year coverage who exit the market and do not offer any individual market coverage in the state but only have carry-over small group coverage that ends in the next benefit year (that is, carry-over of claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold), would be considered an exiting issuer and would be exempt from HHS-RADV for the benefit year with only carry-over coverage. Refer to [Appendix J](#) (Application of Risk Score error rates for Issuers Exiting the Market) for guidance and examples of the application of risk score error rates for issuers exiting the market in a given benefit year. CMS plans to provide each issuer with enrollee-level audit results and their issuer-level error

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<sup>38</sup> For example, an issuer who is an outlier in the 2018 benefit year HHS-RADV results would have its risk score adjusted for its 2019 benefit year RA transfers based on its 2018 benefit year HHS-RADV error rate.

<sup>39</sup> As finalized in the 2020 Payment Notice, adjustments will not be made if an exiting issuer is found to be a negative error rate outlier. See 84 FR at 17503.

rate.

The next four (4) sections further explain and illustrate the Error Estimation process.

- Section 11.3.1 (Categorize HCCs into Groups) describes how sampled enrollees' EDGE server data and IVA sample results will be used to group HCCs into categories.
- Section 11.3.2 (Calculation of Adjustments based on Group Failure Rates) describes how the comparison of sampled enrollees' EDGE server data to IVA results (or SVA results when a pairwise test concludes that significant differences exist) will be used to identify issuers that are statistically different from their peers.
- Section 11.3.3 (Calculation of Error Rates to Adjust Issuer Plan Risk Scores) describes how the sample results are projected to an issuer level adjusted risk score.
- Section 11.3.4 (Illustration of the Pairwise and Error Estimation Processes) shows an example illustrating the pairwise and Error Estimation process. Note that error rates calculated in the 2018 benefit year HHS-RADV will generally be used to adjust 2019 benefit year RA risk scores and RA transfers.<sup>40</sup>

### 11.3.1 Categorize HCCs into Groups

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

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

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

The HCC failure rate ( $FR^h$ ) is the probability of all issuers coding an HCC incorrectly and is defined as one (1) minus the ratio of HCC frequencies in issuer audit results (IVA or SVA) to the EDGE

server:  $(FR^h = 1 - \frac{Freq\_IVA^h}{Freq\_EDGE^h})$ . The HCCs are ordered by their failure rates and assigned to their

<sup>40</sup> CMS will adjust 2018 benefit year risk scores and recalculate transfers if an issuer exiting all of the market risk pools in a state in 2019 is found to be a positive error rate outlier in 2018 benefit year HHS-RADV.

Groups through the following process:

1. Add the HCC with the lowest failure rate into Group One (1); update the size of Group One (1) as  $Freq\_EDGE^{h1}$
2. Add the next HCC from the ordered list into Group One (1); update the group size as  $Freq\_EDGE^{h1} + Freq\_EDGE^{h2}$
3. Repeat until the group size (the cumulative sum of frequencies) reaches approximately 33.3% of the total frequencies of HCCs recorded on EDGE ( $\sum Freq\_EDGE^h$ ).

Note: If an HCC crosses the 33.3% boundary, it will be assigned to the group where the inclusion of the frequencies of the HCC best allows the Group's total frequencies to approximate 33.3% (Group One [1] or Group Two [2], depending on the preponderance of the HCCs).

4. Select the HCCs for Group Two (2) by repeating Steps 1 – 3 using the remaining HCCs in the ordered list, until the size of Group One (1) plus Group Two (2) reaches 66.7% of the total frequencies of HCCs recorded on the EDGE server ( $\sum Freq\_EDGE^h$ ).

Note: if an HCC crosses the 66.7% boundary it will be assigned to Group Three (3).

5. The remaining HCCs are placed in Group Three (3).

At the conclusion of this step, each HCC is assigned to only one (1) of three (3) Groups with an approximately equal number of observed HCCs. Note that the categorization process creates groups based on all sampled enrollees on the EDGE server, across all issuers. Because this categorization process aims to categorize HCCs based on their frequency so that each HCC Group has a relatively equal frequency of total HCCs across all issuers, the number of unique HCCs will not necessarily be distributed evenly per Group.

### 11.3.1 Applying HCC Hierarchies

The Error Estimation methodology supports the HHS-RADV program's purpose to validate the accuracy of data submitted by issuers to their EDGE servers for use in RA calculations, as well as the objective of determining the accurate health status of the sampled enrollees.

HCCs for an enrollee are determined only after the HHS-HCC hierarchy is applied to all final diagnoses for the individual, be it during EDGE data submission, or following submission of IVA findings. Only the HCCs present after imposing hierarchies will be considered in the calculation of EDGE and IVA/SVA HCC frequencies. See **Appendix H** (Examples of Applying HHS-HCC Hierarchies) for a description of examples of applying HHS-HCC hierarchies.

### 11.3.2 Calculation of Adjustments based on Group Failure Rates

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

To illustrate the calculation of adjustment factors based on Group Failure Rates, consider the following notations, where  $i$  stands for issuer  $i$  and  $G$  represents the  $G$ th Group:

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

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

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

Based on the result of the Pairwise Test described above (Sections 11.2.1 – Pairwise Test Between IVA and SVA), issuers who fail the pairwise test require a modified Group Failure Rate per HCC Group that takes the SVA results into consideration. The new  $GFR_i^G$  equation becomes:

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

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

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

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

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

$$w_i = \text{Freq\_EDGE}_i^G.$$

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

$$\text{Sd}(\text{GFR}^G) = \sqrt{\frac{\sum_i (w_i * (\text{GFR}_i^G - \mu(\text{GFR}^G))^2)}{\sum_i w_i}}$$

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

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

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

### 11.3.3 Calculation of Error Rates to Adjust Issuer Plan Risk Scores

An enrollee-level adjustment to sampled enrollees' risk scores will only be computed when the following conditions are satisfied simultaneously:

1. An issuer has at least one (1) HCC Group Failure Rate that falls outside of its corresponding two (2)-sided 1.96 standard deviation confidence interval (described in Section 11.3.2 – Calculation of Adjustments based on Group Failure Rates).
2. A sampled enrollee has an HCC recorded on EDGE that falls in an outlier HCC Group for which the issuer incurs a non-zero adjustment [i.e., a non-zero (0) Group from Condition One (1)].

CMS will calculate the enrollee-level adjusted risk scores for the sample based on the adjustment factors calculated in Section 11.3.2 for the three (3) HCC Groups. CMS will then estimate the issuer-level error rates using the deviation from adjusted sample risk scores to original risk scores. The issuer's error rate is first calculated at the stratum level and then combined to a single value by weighing in the stratum size in the issuer's population and sample.

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

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

(Strata 1-9), when the EDGE HCCs for these enrollees are in an HCC Group for which the issuer is an outlier

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

Term	Definition
<i>i</i>	The <i>i</i> th issuer
<i>e</i>	The <i>e</i> th enrollee
<i>G</i>	The <i>G</i> th HCC group
$RS_{i,e}^{hcc,G}$	The risk score component of a single HCC for the enrollee
<i>Enrollee Adjustment<sub>i,e</sub></i>	The calculated adjustment factor to adjust Enrollee <i>e</i> of issuer <i>i</i> 's sample risk score
<i>EdgeRS<sub>i,e</sub></i>	The sampled Enrollee <i>e</i> of issuer <i>i</i> 's risk score recorded on EDGE
<i>AdjRS<sub>i,e</sub></i>	The sampled Enrollee <i>e</i> of issuer <i>i</i> 's adjusted risk score
<i>ErrorRate<sub>i</sub></i>	The final Error Rate for Issuer <i>i</i> based on the sampled enrollees
<i>w<sub>e</sub></i>	The stratum weight used to compute the Error Rate

CMS will first use the HCC Group level adjustment factor calculated in Section 11.3.2 to determine the enrollee-level adjustment factor for all samples. The enrollee adjustment factor will be calculated as the weighted average of all HCCs' associated Group level adjustment factor(s), where the weight is assigned as the risk score component contributed by the single HCC along ( $RS_{i,e}^{hcc,G}$ )

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

Next, for sampled enrollees, the adjustment factor is applied to the enrollee's EDGE server risk score to obtain their adjusted risk score (*AdjRS<sub>i,e</sub>*).

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

Then, the issuer's error rate is estimated using the total stratum weighted risk scores on EDGE and the adjusted risk scores from the sampled enrollees. The stratum weight is the ratio of the stratum size in the population to the number of sampled enrollees from the stratum.

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

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

The risk score component of a single HCC ( $RS_{i,e}^{hcc,G}$ ) is calculated based on the logic defined in the applicable HHS RA Model table.<sup>41</sup> This calculation for the enrollee adjustment only considers the

<sup>41</sup> 2018 Benefit Year DIY Software Instructions <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-RA-Model-DIY-Instructions.pdf> and 2018 Benefit Year DIY Software Technical Details <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-RA-Model-DIY-Tables.xlsx>

risk factors related to HCCs and ignores any other risk factors (demographic factors, enrollee RXCs, etc.). This assumption only applies to the calculation of enrollee-level adjustment factors. CMS applies calculated enrollee adjustment factors to enrollees' EDGE server risk scores, which include all EDGE server risk score components, to calculate adjusted risk scores for enrollees.

### 11.3.4 Illustration of the Pairwise and Error Estimation Processes

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

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

1. CMS performs a pairwise means test to compare the difference between the IVA risk scores and SVA risk scores for the subsample of twelve (12) enrollees. (See Section 11.2.1 – Pairwise Test between SVA and IVA)
2. Assume the average recorded IVA risk score is 1.50 (post-validation) and the average recorded SVA risk score is 1.25 in the SVA sample of 12 enrollees, resulting in a difference ( $d_i$ ) between the IVA risk score and SVA risk score as  $-0.25$ ;

$$d_i = 1.25 - 1.5 = -0.25$$

For this example, assume the pairwise means test results yield insufficient agreement between the IVA and SVA [i.e., there is a statistically significant difference between the IVA and SVA subsample of twelve (12) risk scores].

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

$$d_i = 1.42 - 1.65 = -0.23$$

For this example, assume the pairwise means test results yield insufficient agreement between the IVA and SVA (i.e., there is a statistically significant difference between the IVA and SVA sample of 100).

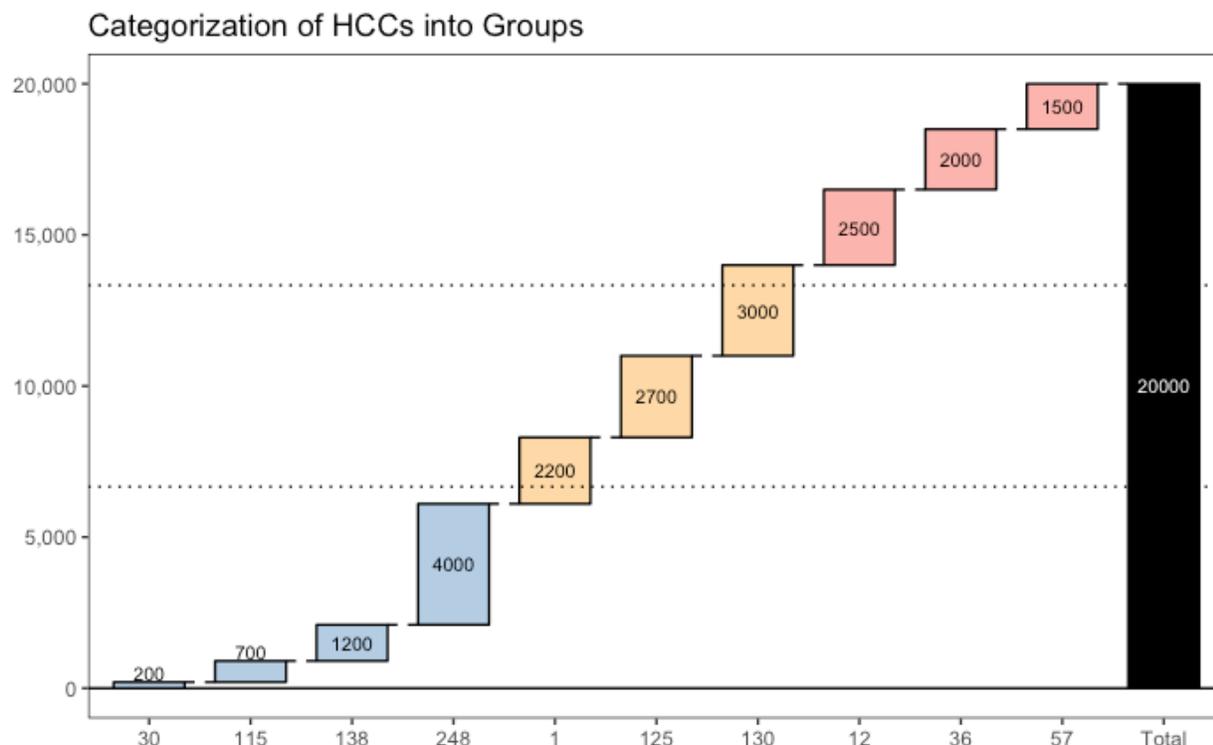
**Step Two (2):** CMS will replace the IVA inconsistent HCCs with the SVA validated HCCs for all 100 enrollees in the IVA subsample reviewed by the SVA. Then, CMS will use the SVA validated HCCs and HCC failure rates – replacing the HCC failure rates from the IVA findings – to calculate HCC Group Failure Rates, any applicable adjustments, and the risk score error rate.

**Step Three (3):** CMS will categorize each HCC into one (1) of three (3) groups using the failure rates and EDGE HCC frequencies across all issuers. Since there are over one hundred (100) HCCs, for simplicity in this example we will assume from the RADV sample of issuers that ten (10) HCCs were recorded on the EDGE servers across all issuers. (See Section 11.3.1 – Categorize HCCs into Groups).

CMS determines the frequencies for the EDGE HCCs and the IVA HCCs respectively, then calculates their HCC failure rates ( $FR^h$ ). The below IVA HCC frequencies are inclusive of the SVA validated HCCs that replaced the IVA HCCs that failed their pairwise test.HCC	$Freq\_EDGE^h$	$Freq\_IVA^h$	$FR^h$
30	200	180	10.0%
115	700	607	13.3%
138	1,200	1,020	15.0%
248	4,000	3,340	16.5%
1	2,200	1,833	16.7%
125	2,700	2,237	17.1%
130	3,000	2,300	23.3%
12	2,500	1,700	32.0%
36	2,000	1,100	45.0%
57	1,500	500	66.7%
<b>Total</b>	<b>20,000</b>	<b>14,817</b>	<b>25.9%</b>

4. The HCCs are placed in ascending order, and two (2) boundaries are selected such that the size of the first two (2) Groups are comprised of approximately 33.3% of HCC frequencies each, for a combined total of 66.7% of the total EDGE frequency.
  - a. The two (2) boundaries to cut the list of ten (10) HCCs into three (3) Groups are 6,660 (20,000 \* 33.3%), and 13,340 (20,000 \* 66.7%) respectively.
  - b. HCC one (1) and HCC 12 are crossing the boundary line so they will be categorized in the higher Group in order to create balanced 33.3% EDGE frequency Groups. See the table below, along with Image 11.3.4.1 for a visual of the categorization.

HCC	$Freq\_EDGE^h$	$Freq\_IVA^h$	$FR^h$	$Freq\_EDGE^h$ Cumulative Probability	Boundary	Group
30	200	180	10.0%	1.0%		G1
115	700	607	13.3%	4.5%		G1
138	1,200	1,020	15.0%	10.5%		G1
248	4,000	3,340	16.5%	30.5%	33.3%	G1
1	2,200	1,833	16.5%	41.5%		G2
125	2,700	2,237	17.1%	55.0%		G2
130	3,000	2,300	23.3%	70.0%	66.7%	G2
12	2,500	1,700	32.0%	82.5%		G3
36	2,000	1,100	45.0%	92.5%		G3
57	1,500	500	66.7%	100.0%	100%	G3
<b>Total</b>	<b>20,000</b>	<b>14,817</b>	<b>25.9%</b>			



**Image 11.3.4.1:** In the image above (Image 11.3.4.1), the x-axis is the sorted list of HCCs in an increasing order of their failure rates. The bar height (and the text in each box) represents Freq\_EDGE of each HCC. The bar on the right shows the total Freq\_EDGE is 20,000. The two (2) boundaries to cut the list of 10 HCCs into three (3) groups are  $(20,000 * 0.333)$ , and  $(20,000 * 0.667)$  respectively, which are shown as the two (2) horizontal dashed lines. The two (2) horizontal lines cut all ten (10) boxes (one (1) for each HCC) into three (3) groups. If a box is crossing a boundary line (e.g., HCC 1 and HCC 130), such box will be added to the Group to achieve equitable boundary cutoffs of 33.3% EDGE frequency allocation. The final grouping result is shown as three (3) colors in the chart.

**Step Four (4):** CMS will evaluate each issuer’s Group Failure Rate and assess if it statistically differs from the weighted mean of the sampled issuer’s Group Failure Rates (See Section 11.3.2 – Calculation of Adjustments based on Group Failure Rates).

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

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

2. For each Group, the weighted mean and standard deviations for the Group Failure Rates are calculated using column GFR<sup>G</sup> by each HCC Group. They will be used to create a 1.96 standard deviation confidence interval. Since the entire universe of participating

issuers are necessary to compute the Group Failure Rate for each HCC Group, for simplicity, we assume here the weighted mean Group Failure Rates for G1, G2, and G3 are 11.8%, 17.1%, and 25.9% respectively in the table below; and the weighted standard deviations are 3.0%, 3.4%, and 4%, respectively).

**Note:** The Group Failure Rate values of 11.8%, 17.1%, and 25.9% referenced in this step, and used in the following steps, do not correspond to data in Step 2 (e.g. Image 11.3.4.1 and the associated data table).

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

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

- a. The Group adjustment is the difference between the issuer's Group Failure Rate and the Group mean.
- b. For Issuer 10001, the Group G1 and G2 failure rates fell outside of the upper boundary of the confidence interval introducing positive adjustment factors. Issuer 10002's Group G3 failure rate fell outside the lower boundary of the confidence interval introducing a negative adjustment factor. Note that the sign of the adjustment corresponds to the opposite impact on the risk score in samples in the next step (i.e., a positive adjustment will reduce the risk score, while a negative adjustment will increase the risk score). In the examples below, the issuer's adjustments and error rate would result in a negative impact to the issuer's risk score, despite being positive numbers.

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

**Step Five (5):** CMS will use the issuer’s Group adjustment to correct enrollee-level risk scores and project a finalized risk score to the population as noted in Section 11.3.3 (Calculation of Error Rates to Adjust Issuer Plan Risk Scores). Note, Issuer 10001’s Group adjustment factors for G1, G2, and G3 are 10%, 8%, and 0% respectively [derived in Step Four (4)], and assume the issuer enrollees have the following profile:

Issuer	Enrollee	Stratum Size in Population	Sample Enrollees from the Stratum	Stratum Level	HCCs	Maturity	Severity	EdgeRS <sub>i,e</sub>
10001	10001-1	352	67	Infant-Medium	125,130,138,248	PREMATURE MULTIPLES	5	126.158
10001	10001-2	1418	37	Adult-High	1,12,30,36,57,115			12.880
10001	⋮			⋮	⋮	⋮	⋮	⋮

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

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

- i. This enrollee has four (4) HCCs recorded on the EDGE server. For EDGE HCCs [125,130,138,248]. Compute the risk score for a single HCC using the logic defined in HHS RA Model table. For an infant enrollee in the sample, the computation of the single HCC risk score takes into consideration the enrollee’s actual maturity and severity levels.
- ii. Assume the four (4) HCC codes [138,248,125,130] were categorized in HCC Groups G1, G1, G2, and G2 respectively [the result of Step Three (3)]. They are associated with the Group level adjustment factors of 10%, 10%, 8% and 8% (the result of Step Four (4)).
- iii. Compute the enrollee adjustment factor as the weighted average of group level adjustment factors, weighting by the risk score of the HCCs. The four (4) HCC codes have HCC risk scores of 8.008, 125.632, 49.916 and 49.916 with group level adjustment factors of 10%, 10%, 8%, and 8% respectively. This results in a weighted enrollee adjustment factor of 9.1% (i.e.,

$$\frac{8.008*10\% + 125.632*10\% + 49.916*8\% + 49.916*8\%}{8.008+125.632+49.916+49.916}$$

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

- i. This enrollee has six (6) HCCs recorded on the EDGE server. For EDGE HCCs [1, 12, 30, 36, 57, 115], compute the risk score of a single HCC using the logic defined in HHS RA Model table.
- ii. Assume the six (6) HCCs [30,115,1,12,36,57] were categorized in HCC groups G1, G1, G2, G3, G3, and G3 respectively (the result of Step Three {3}). They are associated with the Group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0% (the result of Step Four [4]).
- iii. Compute the enrollee adjustment factor as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. The six (6) HCC codes have HCC risk scores of 1.947, 4.903, 0.33, 2.451, 1.963, and 0.864 with group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0% respectively. This results in a weighted enrollee adjustment factor of 5.7%

$$\left( \text{i.e., } \frac{1.947*10\% + 4.903*10\% + 0.33*8\% + 2.451*0\% + 1.963*0\% + 1.0660.864*0\%}{1.947+4.903+0.33+2.451+1.963+0.864} \right)$$

Enrollee	Stratum Level	Plan Metal Level	Age Last	HCC Failure Group	HCC	Severity Associated with HCC	Maturity Associated with HCC	$RS_{i,e}^{hcc,G}$	Group Adjustment $_i^G$	Enrollee Adjustment $_{i,e}$
10001-1	Infant-Medium	Silver	0	G1	138	4	Age 1	8.008	10.00%	9.1%
					248		PREMATURE MULTIPLES	125.632		
				G2	125	5	AGE 1	49.916	8.00%	
					130	5	AGE 1	49.916		
10001-2	Adult-High	Silver	N/A	G1	30			1.947	10.00%	5.7%
					115			4.903		
				G2	1			0.330	8.00%	
					G3	12				
				36				1.963		
				57				0.864		

- c. Use the enrollees' adjustment factors to correct (adjust) the EDGE risk score for samples.
- i. Apply the enrollee level adjustment factor to the EDGE risk scores of the sampled enrollees. Enrollees 10001-1 and 10001-2 have 9.1% and 5.7% adjustment factors applied to their EDGE risk scores, respectively.

Issuer	Enrollee	EDGE HCCs	$EdgeRS_{i,e}$	Enrollee Adjustment $_{i,e}$	$AdjRS_{i,e}$
10001	10001-1	125,130,138,248	126.158	9.1%	114.678
10001	10001-2	1,12,30,36,57,115	12.880	5.7%	12.146

- d. Calculate the issuer's risk score error rate. Since there are one hundred enrollees, for simplicity, we assume here the stratum weighted summation of the EDGE risk score is 20,751 and the stratum weighted summation of adjusted risk score is 20,538.
- i. Compute the risk score error rate of Issuer 10001 using the EDGE risk scores and adjusted risk scores for all sampled enrollees.
- ii. Compute the stratum weight as the ratio of stratum size in population to the number of sampled enrollees from the stratum.
- iii. Finally, we calculate the issuer-level risk score error rate for Issuer 10001 of 1.03%.

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	$w_e$	$w_e * EdgeRS_{i,e}$	$w_e * AdjRS_{i,e}$	$\sum w_e * EdgeRS_{i,e}$	$\sum w_e * AdjRS_{i,e}$	Error Rate
10001	10001-1	Infant-Medium	126.158	114.678	5.25	662.33	602.06	20751	20538	1.03%
10001	10001-2	Adult-High	12.880	12.146	38.32	493.56	465.43			
10001	⋮	⋮	⋮	⋮	⋮	⋮	⋮			

**Step Six (6):** For IVA samples that indicate a statistically significant difference between IVA and SVA100 results following a pairwise means test, the SVA100 results will be used to calculate the issuer's HCC failure rates, enrollee adjustment factors, and error rate. CMS will use bootstrap resampling to determine the standard errors and confidence intervals for the issuers' error rate calculated in Step Five (5). The bootstrap procedure is used to determine if expansion to SVA200 is required.

1. Draw a sample with replacement of enrollees equal to the number of SVA subsample enrollees from issuer 10001. When performing a bootstrap resampling to determine precision after insufficient pairwise agreement after the SVA100, there will be 100 enrollees in the SVA subsample. Repeat drawing a sample of enrollees (100) with replacement at minimum 1,000 times and determine the error rate for each sample.
  - a. The error rates are determined by repeating the above-mentioned steps using the enrollee details corresponding to the bootstrap sample (i.e., 1-1000).

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

2. Compute the bootstrapped standard error by calculating the sample standard deviation across the 1,000 resampled error rates (i.e., the 1,000 error rates from the above table). This results in a standard error of 0.12%.
3. Determine the bootstrapped confidence intervals by identifying the 2.5<sup>th</sup> and 97.5<sup>th</sup> percentiles of the 1,000 resampled error rates (i.e., the 1,000 error rates from the above table). This results in a confidence interval of [0.83%, 1.23%].
4. At the conclusion of this process, CMS reviews the confidence interval to determine if the error rate is statistically accurate and reliable, in order to determine whether the full review of SVA200 is required, or if the SVA100 can be used for calculating the error rate and subsequent payment adjustments. If the result concludes that the precision of the error rate estimate is unacceptable (poor precision) for SVA100 results, CMS will expand the issuer's sample to SVA200. The entire Error Estimation process would be re-performed [starting with Step One (1)] to include these new samples and the associated HCCs since the overall HCC failure distribution changes after some issuers revise their samples.

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

At the conclusion of the HHS-RADV process, including the Discrepancy Reporting and Administrative Appeals process as described in Section 12 (Discrepancy Reporting and Administrative Appeals), the issuer's risk score error rate will be used to calculate the issuer's adjusted plan liability risk score during the RA payment transfer process, using the formula below:

$$(1 - (\text{error rate})) * (\text{plan liability risk score}) = \text{Adjusted Plan Liability Risk Score}$$

The issuer's adjusted plan liability risk scores will then be used in RA transfer calculations to calculate RA payments and charges for the subsequent benefit year.

See [Appendix H](#) (Error Estimation Example) for an additional example of the Error Estimation process.

## **Section 12**

# **HHS Risk Adjustment Data Validation Protocols Discrepancy Reporting and Administrative Appeals**

## 12. Discrepancy Reporting and Administrative Appeals

### 12.1 Overview

Consistent with 45 C.F.R. § 153.630(d)(2), within 30 calendar days of the notification by CMS of the findings of a SVA (if applicable) or the calculation of a risk score error rate, an issuer must confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate as a result of HHS-RADV, or file a discrepancy report to dispute the findings of a SVA (if applicable) or the calculation of a risk score error rate as a result of HHS-RADV.<sup>42</sup> These attestation and discrepancy reporting processes occur annually for each benefit year and consist of two (2) discrepancy windows.

**Discrepancy Window #1 – HHS-RADV SVA Findings Attestation and Discrepancy Reporting Process:** At the conclusion of the SVA, CMS will distribute to each issuer its respective pairwise means test analysis results. If there is **insufficient** agreement between the IVA and SVA pairwise means test analysis, CMS will use the SVA findings for the error rate calculation and the issuer will receive a *HHS-RADV SVA Findings Report*. The issuer will then have 30 calendar days to attest to the *HHS-RADV SVA Findings Report* or qualify that attestation with a discrepancy.

**Note:** Only issuers who have insufficient agreement between the IVA and SVA as a result of the pairwise means test analysis need to complete the Discrepancy Window #1 – HHS-RADV SVA Findings Attestation and Discrepancy Reporting Process. Issuers who have sufficient agreement between the IVA and SVA as a result of the pairwise means test analysis are not subject to this attestation and discrepancy reporting process.

**Note:** CMS will release to issuers a *HHS-RADV SVA Findings Report* for the HIOS IDs that have insufficient pairwise means test agreement. Only HIOS IDs for which CMS generated a HHS-RADV SVA Findings Report are required to complete the Discrepancy Window #1 – HHS-RADV SVA Findings Attestation and Discrepancy Reporting Process.

**Discrepancy Window #2 – HHS-RADV Error Rate Calculation Attestation and Discrepancy Reporting Process:** At the conclusion of the risk score error rate calculation, CMS will distribute the HHS-RADV 2018 Benefit Year Results Memo and Issuer and Enrollee Specific Metrics Reports to all issuers who participate in 2018 benefit year HHS-RADV. Issuers will then have 30 calendar days to attest to these final results reports or qualify that attestation with a discrepancy.

**Note:** **All issuers who participate in 2018 benefit year HHS-RADV must complete this attestation and discrepancy reporting process.**

Issuer risk score error rates determined by CMS and communicated to issuers are generally applied to issuers' RA covered plans' subsequent benefit year risk scores. For example, the 2018 issuer error rates will generally be applied to the 2019 RA risk scores and resulting transfers.<sup>43</sup>

### 12.2 Attestations

As applicable, issuers are required to either attest to their *HHS-RADV SVA Findings Report*, or qualify that attestation by filing a discrepancy during the applicable discrepancy window, within 30

<sup>42</sup> Issuers cannot appeal the results of the IVA as the IVA Entity is under contract with the issuer and HHS does not produce the IVA results. See 81 FR 94056 at 94106.

<sup>43</sup> As noted in Section 11.3 (Error Estimation), CMS will adjust 2018 benefit year risk scores and recalculate 2018 RA transfers if an issuer that is exiting all of the market in a state in 2019 is found to be a positive error rate outlier in 2018 benefit year HHS-RADV.

calendar days of the date of the *HHS-RADV SVA Findings Report*.

All issuers are required to either attest to their HHS-RADV Final Results Reports, or qualify that attestation by filing a discrepancy during the applicable discrepancy window, within 30 calendar days of the date of the HHS-RADV Final Results Reports. The HHS-RADV Final Results Reports includes the Issuer Specific Metrics Report and the Enrollee Level Metrics Report.

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

### 12.3 Discrepancy and Appeals Timeline

Refer to REGTAP (<https://www.regtap.info/>) for any updates to the HHS-RADV Timeline and corresponding discrepancy and appeals deadlines for the applicable benefit year. Note that this timeline is subject to change.

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

CMS will apply the 2018 issuer risk score error rates to 2019 RA risk scores and resulting 2019 RA transfers for issuers who remain in the state risk pool market and to 2018 RA risk scores and resulting 2018 RA transfer for issuers who exited all of the market risk pools in a state in 2019 and are a positive error rate outlier.<sup>44</sup> These adjustments will be announced without regard to any pending discrepancy or appeal.

### 12.5 Attestation and Discrepancy Reporting Process

The annual HHS-RADV Attestation and Discrepancy Reporting processes consists of two (2) discrepancy windows and a Request for Reconsideration process, all of which are outlined in Table 17.

**Table 17: Attestation and Discrepancy Reporting Process**

Discrepancy Window	Purpose	Issuers Eligible to Participate	Action Required by Eligible Issuers
HHS-RADV SVA Findings Attestation and Discrepancy Reporting Process (Attestation and Discrepancy Window #1)	Resolve HCC specific discrepancies between the IVA and SVA results (if applicable) prior to calculating the risk score error rate for all issuers.	Issuers who have insufficient pairwise means test agreement between the IVA and SVA results.  <i>Note: Attestation and Discrepancy Window #1 is not available for issuers that have sufficient pairwise agreement, since IVA findings will be used for Error Estimation and issuers have already attested those IVA results during the IVA submission process.</i>	Attest to the <i>HHS-RADV SVA Findings Report</i> or qualify the attestation with a discrepancy through a form in the Audit Tool.  Issuers with insufficient pairwise agreement must attest or file a discrepancy specific to the <i>HHS-RADV SVA Findings Report</i> during the Attestation and Discrepancy Window #1.
HHS-RADV Error Rate Calculation Attestation and Discrepancy	Resolve discrepancies related to risk score error rate calculation and	All issuers who participate in 2018 benefit year HHS-RADV.	Attest to the 2018 Benefit Year HHS-RADV Results Reports or qualify the

<sup>44</sup> In the 2020 Payment Notice, we finalized a policy to provide that if an exiting issuer is found to be a negative error rate outlier, we would not make adjustments as a result of the negative error rate outlier finding. See 84 FR at 17503 – 17504.

Discrepancy Window	Purpose	Issuers Eligible to Participate	Action Required by Eligible Issuers
Reporting Process (Attestation and Discrepancy Window #2)	methodology.		attestation with a discrepancy through a form in the Audit Tool.  All issuers who participate in 2018 benefit year HHS-RADV must attest during the Attestation and Discrepancy Window #2.
Request for Reconsideration	Provide issuers the opportunity to request a reconsideration to CMS, including review of any discrepancy decision issued by CMS.	All issuers who participate in 2018 benefit year HHS-RADV.  <i>Note: Issuers are required to file a discrepancy prior to filing a reconsideration request, in the event that the issue was identifiable at the time of discrepancy reporting.</i>	Complete the HHS-RADV Reconsideration Request form in the Audit Tool.  Note: Eligible issuers are not required to take any action if they do not wish to request reconsideration.
Appeal to CMS Hearing Officer	Provide issuers the opportunity to request review by the CMS Hearing Officer of CMS's reconsideration decision.	Issuers who filed a request for reconsideration.	Follow the instructions on submitting an appeal to the CMS Hearing Officer included in the Reconsideration Decision.  Note: Eligible Issuers are not required to take any action if they do not wish to appeal to the CMS Hearing Officer.
Appeal to the CMS Administrator (or delegate)	Provide issuers or CMS the opportunity to request review by the CMS Administrator (or delegate) of the CMS Hearing Officer's decision.	Issuers who filed an appeal with the CMS Hearing Officer; or CMS to appeal the decision of the CMS Hearing Officer	Follow the instructions on submitting an appeal to the CMS Administrator (or delegate) included in the CMS Hearing Officer's Decision.  Note: Eligible Issuers are not required to take any action if they do not wish to appeal to the CMS Administrator.

### Guidance for Submitting a Discrepancy

CMS will provide a unique attestation and discrepancy reporting form in the Audit Tool for each discrepancy window. Issuers must utilize the form to submit an attestation or an attestation qualified by a discrepancy during the applicable attestation and discrepancy reporting window.

When filing a discrepancy, the issuer must provide a detailed description and sufficient evidence in support of the discrepancy filed to allow CMS to appropriately identify the issue or finding being disputed, the document location or associated reference to which the dispute is linked, and the evidence or support necessary to evaluate the discrepancy provided.

CMS will not accept additional documentation that was not provided during the IVA Results Submission process to CMS and the SVA Entity, such as additional medical records or screenshots as part of the discrepancy reporting process. Upon review of a reported discrepancy,

CMS may request that additional documentation, reference material, or other supplemental evidence be submitted in support of the discrepancy. Issuers should only submit additional documentation at the request of CMS.

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

For more information on completing the attestation and discrepancy reporting processes, see the applicable attestation and discrepancy reporting user guides made available with each attestation and discrepancy reporting form in the Audit Tool.

<b>Issuers may only file a discrepancy regarding:</b>
<ul style="list-style-type: none"><li>• HHS-RADV SVA Findings Report – which includes the HCCs found by the IVA but not the SVA or HCCs found by the SVA but not the IVA (during Window #1)</li><li>• Risk score error rate calculation (during Window #2)</li></ul>
<b>Issuers are <u>not</u> permitted to file a discrepancy during these Windows to dispute:</b>
<ul style="list-style-type: none"><li>• IVA Results determined by their contracted IVA Entity</li><li>• HHS-RADV sampling reports<sup>45</sup></li></ul>

## 12.6 Request for Reconsideration

*45 C.F.R. § 156.1220 sets forth a three-step administrative appeal process available to issuers.*

*45 C.F.R. § 156.1220(a) provides that an issuer may file a request for reconsideration to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error only with respect to the findings of a SVA as a result of HHS-RADV; or the calculation of a risk score error rate. 45 C.F.R. § 156.1220(a) sets forth the process and procedure to request reconsideration. Issuers must be familiar with, and abide the rules set out in the regulation. Failure to comply with the regulation, including failure to timely file for reconsideration, may bar the request.*

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

In reviewing the reconsideration request, CMS will review the appropriate SVA findings or risk score error rate calculation being challenged, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the issuer. CMS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and

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<sup>45</sup> See Section 8.5: Sampling Report Discrepancy Reporting above for information on the separate attestation and discrepancy reporting process for HHS-RADV sampling reports.

rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

## **12.7 Request for Informal Hearing to CMS Hearing Officer**

An issuer may request an informal hearing before a CMS hearing officer to appeal CMS' Reconsideration Decision. 45 C.F.R. § 156.1220(b) sets forth the process and procedure to request an informal hearing before a hearing officer. Failure to comply with the regulation, including failure to timely request an informal hearing, may bar the request. We note that instructions on how to submit an appeal to the CMS hearing officer will be included in the Reconsideration Decision.

After receiving a request for informal hearing, the hearing officer will acknowledge the request and issue a scheduling order.

The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact. The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer and CMS.

## **12.8 Appeal to Administrator**

Either the issuer or CMS may request review by the CMS Administrator (or delegate) of the CMS hearing officer's decision. 45 C.F.R. § 156.1220(c) sets forth the process and procedure to request a review by the CMS Administrator (or delegate). The CMS Administrator (or delegate) has the discretion to elect to review the CMS hearing officer's decision or to decline to review the CMS hearing officer's decision. Failure to comply with the regulation, including failure to timely request the CMS Administrator (or delegate) to review the CMS hearing officer's decision, may bar the request. We note that instructions on how to submit an appeal to the CMS Administrator (or delegate) will be included in the CMS hearing officer's decision.

If the CMS Administrator (or delegate) elects to review the CMS hearing officer's decision, the Administrator (or delegate) will also review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision.

The issuer or CMS must prove its case by clear and convincing evidence for issues of fact. The CMS Administrator (or delegate) will send the decision and the reasons for the decision to the issuer and CMS. The decision of the CMS Administrator (or delegate) is final and binding.

**Section 13**  
**HHS Risk Adjustment Data Validation Protocols**  
**Appendices**

## 13. Appendices

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### Appendix A: 2018 Benefit Year D&E Documentation Examples

In this appendix, the following subsections 1) Mapping Documentation Example, 2) Source System Screenshot Example, and 3) Workpaper Example are provided for informational purposes only, and are not intended to fully detail documentation requirements and responsibilities of IVA Entities. This format is not required and is intended to serve only as an example of clearly expressed D&E documentation.

Issuers are required to provide IVA Entities with a set of documents that map the issuer's source system data to EDGE server data submissions. Issuers are required to provide mapping documentation and source system screenshots. Issuers may also provide workpapers documenting any deviations or steps taken that will assist the IVA Entity in performing the validation steps.

The examples below show how a mapping document is used to validate the information on a source system screenshot. Additionally, the example provides cases where a workpaper may be required to document validation steps used to determine a final value for the data element.

**Note:** The examples of mapping documentation, screenshots, and workpapers in the sections below are specific to the D&E validation process and the corresponding D&E data elements.

For mapping documentation, screenshots, and workpapers developed for the purposes of RXC validation, the examples provided in this appendix can be similarly applied. However, RXC data elements would replace those D&E data elements captured in the examples. Since the 2018 benefit year HHS-RADV RXC validation will be treated as a pilot year, CMS will evaluate the documentation submitted by issuers and IVA Entities for the purposes of RXC validation for the 2018 benefit year and will revisit RXC validation documentation examples to include in this appendix for subsequent benefit years.

## 1. Mapping Document Example

Figure 1 provides an example of mapping documentation required for submission as outlined in Section 9.4 (Phase 1 – Creating Mapping Documentation – Issuer) of the 2018 benefit year HHS-RADV Protocols.

The tick-marks in Figure 1 below correlate to the location of each data element within the source system screenshot provided by the issuer.

Data elements with “Format Change from EDGE?” marked “X” indicate that the system captures the data elements differently vs. the EDGE Server. Additional information and mapping documentation references, indicated next to each data element, should list all transformational steps applied across enrollees for that specified element.

**Figure 1: Tick-Mark and Mapping Reference Table for D&E Data Elements**

In this example we are using Tick-Marks (A – J). IVA Entities may use any identifiers as tick marks.

<i>Tick-Mark</i>	Data Element	Format Change from EDGE?	Additional Information	Mapping Document Reference
<b>A</b>	Member ID			
<b>B</b>	First Name			
<b>C</b>	Last Name			
<b>D</b>	DOB			
<b>E</b>	Gender	X	0 = male, 1 = female	
<b>F</b>	Plan ID	X	On-screen Plan ID maps to EDGE Plan Table, found in the mapping document reference.	61110_Mapping Document.pdf – Page 1
<b>G</b>	Enrollment Start Date			
<b>H</b>	Enrollment End Date		Source system end dates of 2999-12-31 are used to indicate ongoing enrollment. For purposes of EDGE Submission, enrollment end-dated to end of the benefit year (2018-12-31).	61110_Mapping Document.pdf – Page 3
<b>I</b>	Premium Amount			
<b>J</b>	Rating Area	X		61110_Mapping Document.pdf – Page 5

## 2. Source System Screenshot Example

The source system screenshot in Figure 2 contains both primary and dependent information. The primary information is **tick-marked in red by the auditor** to assist SVA in identifying the correct enrollee and associated data values for validation. Tick-marks (A – J) in Figure 1 have been added to Figure 2 to link the screenshot data to the required data elements.

**Figure 2: Source Enrollment System Example Screenshot**

Date: 6/1/2018 3:38:54 PM

XXXXSYSTEM  
SOURCE SYSTEM INTERFACE

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PLAN IDENTIFIER	PP1075-90 <b>F</b>	ENROLLMENT START	2017-02-01 <b>G</b>
FNAME	JANICE <b>B</b>	ENROLLMENT END	2999-12-31 <b>H</b>
LNAME	DOE <b>C</b>	GROUP	930284-289-92838
ENROLLEE IDENTIFIER	12345 <b>A</b>	PCP ELECTION	None
RX BIN#	199322		
DOB	1987-01-01 <b>D</b>		
GENDER	<b>F E</b>		
MARITAL STATUS	SINGLE		

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SUBSCRIBER DETAIL

HOME ADDRESS	1425 Virginia Blvd, Arlington VA 20002 <b>J</b>
WORK ADDRESS	1865 Maryland Ave, Baltimore MD 21204
PRIMARY PHONE	938-394-9904
PREMIUM VALUE	501.95 <b>I</b>

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DEPENDENT DETAIL

PLAN IDENTIFIER	PP1075-90	ENROLLMENT START	2017-02-01
FNAME	ROBERT	ENROLLMENT END	2999-12-31
LNAME	DOE		
ENROLLEE IDENTIFIER	12345-A		
DOB	1999-12-12		
GENDER	M		

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DEPENDENT DETAIL

HOME ADDRESS	1425 Virginia Blvd, Arlington VA 20002
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Issuer name redacted

Example screenshot captured from source enrollment system. The screenshot contains both primary and dependent information. The primary information is tick-marked in red by the auditor to assist SVA in identifying the correct enrollee and associated data values for validation.

Tick-Marks (A - J) added to link the screenshot data to the CMS data elements per Figure 2.

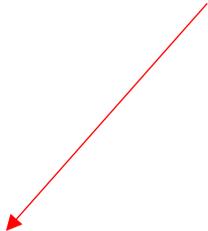
### 3. Workpaper Example

To assist in a comprehensive and logical audit, issuers may provide workpapers to IVA Entities, and IVA Entities may submit workpapers to CMS and the SVA Entity along with screenshots and mapping documentation.

Figure 3 is an example of a workpaper which provides additional information to substantiate the data seen in the screenshot (Figure 2), which would assist the SVA Entity in understanding the process of determining a final value.

**Figure 3: Additional IVA Explanation Workpaper Example**

This is an example of additional information provided to substantiate the data seen in the screenshot, which would assist the SVA in understanding the process of determining a final value.



<i>Tick Mark</i>	Data Element	Enrollee	D&E Document Reference
I	Premium Amount	12343	613420_D&E Doc.pdf
<p><b>Example of EDGE Agreement:</b> CMS selected the month of April (2016-04) for purposes of premium validation. Enrollee is a subscriber, as such the premium was validated. Monthly premium consistent throughout the benefit year at \$501.95.</p> <p><b>Example of Difference Identified:</b> Per the mandate, a newborn can't be billed until the first of the month following 30 days from birth. A newborn was added on 6/28/2017 and wouldn't be billed for the first time as of August 2017. The July 2017 screenshot will show a premium of \$501.95. Included for this enrollee is a screenshot for the month of July 2017. It highlights the addition of the dependent for \$299.99, so the member total now equals \$501.95 + \$299.99 = \$705.98.</p> <p><b>Example of Difference Identified:</b> The screenshot will show a premium of \$501.95. EDGE data submission shows a premium of \$1,001.95. The IVA Entity contacted the issuer to obtain additional documentation to support the difference between EDGE and the source system screenshot. The issuer was unable to provide additional information regarding the root cause of the differences.</p>			
<i>Tick Mark</i>	Data Element	Enrollee	D&E Document Reference
J	Rating Area	12343	613420_D&E Doc.pdf
<p><b>Example of EDGE Agreement:</b> Enrollee is a subscriber, as such Rating Area was validated. The issuer indicated that the Rating Area is determined using the County Code Mapping. We noted that the issuer uses City and Zip to identify County Code, which then corresponds to the Rating Area. See mapping document indicated above for City/Zip to County Code to Rating Area look-up.</p> <p><b>Example of Differences Identified:</b> Based on our review, it appears that we correctly submitted the Rating Area as one (1); however, in our system it is incorrectly captured as</p>			

Rating Area 4. For the coverage period from 12/1/16 to 11/30/17 (first screenshot on page one [1]), the member rating in our system was incorrectly coded as 4; however, for 12/1/17 to 11/30/18 (second screenshot on page one [1]), the Rating Area is one (1). This is also supported by the fact that we submitted Rating Area 1 for both coverage periods.

**Example of Differences Identified:** To validate the Rating Area per the Source System, we utilized the “Area” field on the screenshot. In each case, the screenshot includes ‘RA’ along with the 4-digit code. We have mapped each Rating Area to the proper rating area in the provided mapping document. Page 5 explains you can map the data from the screenshot to the EDGE submission value used by eliminating the ‘RA’ and the first digit. For this enrollee, it looks as though the data was incorrectly submitted. The screenshot shows a value of RA1001, but EDGE submission shows 003. The correct Rating Area should be 001. By using the zip code in field ‘ZIP’ in the screenshot along with the mapping document, it is evident that the enrollee’s zip code is aligned to Rating Area 003.

<b>Tick Mark</b>	<b>Data Element</b>	<b>Enrollee</b>	<b>D&amp;E Document Reference</b>
F	Plan ID	12343	613420_D&E Doc.pdf

**Example of EDGE Agreement:** Enrollee Plan Identifier is indicated in the source system, evidenced by tick-mark F. In mapping documentation, issuer processes specific to the mapping and determination of EDGE Plan ID components (HIOS Issuer ID + State Code + HIOS Product ID + HIOS Component ID + Variant) are described in detail and support the characteristics for the enrollee selected. EDGE Plan Table also included, supports this crosswalk. EDGE Plan ID value of ‘12345VA001999901’ for the enrollee is confirmed.

**Example of Differences Identified:** The IVA Entity was unable to map the Plan ID to the selected enrollee. The IVA Entity contacted the issuer to obtain additional documentation to support the Plan ID that was linked to the enrollee. The issuer was unable to provide additional information regarding the plan enrollment for the specified enrollee. The IVA Entity was unable to verify the correct plan was submitted to EDGE for the enrollee.

**Example of Differences Identified:** The IVA Entity determined the screenshots did not indicate the plan for the enrollee. During the XML submission, we submitted the plan as indicated on the D&E Subsample Report, however, the screenshots provided by the issuer do not indicate a plan. The mapping document provides a list of the enrollees with the plan ID as listed on the D&E Subsample Report but no further mapping to the screenshots. The IVA Entity was unable to verify the correct plan was submitted to EDGE for the enrollee.

## Appendix B: D&E Subsample Data Elements

This appendix provides guidance regarding the 2018 benefit year HHS-RADV D&E subsample data elements and the business data elements associated with the D&E Subsample Report.

### Data Element – Date of Birth

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

The IVA Entity must validate the DOB of the enrollee in the D&E subsample against the DOB for the enrollee in the issuer's source system. Screenshots of the enrollment system showing the enrollee's DOB are required for this validation. Additionally, the issuer must provide the IVA Entity with the source system format used for DOB and provide any mapping used to transform the data to the EDGE server submission format of year, month, date (YYYY-MM-DD). If the DOB in the issuer source system does not match the month, date, and year of birth for the enrollee in the RADVEE Report, the IVA Entity shall record the DOB from the issuer's source system in the *IVA Entity Audit Results Submission XML*.

### Data Element – Gender

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

### Data Element – Plan ID

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

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

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

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

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

The Market Rules and Rate Review Final Rule (45 C.F.R. Part 147) provides that each state will have a set number of geographic rating areas that all issuers in the state must uniformly use as part of their rate setting. Information about each state's market rating areas in the individual and Small Group Markets, and methodology for dividing the state into rating areas, has been made available to issuers for the 2018 benefit year by CMS<sup>46</sup>.

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

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

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

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

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

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

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

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

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

To determine if a D&E subsample enrollee is a subscriber, see the Subscriber Indicator

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<sup>46</sup> <https://www.cms.gov/cciiio/programs-and-initiatives/health-insurance-market-reforms/state-gra.html>

(XML tag 'subscriberIndicator') data element in the Enrollment Period Category of the RADVEE Report. If the value in the data field is an "s," then the enrollee is identified as a subscriber. If the XML data element is "null", then the enrollee is not the subscriber.

The issuer must explain to the IVA Entity, in mapping documents, how the premium amount submitted to the EDGE server was derived. If there are multiple members under one (1) subscriber's policy, the premium is equal to the sum of all individual rates for all rated members on a policy and not the rate associated with the subscriber. Normally, these rates are only derived during policy initiation or renewal and are not carried forward to premium billing systems, which normally have the full premium less any APTC. The sum of the billed premium and APTC must be aggregated and submitted under the subscriber to the EDGE server. This aggregated premium amount will then be validated.

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

### **Clarification of APTC Validation**

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

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

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

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

Examples:

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

For example, the premium amount in the issuer's source system is not inclusive of

APTC. The issuer reported a total premium of \$1,400 to EDGE and \$400 of the premium amount is APTC. The IVA Entity would record '1000' for the premium amount ('policyPremiumAmount' tag) and '400' for the APTC amount ('aptcAmount' tag) in the IVA Entity Audit Results Submission (XML).

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

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

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

### **Validating Premium Amount for Subscriber Enrollees in Small Group Plans**

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

### **Premium Validation – Non-Subscriber Enrollees**

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

### **Data Element – Enrollment Start and End Dates**

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

Examples:

1. If the enrollee's Enrollment Start Date, as indicated in the issuer's source system screenshot, contains an Enrollment Start Date prior to the start of the 2018 benefit year audit, the IVA Entity must record the month, day, and year from the issuer's source system screenshot.

2. The Enrollment End Date value is 'blank' or no data is captured in the issuer's source system, as observed in the source system screenshots. If the issuer confirmed in the mapping document that a 'Blank' value indicates that the enrollee is enrolled through the current benefit year the IVA entity must capture the 'enrollmentEndDateSourceSystem' as the last day of the current benefit year. For benefit year 2018, the date captured would be: 2018-12-31.
3. The Enrollment End Date value is captured in the issuer's source system, as observed in the source system screenshots, and is past the last day of the benefit year being audited (post 12/31/2018 for the 2018 benefit year) then the value should be recorded in the IVA Entity Audit Results Submission (XML) in the format YYYY-MM-DD using the month, date, and year (as seen in the issuer's source system).

## Appendix C: Final Drug Diagnosis (RXC-HCC) Pairs for the 2018 Adult Model

RXC	RXC label	HCC	HCC label	RXC use
1	Hepatitis C Antivirals	037C, 036, 035, 034	Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications	imputation/severity
2	HIV/AIDS Antivirals	001	HIV/AIDS	imputation/severity
3	Antiarrhythmics	142	Specified Heart Arrhythmias	imputation/severity
4	End Stage Renal Disease (ESRD) Phosphate Binders	184, 183, 187, 188	End Stage Renal Disease, Kidney Transplant Status, Chronic Kidney Disease, Stage 5, Chronic Kidney Disease, Severe (Stage 4)	imputation/severity
5	Anti-inflammatories for inflammatory bowel disease (IBD)	048, 041	Inflammatory Bowel Disease, Intestine Transplant Status/Complications	imputation/severity
6a	Anti-Diabetic Agents, Except Insulin and Metformin Only	019, 020, 021, 018	Diabetes with Acute Complications, Diabetes with Chronic Complications, Diabetes without Complication, Pancreas Transplant Status/Complications	imputation/severity
6b	Insulin	019, 020, 021, 018	Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications	imputation/severity
7	Multiple Sclerosis Agents	118	Multiple Sclerosis	imputation/severity
8	Immune Suppressants and Immunomodulators	056, 057, 048, 041	Rheumatoid Arthritis and Specified Autoimmune Disorders, Systemic Lupus Erythematosus and Other Autoimmune Disorders, Inflammatory Bowel Disease, Intestine Transplant Status/Complications	imputation/severity
9	Cystic Fibrosis Agents	159, 158	Cystic Fibrosis, Lung Transplant Status/Complications	imputation/severity

<b>RXC</b>	<b>RXC label</b>	<b>HCC</b>	<b>HCC label</b>	<b>RXC use</b>
10	Ammonia Detoxicants	036, 035, 034	Cirrhosis of Liver, End-Stage Liver Disease, Liver Transplant Status/Complications	severity-only
11	Diuretics, Loop and Select Potassium-Sparing	130, 129, 128	Congestive Heart Failure, Heart Transplant, Heart Assistive Device/Artificial Heart	severity-only

## **Appendix D: ICD-10-CM Official Guidelines for Coding and Reporting**

See CMS.gov for the latest ICD-10-CM guidelines at the following link:

<https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2018-ICD-10-CM-Coding-Guidelines.pdf>

## Appendix E: Lifelong Permanent Conditions

For the 2018 benefit year HHS-RADV, CMS has implemented new HHS-RADV specific guidance related to chronic/lifelong conditions by updating and replacing the 'Chronic Condition HCC' list from the 2017 benefit year HHS-RADV Protocols with a simplified list of Lifelong Permanent Conditions. The list of Lifelong Permanent Conditions shares similar characteristics of being lifelong, permanent conditions which last for multiple years, require ongoing medical attention, and are typically unresolved once diagnosed.

Conditions selected by CMS and included in the 'Lifelong Permanent Conditions' list may be abstracted if documented in any of the documentation provided in an enrollee's medical history included in a medical record for the applicable benefit year (2018). As noted in the ICD-10-CM Official Guidelines for Coding and Reporting, Section IV, J. Code all documented conditions that coexist at the time of the encounter / visit, and require or affect patient care treatment or management can be abstracted. **If a Lifelong Permanent Condition is identified in the medical record and exists at the time of the encounter/visit within the benefit year (2018), the diagnosis should be abstracted. For these Lifelong Permanent Conditions to be abstracted, no other supporting documentation is required.** If a Lifelong Permanent Condition is identified in the enrollee's medical history included in a medical record for the applicable benefit year, the condition does not require additional documentation / validation in order to substantiate the diagnosis, as noted in the steps below.

If a condition, which may be considered by some to be chronic, is identified in the medical record and is **not** on the Lifelong Permanent Conditions list, **IVA Entities should utilize in sequential order the following coding resources when abstracting diagnoses from a medical record:** ICD-10-CM Official Guidelines for Coding and Reporting, the AHA Coding Clinic, and the HHS-RADV 2018 benefit year Protocols, along with exercising professional judgment to make final determinations when abstracting diagnoses.

Below are some recommended steps to follow:

Step	Description	Detail
1	Determine if the condition identified is on the 'Lifelong Permanent Condition' list in the enrollee's medical history for the medical record documentation provided	The condition may be referenced from multiple sources in the record including: <ul style="list-style-type: none"> <li>- Past Medical History (PMH)</li> <li>- Problem Lists</li> <li>- Progress Notes</li> <li>- Assessment and Plan</li> <li>- History of Present Illness (HPI)</li> </ul>
1a	The condition is present on the 'Lifelong Permanent Condition' list	The associated diagnosis should be abstracted by the medical coder and entered into the <i>IVA Entity Audit Results Submission (XML)</i>

Step	Description	Detail
1b	The condition is <b>not</b> present on the 'Lifelong Permanent Condition' list	<p>If the condition is <b>not</b> on the 'Lifelong Permanent Condition' list, the diagnosis should be treated as any other diagnosis. Additional documentation, outlined in Section 9.8.9, is required to substantiate the diagnosis. Without the additional documentation, the diagnosis should not be abstracted by the medical coder.</p> <p>Note, if a diagnosis is identified on the following sources in the record, the medical coder should follow ICD-10-CM Official Guidelines for Coding and Reporting, the AHA Coding Clinic, and the HHS-RADV 2018 benefit year Protocols:</p> <ul style="list-style-type: none"> <li>- Progress Notes</li> <li>- Assessment and Plan</li> <li>- History of Present Illness (HPI)</li> </ul>

See below for examples on how to utilize the 'Lifelong Permanent Conditions' list:

**Example 1:** Multiple Sclerosis, a Lifelong Permanent Condition, diagnosed in 2013 is identified in the PMH section of the medical record. The provider does not address Multiple Sclerosis in the progress notes or anywhere else in the medical record for the current encounter in the benefit year (2018). Multiple Sclerosis **can be** abstracted by the medical coder since the HCC is listed on the 'Lifelong Permanent Condition' list and the diagnosis is listed in the PMH section of the medical record.

**Example 2:** Asthma is identified in the problem list and the PMH of the enrollee's medical record. The provider **does not** address Asthma in the HPI or progress notes in the medical record for the current encounter in the benefit year (2018). Without additional documentation from the provider addressing Asthma, the medical coder **cannot** abstract the Asthma diagnosis as it is not found on the 'Lifelong Permanent Condition' list.

**Example 3:** Bipolar Disorder is only documented under the active problem list in the Emergency Room medical record. Bipolar disorder **can be** abstracted by the medical coder because the condition is listed on the "Lifelong Permanent Condition List" and the diagnosis is listed in the active problem list.

**Example 4:** Diabetes and polyneuropathy are documented in the HPI. The primary care physician orders laboratory test, refills medication and schedules a follow-up visit in three months. Although diabetes is only documented in the HPI, it **can be** abstracted by the medical coder as the patient received treatment and care for the condition.

At a minimum, all medical records must meet the following requirements to avoid the record being

deemed invalid:

- Acceptable risk adjustment provider type, source, and physician specialty.
- Dates of service and/or discharge date must fall within the benefit year being audited (2018).
- Linked to an EDGE server accepted RA eligible claim from the RADVMCE Report where the claims statement covers from/through date aligns to at least one (1) of the dates of service found on the medical record, or to a RA eligible paid/positively adjudicated NEC for the specified sampled enrollee.
- Contain valid signatures and credentials for the provider in the state which they are practicing, or a valid attestation for the encounter.
- Correct enrollee.
- Medical coders should **utilize in sequential order the following coding resources** when abstracting diagnoses from a medical record: Coded according to the official conventions and instructions provided within ICD-10-CM Official Guidelines for Coding and Reporting, the AHA Coding Clinic, and the 2018 benefit year HHS-RADV Protocols. Refer only to issue dates effective at the time of encounter.

Listed below are the conditions selected by CMS and included in the 'Lifelong Permanent Conditions' list.

**Lifelong Permanent Conditions List:**

HHS-HCC	HHS-HCC Label
26	Mucopolysaccharidosis
27	Lipidoses & Glycogenosis
28	Congenital Metabolic Disorders, NEC
29	Amyloidosis, Porphyria & Other Metabolic Orders
46	Chronic Pancreatitis
57	Systemic Lupus Erythematosus and Other Autoimmune Disorders
61	Osteogenesis Imperfecta & Other Osteodystrophies
62	Congenital /Developmental Skeletal & Connective Tissue Disorders
66	Hemophilia
70	Sickle Cell Anemia (Hb-SS)
71	Thalassemia Major
73	Combined & Other Severe Immunodeficiencies
87	Schizophrenia
88	Major Depressive & Bipolar Disorders
90	Personality Disorders
96	Prader-Willi, Patau, Edwards, & Autosomal Deletion Syndromes
97	Down Syndrome, Fragile X, Other Chromosomal Anomalies, & Congenital Malformation Syndromes
102	Autistic Disorder
103	Pervasive Developmental Disorders, Except Autistic Disorder
107	Quadriplegia
109	Paraplegia
111	Amyotrophic Lateral Sclerosis & Other Anterior Horn Cell Disease
112	Quadriplegic Cerebral Palsy

<b>HHS-HCC</b>	<b>HHS-HCC Label</b>
114	Spina Bifida & Other Brain/Spinal/Nervous System Congenital Anomalies
117	Muscular Dystrophy
118	Multiple Sclerosis
119	Parkinson's, Huntington's, Spinocerebellar Disease & Other Neurodegenerative Disorders
128	Heart Assistive Device/Artificial Heart
159	Cystic Fibrosis

**NOTE: CMS realizes the above list is not all encompassing and intends to re-assess this list of permanent lifelong conditions on an annual basis. If a condition is not listed in the above table, additional documentation is required to substantiate the diagnosis. Refer to Section 9.8 for additional information on Health Status Data Validation.**

## Appendix F: Guidance to Coders

The HHS-RADV Guidance to Coders document was created as a tool to facilitate medical record review and coding. This document is intended to assist IVA Entity and SVA Entity coders in reaching consistent decisions when faced with medical records with similar documentation anomalies. At the end of the evaluation process, each medical record submitted for medical record review has been determined to be valid or invalid. **This document is intended as guidance only.** Nothing herein mandates the manner in which medical records are coded. Medical record coders are expected to comply with the professional standards for coding as held by the AAPC or AHIMA.

As noted above in Appendix E, at a minimum, all medical records must meet the following requirements to avoid the record being deemed invalid:

- Acceptable risk adjustment provider type, source, and physician specialty.
- Dates of service and/or discharge date must fall within the benefit year being audited (2018).
- Linked to an EDGE server accepted RA eligible claim from the RADVMCE Report where the claims statement covers from/through date aligns to at least one (1) of the dates of service found on the medical record, or to a RA eligible paid/positively adjudicated NEC for the specified sampled enrollee.
- Contain valid signatures and credentials for the provider in the state which they are practicing, or a valid attestation for the encounter.
- Correct enrollee.
- Medical coders **should utilize in sequential order the following coding resources** when abstracting diagnoses from a medical record: Coded according to the official conventions and instructions provided within ICD-10-CM, Official Guidelines for Coding and Reporting, and guidance provided in the “Coding Clinic for ICD-10-CM” published quarterly by the American Hospital Association and the 2018 benefit year HHS-RADV Protocols. Refer only to issue dates effective at the time of encounter.

**The following guidance topics are included in this appendix.**

- A. Medical Record Attestations
- B. Attestation to MR linkage Issues
- C. Signatures and Credentials
- D. Consultation Notes
- E. Date Issues
- F. Provider Type
- G. Documentation Issues

## A. Medical Record Attestations

CMS will accept attestations to authenticate medical documentation that was not authenticated at the date of service. Specifically, if a signature is missing, the IVA Entity may consider evidence in an attestation statement to determine the identity of the author of a medical record entry. Note, signatures dated greater than 180 calendar days from the date of service must include a valid attestation in order for the medical record to be considered valid.

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

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

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

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

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

## B. Common Attestation Issues

The following table represents examples of various attestation issues and how to evaluate them.

<b>What the Reviewer May Encounter</b>	<b>Examples</b>	<b>Attestation Acceptable Yes/No</b>
a. Physician/Practitioner signed the record for another practitioner, or a signature stamp was used.	<ol style="list-style-type: none"> <li>1. Jane Doe, M.D. signing for James Smith, M.D.</li> <li>2. Jane Doe, M.D. as Power of Attorney for James Smith, M.D.</li> <li>3. Signed by Jane Doe, M.D. in the absence of James Smith, M.D.</li> </ol>	No
b. Date of service is marked through.	March 46, 2018 (4 is written above or below the incorrect 16 <sup>th</sup> date.	Yes
c. Information missing from attestation.	Name, date of service, signature, or credential is missing.	No

<b>What the Reviewer May Encounter</b>	<b>Examples</b>	<b>Attestation Acceptable Yes/No</b>
d. Handwriting error/strikethrough.	Date of service, signature, or credential strikethrough and correction rewritten.	Yes
e. Date of service outside of the benefit year being audited.	12/30/17 or 1/2/19.	No
f. Partially illegible date of service.	01/H/2018 – It could be 4 or 11. Check the medical record to confirm and use the date on the medical record.	Yes
g. Date range.	Jan. 4, 2018 – Oct. 10, 2018.	Yes/No Pass only if medical record matches the first or last date
h. Invalid risk adjustment physician/practitioner credentials.	Medical Assistant, LPN, Dietician	No
i. Multiple, individual dates of service.	March 4, 2018, June 30, 2018, Dec. 16, 2018 Jan. 1–8, May 2, Oct. 4	Yes/No Accept only the date matching the medical record date of service.

### C. Signatures and Credentials

IVA and SVA coders are certified coders who are familiar with acceptable medical record layouts and handwriting techniques. Signature issues must often be evaluated on a case-by-case basis since each one (1) is a little different. Do not hesitate to escalate the case to senior coders in the event of any question/doubt regarding valid signatures. The following table presents issues that may require reviewer discretion and guidance to evaluate and resolve the issue.

**Note:** EMR formats are not standardized and the industry changes rapidly. Both the acceptable and unacceptable provider signature lists are not exhaustive and are intended to offer guidance only.

#### **Provider Specialty and Credentials**

- Medical records submitted for HHS-RADV must be from an acceptable physician specialty type and must be authenticated by the provider. Issuers must ensure that the provider of service for face-to-face encounters is appropriately identified on medical records via signature and specialty credentials, and that the physician/practitioner's credential is acceptable within the state. This means that the credentials must appear somewhere on the medical record, i.e., next to the physician/practitioner's signature (handwritten or electronic) or pre-printed with the physician/practitioner's name on the stationary of the practice.
- For the purposes only of attesting to the provider's credentials, a **signature log** or a **provider directory** of a private practice may be attached to a medical record that is signed with initials or a signature. The practice's signature log must be on the practice's stationary and **must** contain the provider's signature, and full credentials.
- While CMS is not requiring IVA Entities to document or submit specific signature and credentialing data, IVA Entities are required to validate this information identified on the medical record in accordance with coding guidelines. This is in order to verify that the medical record meets CMS requirements to validate the issuer-submitted data for enrollee risk scores. Certified medical coders must verify that the medical record originates from the provider of the medical service(s) and reflects acceptable providers and services specific to the state in which they are practicing.

### **Acceptable Provider Signatures:**

Acceptable physician/practitioner authentication comes in the form of handwritten signatures and electronic signatures.

- Transcribed reports – Electronic signatures are an acceptable form of medical record authentication so long as the system requires the provider to authenticate the signature on the note. In all cases, the signature must contain the practitioner’s name and credentials. Examples of acceptable electronic signatures include:
  - Electronically signed by
  - Authenticated by
  - Approved by
  - Authored by
  - Completed by
  - Finalized by
  - Verified by
  - Validated by
  - Performed by
- Electronic Medical Records – Electronic point of service type medical record entries are typically considered authenticated at login since the physician/practitioner is directly entering the content into a template and populating from other sections of the EMR. Often only the provider name will be documented at the beginning or end of the note, without the “electronically signed by” dated notation. This format is acceptable. Since EMR formats differ, the presence and significance to HHS-RADV of a signature authentication statement and a date in a signature line depends on the structure of the EMR. Escalate to a Senior Coder if any uncertainty in authentication.
- Handwritten provider signatures on paper medical records need not have an accompanying signature date. CMS attempts to associate each signature with a date of service on the record. Accordingly, please be sure that each signature is clearly associated with a date of service for the note in question.
- All medical record entries must be complete and must be authenticated by the physician or practitioner who was responsible for ordering, providing, or evaluating the service furnished.
- Copies of dictated consultations from physician/practitioner office and hospital outpatient visits are often released prior to obtaining a consultant’s signature. These reports then are filed in another physician/practitioner’s record in an “acceptable” form. Diagnoses from these reports will be coded and abstracted from a physician/practitioner record when either of the following conditions applies: 1) the physician/practitioner has referenced the report diagnosis as part of his/her documentation in the office record; or 2) the consultation to which the physician/practitioner is referring is signed and valid as a standalone encounter in the data collection period. If the corresponding medical record has a missing physician/practitioner signature and/or credential, an attestation must be attached.
- For Hospital Inpatient discharges: For hospital records a typed signature alone is not acceptable. All records must be signed and authenticated by the treating physician/practitioner. Within a lengthy inpatient record, there may be a few unsigned progress notes or unsigned consultation reports. In this case, the inpatient medical record must contain sufficient signed documentation to validate any of the audited HCC(s). The coder will review only the signed documentation when coding the principal and secondary diagnoses for the enrollee’s discharge; unsigned documentation will not be used for coding. Auditors must determine on a case-by-case basis if a record suffices to substantiate the HCC

being validated.

- It is unusual for a provider to sign a medical record entry at the beginning of a transcribed or handwritten note. Traditionally, the signature follows the medical record entry but there could be circumstances where the signature is in an unusual place and the evaluator can relate it to the encounter. For example, many providers are using bedside EMRs whereby upon login the entry date, time and provider are electronically stamped at the beginning of the note. A final authentication is not always programmed into specific EMR software.
- Although a signature may appear illegible, (squiggles, etc.) if it is located in an appropriate section of the medical record it is acceptable.

### **Unacceptable Provider Signatures**

- Unacceptable electronic signatures:
  - Administratively signed by
  - Dictated, but not signed
  - Electronic signature on file
  - Electronically signed to expedite delivery
  - Proxy signature – Signed with approval by ...
  - “Electronically signed by” where there is no provider name noted
  - Electronically signed by, but not authenticated
  - Electronically signed by, but not verified
  - Auto-authenticated

In these cases, an attestation for the Physician/Practitioner face-to-face encounter is required.

- Stamped signatures are not acceptable.
- Signature log may not be attached to correct records that have a missing signature.

## D. Consultation Notes

<b>Possible Issue Requiring Reviewer Discretion</b>	<b>Explanation/Comments</b>	<b>Guidance</b>
Consultation report without a signature as part of an authenticated inpatient provider type medical record – consultation report is not submitted as standalone documentation.	A consultation report within an inpatient medical record is a typed (usually dictated) report detailing the evaluation of a condition and performed at the request of the attending physician. There is typically an associated progress note signed by the consultant on the date of the patient evaluation.	Unless the attending physician disagrees with the consultant’s findings, the coder should code all reportable conditions documented in a signed consultation report per ICD-10 CM guidelines.
Inpatient consultant/specialist unconfirmed diagnoses not mentioned by attending physician.	The attending physician will generally refer to the consultant’s diagnosis in subsequent progress notes and her/his final summary. There may be instances where disagreement or further work-up eliminates the consultant’s diagnosis from consideration. As in all medical record documents, the consultation report is expected to be authenticated by the consultant. However, the absence of a consultant’s signature does not preclude the attending physician from including the consultant’s findings in her/his final diagnosis.	If the final assessment by the consultant/specialist includes an unconfirmed diagnosis/statement (rule-out, suspected, likely, etc.) and the diagnosis is not eliminated elsewhere in the record yet not mentioned in the final discharge diagnosis, consider escalating this to a Senior Coder for review as the diagnosis may have been ruled-out.
Consultant report submitted as a standalone provider document/ with no other documentation submitted with the report.	The documentation is typed, usually dictated, and submitted as a standalone document. The report is submitted on the provider’s letterhead and a typed name at the end of the report but does not have the consultant’s signature.	Code only the unsigned record that is covered by an attestation.
Signed office or hospital outpatient note that references signed or unsigned transcribed report.	<p>Hospitals/Specialists often release copies of dictated reports prior to obtaining the dictator’s signature. These reports are filed in another provider’s record in an “acceptable” form.</p> <p>A provider’s note including a statement such as “see discharge summary from &lt;date&gt; hospitalization” or “see consultation report &lt;date&gt;”, would be sufficient to link the current visit/progress note to the dictated summary without having to rewrite all of the findings.</p>	The circumstances of the current encounter would determine which diagnoses from the hospitalization or other visit are still applicable, i.e., acute, chronic, status post.

## E. Date Issues

Possible Issue Requiring Reviewer Discretion	Explanation/Comments
Inpatient Record	<p>Inpatient records must have both <b>admission</b> and <b>discharge date</b> documented at least one (1) place in the record (face sheet, summary, discharge orders etc.). An exception may be applicable on a case-by-case basis when a discharge or transfer summary contains the admission date but lacks the discharge date and the medical record links to an accepted RA eligible claim from the RADVMCE Report or a RA eligible paid or positively adjudicated NEC.</p> <p>For details specific to professional service claims documented within inpatient stays, please refer to Section 9.8.6.1 (Inpatient Considerations).</p>
Inpatient dates of service continuing outside the benefit year being reviewed.	<p>For an inpatient medical record with an admission date in the benefit year being reviewed and the inpatient status extending into the next benefit year, <b>is not considered valid in the benefit year being audited.</b></p> <p>Example: Admission date is December 19, 2018 with a discharge date of January 3, 2019, the care and treatment that was provided in both Dec. 2018 and Jan. 2019 are considered in the 2019 benefit year audit.</p>
Outpatient/physician	<p><b>Outpatient/physician:</b> A medical record submitted is from a physician office or a hospital outpatient medical record, must be dated to be acceptable.</p>
Physician follow up/consult in letter format and Date of Service on Letter	<p>The documentation submitted is a typed, signed and dated letter (within data collection period) from a provider describing the treatment and evaluation of a patient. If the date of service is referenced by the specialist in the body of the letter, use that date. If there is no date of service mentioned in the letter, assume the date of the letter is the face-to-face date of service.</p>
Date of Service on the medical record does not agree with the claim on the RADVMCE Report.	<p>Assume there is a date of service billing error if it can be determined through investigation that the facts regarding the services rendered are consistent between the medical record and the RADVMCE Report or the NEC. Note, a workpaper should be submitted to explain the claim linkage error.</p>
Addressograph or other type of demographic “stamp” with date of service.	<p>An addressograph type stamp or other electronic demographic identification typically notes the patient’s name, birth date, patient number, and physician and admission date. This date may be interpreted as the date of service for emergency room records or other hospital outpatient single date records.</p>

## F. Provider Type

Possible Issue Requiring Reviewer Discretion	Explanation/Comments
Face-to-Face Visit	<p>The submitted record documents a face-to-face encounter with the enrollee from an acceptable HHS-RADV provider type and data source. The three (3) acceptable RA provider types are: Hospital inpatient, Hospital Outpatient, and Professional.</p> <p><b>Note:</b> that there are specific facility sources not included as acceptable inpatient and outpatient facilities; however, acceptable provider type documentation may occur in most any facility, including the patient home. The HHS-RADV process does not include determining the type of claim supporting the original RA data submission.</p>
Standalone Discharge Summary	<p>A standalone discharge summary is considered an acceptable provider type face-to-face visit for the date of inpatient discharge <u>or</u> the date of service documented.</p> <p><b>Inpatient Note:</b> An appropriately detailed discharge summary that documents at least one (1) reportable condition and includes the admission and discharge date indicating inpatient provider type is acceptable for review as an inpatient record.</p>
Face-to-face encounter with an acceptable provider specialty with a reference to non-acceptable practitioner specialty documentation.	<p>Unacceptable provider specialty findings or impressions such as diagnostic radiologist, dietitians, or lab results must be acknowledged or referenced in the acceptable provider's note in order to be coded. The acknowledgement or reference will need to be considered on a case-by-case basis.</p>
Emergency room (ER) as a standalone document	<p>Medical record for an ER visit. ER records often consist of multiple check-off sheets from various members of the treatment team with signatures not always on the same page as the documentation.</p> <p>Coders should review all pages of the ER record whether dated or not. Coders should report only conditions either documented by or clearly reviewed and signed off by an acceptable provider type.</p> <p>Conditions ruled out during the ER testing or conflicting with the ER acceptable provider type's final note should not be reported.</p>
Skilled Nursing Facility (SNF) – An acceptable provider specialty encounter medical record documentation	<p>The issuer submits an acceptable provider's visit from a SNF record that indicates that the enrollee is a resident of the SNF. Although CMS does not accept risk adjustment data from nursing home facilities (as an inpatient provider type), some beneficiaries who reside in a nursing home will have a nursing home medical record (single acceptable provider type specialty encounter) as the only source to support their diagnostic data. The acceptable provider type's encounter must have been face-to-face with the enrollee.</p>
Home Health – An acceptable provider type specialty encounter medical record documentation	<p>The issuer submits an acceptable provider's home visit record. Although CMS does not accept risk adjustment data from home health agencies, some beneficiaries will have a home visit medical record (single acceptable provide type specialty encounter) as the only source to support their diagnostic data. The acceptable provider type's encounter must have been face-to-face with the enrollee.</p>

## G. Documentation Issues

Possible Issue Requiring Reviewer Discretion	Explanation/Comments
Illegible diagnosis due to handwriting	<p>A. The <i>only</i> diagnoses in the medical record submitted are illegible due to handwriting.</p> <p>B. Some illegible (or non-English or both) words that are possibly a diagnosis. Be careful of illegible negative findings (e.g., [No or R/O] CHF) where the preceding word is illegible.</p> <p>Steps:</p> <p>If after review of context, similar words, medications, etc., the coder is not able to decipher an illegible word that is documented in areas typically containing diagnoses or with other legible diagnoses:</p> <ol style="list-style-type: none"> <li>1. Escalate to senior coder for another opinion.</li> <li>2. Senior coder should review the medical record to determine if that condition is legible.</li> <li>3. If the coders agree with the outcome, or agree the words are not diagnoses or not pertinent HCC related diagnoses, proceed with coding the interpreted and legible findings.</li> </ol>
Illegible diagnosis due to a document image issue	If the only diagnoses in the medical record submitted are illegible due to a document image that is too light, too dark, or distorted, the record is deemed invalid.
Non-English documentation	The record submitted includes diagnoses, but the words are not English. Access resources for medical translation of pertinent sections of the medical record.
Abbreviations with multiple meanings.	<p>Several common abbreviations have more than one (1) meaning.</p> <p><b>EXAMPLES:</b> MD – major depression, muscular dystrophy, macular degeneration</p> <p>CRF – chronic renal failure, chronic respiratory failure</p> <p>If more than one (1) meaning applies and documentation is too limited to discern the meaning, coder must use discretion to code based using other notations in the record. If coder/senior coder is unable to determine the meaning of the abbreviation using the entirety of the record, the record must fail.</p>
Medical Record amendments submitted as part of the original record.	<p>An amendment must be completed in a timely manner; however, there could be exceptions such as extended specialized or revised lab/path results or autopsies, legal cases sequestered before completing record, natural disasters, or physician called to military service. In most instances an amendment is based on an observation of the patient, by a supervising physician, on the date of service, or a diagnostic test ordered and test results received subsequent to the patient visit.</p> <p>Sufficient information must be contained in the amendment to verify the documentation was completed in a timely manner by the attending or treating physician.</p>
Missing pages	<p>In some instances, it is possible to identify missing pages from a pre-numbered medical record, or a partial record submission.</p> <p><b>EXAMPLE:</b> A History &amp; Physical (H&amp;P) with pages 1 and 3, however page 2 is missing.</p> <p><b>EXAMPLE:</b> First line of a document submitted appears to be a continuation from a previous page.</p>

Possible Issue Requiring Reviewer Discretion	Explanation/Comments
	If possible, code from available pages. If unable to code from the pages submitted, the record is invalid.
Medical record documentation is distorted or obscured	In some instances, the record documentation is obscured by sticky notes or other markings on the document. If possible, code from available pages. If unable to code from the pages submitted, the record is invalid.
Medical record documentation is too light or too dark.	Some medical record documentation is of poor image quality and the coder is unable to identify key elements. This is common in photographed records. If possible, code from available pages. If unable to code from the pages submitted, the record is invalid.
Pages or margins of the medical record are cut off	Some medical record documentation can have portions of the record text cut off during the submission. If possible, code from available pages. If unable to code from the pages submitted, the record is invalid.

## Appendix G: Examples of Applying HHS-HCC Hierarchies

This section outlines general examples of applying HHS-HCC hierarchies.

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

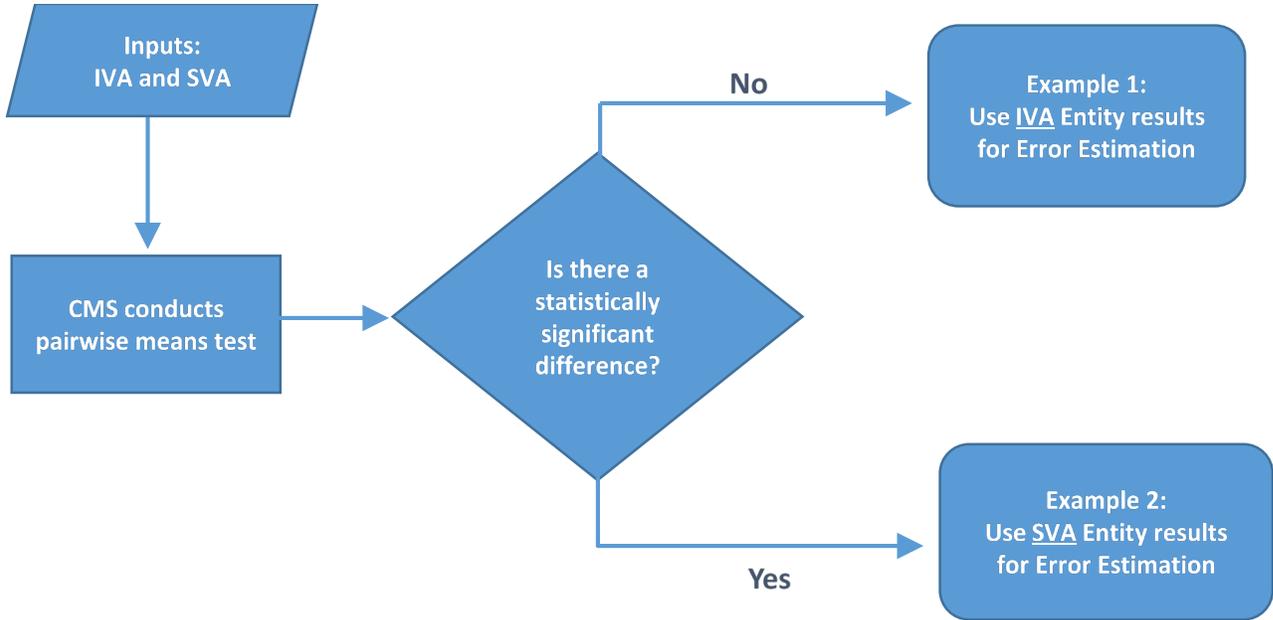
**Example 2:** An issuer's EDGE data reflects multiple diagnoses linking to both CC 9 and CC 10 for a particular enrollee. When HHS-HCC hierarchies are imposed, HCC 9 is determined to be the final HCC for the enrollee on EDGE. The HCC failure rate would be impacted by the IVA Entity's ability to validate HCC 9. In this example, the IVA Entity abstracts diagnoses that in isolation, map to CC 8, CC 9, and CC 10. Like the EDGE server, CMS applies HCC hierarchies to all IVA Entity abstracted diagnoses to determine final IVA HCCs for the enrollee. After applying the HHS-HCC hierarchies, only HCC 8 would be considered as the final IVA HCC for the enrollee. In this situation, two outcomes occur: 1) The EDGE HCC 9 failure rate increases as the IVA Entity did not substantiate the HCC determined as final for the enrollee in EDGE; and 2) HCC 8 failure rate would decrease as the IVA Entity has identified a new occurrence of HCC 8 that was not on EDGE. Note that HCC 8 and HCC 9 may be assigned to different HCC Failure Rate Groups.

# Appendix H: Error Estimation Example

The purpose of this section is to provide stakeholders with an additional example of the Error Estimation process, supplemental to the information provided in Section 11 of these Protocols. All examples are for illustrative purposes only and are not based on real HHS-RADV data.

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

## 1) Establish Final Enrollee Results



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

### Compare IVA and SVA results

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

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

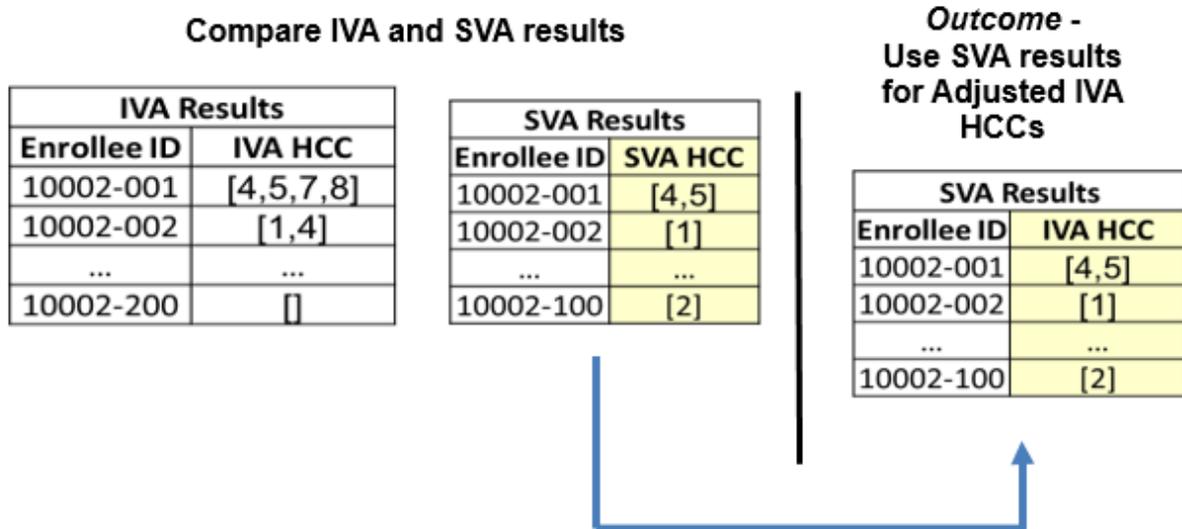
### Outcome - Use IVA results

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



- Example 2: Outcome – Use SVA Results

- Issuer 10002 has 200 IVA sampled enrollees
- The pairwise test results in a significant difference between IVA and SVA results for the 100 enrollees reviewed and the SVA determined the precision to be high<sup>47</sup>



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

- Example 3: Introduction

- Assume there are 50,000 total enrollees sampled during one (1) year’s HHS-RADV process, across all issuers
- The EDGE HCCs and adjusted IVA HCCs are stored as shown in the table

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

<sup>47</sup> In the event that the IVA fails pairwise 100, a precision analysis will be conducted to determine whether to use the SVA100 level findings (a result of high precision) or expand to the full IVA sample of enrollees, which would then be evaluated by the SVA, and utilized for Error Estimation purposes.

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

$$1 - (\text{Freq\_IVA} / \text{Freq\_EDGE}) = \text{Failure Rate}^h$$

$$\text{Ex: } 1 - (180 / 200) = \mathbf{10.0\%}$$

<b>HCC</b>	<b><i>Freq_EDGE<sup>h</sup></i></b>	<b><i>Freq_IVA<sup>h</sup></i></b>	<b><i>Failure Rate<sup>h</sup></i></b>
30	200	180	10.0%
115	700	607	13.3%
138	1,200	1,020	15.0%
248	4,000	3,340	16.5%
1	2,200	1,833	16.7%
125	2,700	2,237	17.1%
130	3,000	2,300	23.3%
12	2,500	1,700	32.0%
36	2,000	1,100	45.0%
57	1,500	500	66.7%
<b>Total</b>	<b>20,000</b>	<b>14,817</b>	<b>25.9%</b>

\*Freq\_EDGE = Total number of enrollees containing such HCC on EDGE

\*\*Freq\_IVA = Total number enrollees containing such HCC in the adjusted IVA results

- Example 3 (b): Tier HCCs nationally into Low, Medium, and High failure rate groups
  - The first boundary to segment Low and Medium failure HCCs is drawn between HCCs 248 and 1, because the total EDGE frequencies of the first four (4) HCCs from the list (30, 115, 138, 248) makes the Group size close to 33.33% of all EDGE frequencies
  - The second boundary to segment Medium and High failure HCCs is drawn between HCC 130 and HCC 12, because the Group size is close to 67% of all EDGE frequencies

HCC	<i>Freq_EDGE<sup>h</sup></i>	<i>Freq_IVA<sup>h</sup></i>	<i>FR<sup>h</sup></i>	<i>Freq_EDGE<sup>h</sup></i> Cumulative Probability	Boundary	Group
30	200	180	10.0%	1.0%		Low
115	700	607	13.3%	4.5%		Low
138	1,200	1,020	15.0%	10.5%		Low
248	4,000	3,340	16.5%	30.5%	<b>33.33%</b>	Low
1	2,200	1,833	16.7%	41.5%		Medium
125	2,700	2,237	17.1%	55.0%		Medium
130	3,000	2,300	23.3%	70.0%	<b>66.7%</b>	Medium
12	2,500	1,700	32.0%	82.5%		High
36	2,000	1,100	45.0%	92.5%		High
57	1,500	500	66.7%	100.0%	100%	High
<b>Total</b>	<b>20,000</b>	<b>14,817</b>	<b>25.9%</b>			

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

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

HIOS ID	Enrollee ID	EDGE HCC	Adjusted IVA HCC
10001	10001-001	[30, 115, 138]	[30, 115]
10001	10001-002	[1, 30]	[1, 30]
...	...	...	...
10001	10001-200	[248, 125]	[125]
10002	10002-001	[30, 57]	[57]
10002	10002-002	[125]	[125]
...	...	...	...
10002	10002-200	[36]	[36]

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

• Example 4 (a): Determine Group Failure Rate

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

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

HCC Group	Issuer	Freq_EDGE <sup>6</sup>	Freq_IVA <sup>6</sup>
Low	10001	133	104
	10002	96	87
	⋮	⋮	⋮
Medium	10001	171	128
	10002	111	86
	⋮	⋮	⋮
High	10001	131	96
	10002	96	79
	⋮	⋮	⋮

- Using the Freq\_EDGE and Freq\_IVA data collected above, calculate Group Failure Rate for each issuer’s HCC Groups:

$$1 - (\text{Freq\_IVA}) / (\text{Freq\_EDGE}) = \text{Group Failure Rate (GFR)}$$

$$\text{Ex: } 1 - (104 / 133) = \mathbf{21.8\%} \text{ for Issuer 100001 (Group Low)}$$

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

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

HCC Group	HIOS ID	Freq_EDGE <sup>G</sup>	Freq_IVA <sup>G</sup>	GFR <sup>G</sup>	$\mu(\text{GFR}^G)$	$\text{Sd}(\text{GFR}^G)$
G1	10001	133	104	21.8%	<b>11.8%</b>	<b>3.0%</b>
	10002	96	87	9.4%		
	⋮	⋮	⋮	⋮		
G2	10001	171	128	25.1%	<b>17.1%</b>	<b>3.4%</b>
	10002	111	86	22.5%		
	⋮	⋮	⋮	⋮		
G3	10001	131	96	26.7%	<b>25.9%</b>	<b>4.0%</b>
	10002	96	79	17.7%		
	⋮	⋮	⋮	⋮		

- Example 4 (c): Create a confidence interval
  - Use the HCC Group weighted mean and standard deviation calculated in step (b) to create a two (2)-sided 1.96 confidence interval:

Weighted Mean – Sigma Cutoff \* Standard Deviation = Confidence Interval Lower Boundary

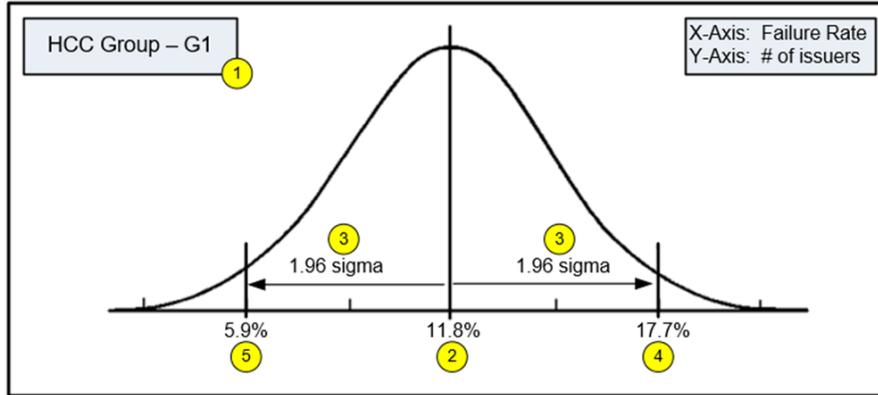
$$11.8\% - 1.96 * 3\% = \mathbf{5.9\%} \text{ for G1}$$

Weighted Mean + Sigma Cutoff \* Standard Deviation = Confidence Interval Upper Boundary

$$11.8\% + 1.96 * 3\% = \mathbf{17.7\%} \text{ for G1}$$

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

G1 Group Distribution Example:



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

• Example 4 (d): Calculate adjustments for Group outliers

- If the issuer's Group Failure Rate falls outside of the confidence interval, then an issuer's Group adjustment factor is calculated:

$$\text{GFR} - \mu(\text{GFR}^G) = \text{Group Adjustment}$$

21.8% - 11.8% = **10%** for G1 (Issuer 10001)  
25.1% - 17.1% = **8%** for G2 (Issuer 10001)  
17.7% - 25.9% = **-8.2%** for G3 (Issuer 10002)

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

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

- Example 5: Introduction

- As a result of Example 4, Issuer 10001 received the adjustment factors of 10%, 8%, and 0% for the three (3) HCC Failure Groups (1 - Low, 2 - Medium, 3 - High), respectively
- Assume the first two (2) sampled enrollees of Issuer 10001 have the detailed information in the table below:

Issuer	Enrollee	Stratum Size in Population	Sample Enrollees from the Stratum	Stratum Level	Plan Metal Level	Age Last (Infant or No HCCs)	EDGE HCCs
10001	10001-1	352	67	Infant-Medium	Silver	0	125,130,138,248
10001	10001-2	1418	37	Adult-High	Silver	-	1,12,30,36,57,115
10001	...	...	...	...			...

- Example 5 (a): Determine enrollee-level adjustments

- Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
  - o Enrollee 10001-1 has four (4) HCCs recorded on EDGE [125, 130, 138, 248]
  - o For each EDGE HCC, compute the risk score for a single HCC using the logic defined in HHS RA Model table. Since the enrollee is an infant, the computation of the single HCC risk score takes into consideration the enrollee's actual maturity and severity levels. This results in risk scores for a single HCC as **8.008, 125.632, 49.916, and 49.916** respectively:

Enrollee	Stratum Level	Plan Metal Level	Age Last	HCC Failure	HCC	Severity Associated with HCC	Maturity Associated with HCC	Enrollee's Severity	Enrollee's Maturity	Variable Used for Risk Score Calculation	$RS_{i,e}^{hcc,G}$
10001-1	Infant-Medium	Silver	0	G1	138	4	Age 1	5	PREMATURE MULTIPLE	AGE1_X_SEVERITY4	8.008
					248		PREMATURE MULTIPLE			PREMATURE_MULTIPLES_X_SEVERITY5	125.632
				G2	125	5	Age 1			AGE1_X_SEVERITY5	49.916
					130	5	Age 1			AGE1_X_SEVERITY5	49.916

- Enrollee's Severity is the highest Severity Associated with HCC among all HCCs
- Enrollee's Maturity is the highest Maturity Associated with HCC among all HCCs
- Variable Used for Risk Score Calculation is the variable used to identify coefficient in HHS RA Model table
  - For HCCs associated with Severity level (e.g., 138, 125, 130), the variable is Enrollee's Maturity X Severity Associated with HCC
  - For HCCs associated with Maturity level (e.g., 248), but with no associated severity level, the "Enrollee's Severity" is used, and the variable is Maturity Associated with HCC X Enrollee's severity
- Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
  - Enrollee 10001-1 HCCs are categorized in HCC Groups G1, G1, G2, and G2 respectively. They are associated with the Group level adjustment factors of 10%, 10%, 8% and 8%
  - Compute the enrollee adjustment score as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. This results in a weighted adjustment score of **9.1%**

Enrollee	Stratum Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$	Group Adjustment $_i^G$	Enrollee Adjustment $_{i,e}$
10001-1	Infant-Medium	G1	138	8.008	10.00%	9.1%
			248	125.632		
		G2	125	49.916	8.00%	
			130	49.916		

- Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
  - Enrollee 10001-2 has six (6) HCCs recorded on EDGE [30, 115, 1, 12, 36, 57]
  - For each EDGE HCC, compute the risk score of a single HCC using the logic defined in HHS RA Model. This results in risk scores for a single HCC as listed in the last column of the table:

Enrollee	Stratum Level	Plan Metal Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$
10001-2	Adult-High	Silver	G1	30	1.947
				115	4.903
			G2	1	0.330
			G3	12	2.451
				36	1.963
				57	0.864

- Enrollee level adjustment factors are calculated using the weighted average from its issuer's Group level adjustment factors
  - o Enrollee 10001-2 HCCs are categorized in HCC groups G1, G1, G2, G3, G3, and G3 respectively. They are associated with the Group level adjustment factors of 10%, 10%, 8%, 0%, 0%, and 0%
  - o Compute the enrollee adjustment score as the weighted average of Group level adjustment factors, weighting by the risk score of the HCCs. This results in a weighted adjustment score of 5.7%

Enrollee	Stratum Level	HCC Failure Group	HCC	$RS_{i,e}^{hcc,G}$	Group Adjustment <sup>G</sup> <sub>i</sub>	Enrollee Adjustment <sub>i,e</sub>
10001-2	Adult - High	G1	30	1.947	10.00%	5.7%
			115	4.903		
		G2	1	0.330	8.00%	
		G3	12	2.451	0%	
			36	1.963		
			57	0.864		

• Example 5 (b): Adjust EDGE risk scores

- Use the enrollees' adjustment factors to adjust the EDGE risk score for samples
  - o Apply the enrollee level adjustment factor to the EDGE risk score of the sampled enrollee. Enrollees 10001-1 and 10001-2 have 9.1% and 5.7% adjustment factors applied to their EDGE risk scores, respectively:

Enrollee 10001-1 has an adjusted risk score of

$$(126.16 * (1 - 9.1\%)) = \mathbf{114.678}$$

Enrollee 10001-2 has an adjusted risk score of

$$(12.88 * (1 - 5.7\%)) = \mathbf{12.146}$$

Issuer	Enrollee	EDGE HCCs	EdgeRS <sub>i,e</sub>	Enrollee Adjustment <sub>i,e</sub>	AdjRS <sub>i,e</sub>
10001	10001-1	125,130,138,248	126.158	9.1%	114.678
10001	10001-2	1,12,30,36,57,115	12.88	5.7%	12.146

- Example 5 (c): Determine issuer Error Rate

- For Issuer 10001, sum the EDGE risk scores and adjusted risk scores for all enrollees in the sample
- For each stratum, compute the stratum weight as the ratio of stratum size in the issuer population on EDGE to the number of sampled enrollees from the stratum
- Compute the issuer-level error rate for Issuer 10001 as one (1) minus the stratum weighted sum of adjusted risk scores (20,538) over the EDGE risk scores (20,751).

Issuer 10001 has a final error rate of  
 $(1 - 20,538/20,751) = 1.03\%$

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	$w_e$	$w_e * EdgeRS_{i,e}$	$w_e * AdjRS_{i,e}$	$\sum w_e * EdgeRS_{i,e}$	$\sum w_e * AdjRS_{i,e}$	Error Rate
10001	10001-1	Infant-Medium	126.158	114.678	5.25	662.33	602.06	20751	20538	1.03%
10001	10001-2	Adult-High	12.88	12.146	38.32	493.56	465.43			
10001	⋮	⋮	⋮	⋮	⋮	⋮	⋮			

- The table below depicts the results for HIOS ID 10001 calculated in the steps above, alongside additional example information for other HIOS IDs (10002; 10003).

Issuer	Enrollee	Stratum Level	$EdgeRS_{i,e}$	$AdjRS_{i,e}$	$w_e$	Error Rate
10001	10001-1	Infant-Medium	126.158	114.678	5.25	1.03%
10001	10001-2	Adult-High	12.88	12.146	38.32	
10001	⋮	⋮	⋮	⋮	⋮	
10002	10002-1	Child-Medium	101.834	98.459	50.1	1.50%
10002	10002-2	Adult-Low	1.064	1.037	1.32	
10002	⋮	⋮	⋮	⋮	⋮	
10003	10003-1	Adult-Medium	28.325	28.325	15.53	0%
10003	10003-2	Adult-High	119.468	119.468	10.11	
10003	⋮	⋮	⋮	⋮	⋮	

- Example 6: Introduction

- Output from Example 5 – enrollee level EDGE risk scores, adjusted risk scores, and stratum weightings
- Assume Issuer 10001 pairwise test results indicated statistically significant differences between IVA and SVA100 findings

- Example 6 (a): Execute bootstrap resampling

- Draw 100 enrollees from Issuer 10001’s sample of 100 enrollees with replacement at least 1,000 times and calculate the error rate for each sample.

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

- Example 6 (b): Calculate standard errors and confidence intervals for issuers

- Compute the bootstrapped standard error by calculating the sample standard deviation across the 1,000 samples
  - This results in a standard error of 0.12%
  - Standard Error: Standard deviation divided by the square root of the sample size
- Determine the bootstrapped confidence intervals by identifying the 2.5<sup>th</sup> and 97.5<sup>th</sup> percentiles of the 1,000 samples of resampled error rates
  - This results in a confidence interval of [0.83%, 1.23%]
- CMS assesses the standard error and confidence intervals calculated and will expand the SVA sample size to SVA200 in the event the bootstrap precision indicates poor precision. In the event the sample increases to 200 enrollees in this way, SVA200 findings will be used as final and the Error Estimation calculation will be re-run

Issuer	Error Rate	Standard Error	Confidence Interval	
			Lower	Upper
10001	1.03%	0.12%	0.83%	1.23%
10002	1.50%	0.27%	1.19%	1.78%
⋮	⋮	⋮	⋮	⋮

- Following the conclusion of the HHS-RADV process, including the Discrepancy Reporting and Administrative Appeals process as described in Section 12 (HHS-RADV Discrepancy Reporting and Administrative Appeals), the issuer’s error rate will be used to calculate the issuer’s adjusted risk score during the RA payment transfer process, using the formula below:

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

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

## Appendix I: IRR Scenarios

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

### Scenario 1 – Primary Coder First Iteration – Pass

Step	Description	Scenario 1
1	Primary Coder Performs Health Status Data Validation	The Primary Coder performs health status data validations and is selected for IRR evaluation following the review of 25 medical records.
2	IRR Sample Selection	25 completed medical records are selected and allocated to Senior Coders for review.
3	Senior Coder Performs Health Status Data Validation	The 25 medical records are allocated to Senior Coders for review. Senior Coders performs health status data validations and records diagnoses abstracted for each of the evaluated medical records.
4	Calculate Primary Coder Consistency Measure	<p>After completing the review of the 25 medical records, the abstracted diagnoses are mapped to HCCs and the Primary Coder findings are used with the Senior Coder findings to calculate the Primary Coder's consistency measure.</p> <p>Within the 25 medical records, the Primary Coder identified diagnoses mapping to four (4) HCCs, which were also found by Senior Coders for the same enrollees. The Senior Coder found no other diagnoses assigned to additional HCCs.</p> <p>The Primary Coder consistency measure (<math>CM_{PC}</math>) for the sample of 25 medical records is calculated using the following formula:</p> $CM_{PC} = \frac{\text{Count of Primary Coder and Senior Coder HCC Matches}}{\text{Count of Unique HCCs (Primary Coder \& Senior Coder)}}$ $CM_{PC} = \frac{4}{4} = 100\%$ <p><b>NOTE:</b> Senior Coder results are captured as final for all medical records reviewed if deviations are identified, even when the calculated consistency measure meets the required 95%. See Scenario Two (2) for additional detail.</p>
5	Finalize IRR or Adjust Sample	The Primary Coder's calculated consistency measure meets the required 95%. The Primary Coder has completed the requirements for IRR evaluation.

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

Step	Description	Scenario 2
1	Primary Coder Performs Health Status Data Validation	The Primary Coder performs health status data validations and is selected for IRR evaluation following the review of 25 medical records.
2	IRR Sample Selection	25 completed medical records are selected and allocated to Senior Coders for review.
3	Senior Coder Performs Health Status Data Validation	The 25 medical records are allocated to Senior Coders for review. Senior Coders performs health status data validations and records diagnoses abstracted for each of the evaluated medical records.
4	Calculate Primary Coder Consistency Measure	<p>After completing the review of the 25 medical records, the abstracted diagnoses are mapped to HCCs and the Primary Coder findings are used with the Senior Coder findings to calculate the Primary Coder’s consistency measure.</p> <p>Within the 25 medical records, the Primary Coder identified diagnoses mapping to seven (7) HCCs. Four (4) of the seven (7) HCCs were also assigned to diagnoses abstracted by the Senior Coder for the same enrollees, and three (3) HCCs were unsubstantiated. Additionally, the Senior Coder found additional diagnoses which were assigned to two (2) HCCs not found by the Primary Coder.</p> <p>The Primary Coder consistency measure (<math>CM_{PC}</math>) for the sample of 25 medical records is calculated using the following formula:</p> $CM_{PC} = \frac{\text{Count of Primary Coder and Senior Coder HCC Matches}}{\text{Count of Unique HCCs (Primary Coder \& Senior Coder)}}$ $CM_{PC} = \frac{4}{9} = 44.44\%$ <p>Senior Coder results are captured as final for all medical records reviewed with deviations identified.</p>
5	Finalize IRR or Adjust Sample	The Primary Coder’s calculated consistency measure does not meet the required 95%. The Primary Coder is required to re-perform the IRR assessment, re-performing steps 1 – 5.

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

## **Appendix J: Application of Risk Score Error Rates for Exiting Issuers**

**Example 1:** Issuer offers coverage in a state in the 2018 benefit year and exits all the markets in a state for the 2019 benefit year (i.e., no membership in the state in the 2019 benefit year). The issuer is not subject to risk adjustment for that state in the 2019 benefit year, but it was identified as a positive error rate outlier during 2018 HHS-RADV. As a result, CMS will apply the issuer's resulting risk score error rate to its 2018 benefit year risk score and recalculate its 2018 benefit year RA transfers. Other issuers in the same state market risk pools in the 2018 benefit year will see their 2019 risk scores and transfers adjusted as a result of the exiting issuer's positive error rate outlier finding.

**Example 2:** Using the same scenario in Example 1, if the same issuer decides to re-enter the market in the 2020 benefit year, after exiting in the 2019 benefit year, the base period used for RADV would be the benefit year for which the issuer re-entered (the 2020 benefit year in this example). Assuming the issuer does not exit all of the markets in the state for the 2021 benefit year, any HHS-RADV adjustments would generally be applied to the issuer's average plan-level risk scores and RA transfers for the benefit year subsequent to the benefit year being audited.

## Appendix K: Updates Log

CMS RADV Protocols Updates Log – Major Updates				
Item	Subject	Protocols Section Reference	Page #	Summarized Update
1	Delete all PHI and PII	Section 1.5 (Securing Protected Health Information)	P. 9	<ul style="list-style-type: none"> <li>Clarified that CMS will delete any and all PHI or PII information that is transmitted directly to CMS by issuers, IVA Entities, or providers outside of the secured IVA submission process and within the Audit Tool, including any PHI or PII communicated via email or regarding sampling reports.</li> </ul>
2	HHS-RADV exemption	Section 1.6.1 (Exemption from HHS-RADV)	P. 9 – 11	<ul style="list-style-type: none"> <li>Updated the definition of the materiality threshold as total annual premiums at or below \$15 million statewide. Beginning with the 2018 benefit year HHS-RADV, the materiality threshold exemption would apply. The random and targeted sampling would however apply to issuers below the materiality threshold. These issuers would be subject to random and targeted sampling every three (3) years (barring any risk-based triggers based on experience that will warrant more frequent audits). Issuers below 500 billable member months remain exempt from random (and targeted) sampling.</li> <li>Beginning with the 2018 benefit year, CMS created a new HHS-RADV Issuer Exemption and DDVC Web Form, which must be completed by all issuers meeting one of the exemptions or who wish to request a DDVC. Issuers can also request an exemption based on liquidation status or DDVC through this web form.</li> <li>Based on the 2020 Payment Notice, updated the liquidation exemption guidance and definition for liquidation.</li> <li>Provided updated guidance indicating that a sole issuer in a state market risk pool in a benefit year is not required to conduct HHS-RADV for that state market risk pool; however, if the sole issuer participates in multiple risk pools in the state during that benefit year where it is not the sole issuer, it would be subject to HHS-RADV for those risk pools where RA transfers are occurring with other issuers.</li> <li>Based on the 2020 Payment Notice, added and defined the exiting issuer exemption for small group market issuers with off-calendar year coverage who exit the market, and where carry-over coverage ends in the next benefit year</li> </ul>

**CMS RADV Protocols Updates Log – Major Updates**

Item	Subject	Protocols Section Reference	Page #	Summarized Update
3	<b>IVA Entity conflict of interest</b>	Section 2.1.3 (IVA Entity Not Free of Conflict of Interest (COI) or Not in Good Standing)  Section 6.5 (Criteria for Assessing IVA Entity Capabilities)	P. 13 – 14 P. 28 – 30	<ul style="list-style-type: none"> <li>• Clarified that CMS does not comment on COI or determine permissibility of IVA Entity selection outside of the parameters stated in the HHS-RADV Protocols</li> <li>• Updated language to indicate that Third Party Administrators (TPAs) or any organization/company/entity responsible for reviewing, analyzing, submitting claims or supplemental diagnosis records on behalf of an issuer via their EDGE server for RA calculation is considered to be in COI and may not be designated as an IVA Entity</li> </ul>
4	<b>Issuer responsibility</b>	Section 2.1.4 (Incomplete Audit Results Submission)	P. 14	<ul style="list-style-type: none"> <li>• Clarified issuer responsibility and requirement to confirm the completion and submission of their IVA results in the Audit Tool</li> </ul>
5	<b>Determining the amount and allocation for DDVC</b>	Section 2.2.2 (Default Data Validation Charge)	P. 15	<ul style="list-style-type: none"> <li>• Established that a Default Data Validation Charge (DDVC) will be assessed to issuers who fail to engage an IVA Entity or fail to submit the results of an IVA within the designated time to CMS</li> <li>• Based on the final decision from the 2020 Payment Notice, CMS will allocate any DDVC collected from noncompliant issuers among the compliant and exempt issuers in the same benefit year risk pool(s) in proportion to their respective market shares and RA transfer amounts for the benefit year being audited for HHS-RADV</li> </ul>
6	<b>DDVC publication and clarification</b>	Section 2.2.2 (Default Data Validation Charge)	P. 15	<ul style="list-style-type: none"> <li>• Clarified that CMS will publish DDVC data in the August 1 report</li> <li>• Clarified that the DDVC is separate from the RA transfer amount for the benefit year, and an issuer may owe both a RA charge and a DDVC</li> </ul>

**CMS RADV Protocols Updates Log – Major Updates**

Item	Subject	Protocols Section Reference	Page #	Summarized Update
7	<b>IVA Entities roles and responsibilities</b>	Section 4.3 (IVA Entities– Roles and Responsibilities)	P. 20 – 22	<ul style="list-style-type: none"> <li>Updated to include IVA Entity’s responsibility to perform RXC validation activities</li> <li>Clarified that CMS is not imposing a deadline for the issuer to complete the IVA Entity Designation Form and noted that the IVA Entity will not have access to the issuer’s sample reports until the IVA Entity is designated by the issuer and accepted by CMS</li> <li>Described the responsibilities of the IVA Entity’s “Medical Coders”, “D&amp;E/RXC Reviewers”, and “IVA Entity SO and Backup SO”</li> </ul>
8	<b>SVA Entity roles and responsibilities</b>	Section 4.4 (SVA Entity – Roles and Responsibilities)	P. 22	<ul style="list-style-type: none"> <li>Updated to include SVA Entity’s responsibility to perform RXC validation activities</li> <li>Described the responsibilities of the SVA Entity’s “Medical Coders” and “D&amp;E/RXC Reviewers”</li> </ul>
9	<b>RADVPCE description</b>	Section 8.3 (RADV Sampling Reports)  Appendix L (Glossary of Terms, Acronyms, and Definitions)	P. 40 – 42 P. 175 – 180	<ul style="list-style-type: none"> <li>Added a description of the RADV Pharmacy Claims Extract (RADVPCE) Report, new for the 2018 benefit year, which contains all active RXC eligible pharmacy claims that were submitted by the issuer for each adult enrollee with RXCs included in the RADV IVA sample</li> </ul>
10	<b>RXC validation</b>	Section 1.1 (Purpose)  Section 9.2 (Process Overview and Audit Execution)  Section 9.7 (Phase 4 – RXC Validation)	P. 7 P. 49 – 50 P. 60 – 67	<ul style="list-style-type: none"> <li>Defined and inserted the RA Prescription Drug Categories (RXC) data validation into the audit process</li> <li>Added new guidance for validating enrollee RXC data elements and indicated that beginning with the 2018 benefit year HHS-RADV, IVA Entities will be required to validate the RXCs of enrollees in the IVA sample</li> </ul>
11	<b>Screenshot automation</b>	Section 9.3.2.1 (Screenshot Automation)	P. 52	<ul style="list-style-type: none"> <li>Updated guidance to indicate that if the issuer and IVA Entity elect to utilize an automated screenshot process, the listed guidelines in the Protocols would be recommended but not required for the 2018 benefit year</li> </ul>
12	<b>Single file mapping documentation</b>	Section 9.4 (Phase 1 – Creating Mapping Documentation – Issuer)	P.53 – 56	<ul style="list-style-type: none"> <li>Updated to require that issuers create and IVA Entities submit at minimum one (1) mapping document containing all required data elements.</li> </ul>

**CMS RADV Protocols Updates Log – Major Updates**

Item	Subject	Protocols Section Reference	Page #	Summarized Update
13	<b>Medical record claim linkage and statement covers from/through dates</b>	Section 9.8 (Phase 5 – Health Status Data Validation)  Section 9.8.6 (Acceptable Date of Medical Record Claim)	P. 68 – 89 P. 73	<ul style="list-style-type: none"> <li>Updated all references to the medical record claim linkage to indicate that the claims statement covers from/through date must align to at least one (1) of the dates of service found on the medical record</li> </ul>
14	<b>Professional Judgment</b>	Section 9.8.4 (Key Considerations of Medical Record Intake)	P. 72 – 73	<ul style="list-style-type: none"> <li>Clarified guidance on situations where the IVA Entity should submit a medical record workpaper detailing the professional judgment used</li> </ul>
15	<b>Medical record chart retrieval</b>	Section 9.8.1 (Medical Record Chart Retrieval)	P. 69 – 70	<ul style="list-style-type: none"> <li>Updated Provider Medical Record Request Memo guidance to emphasize the need for providers to submit all progress notes and discharge summaries, if applicable, for the enrollee under review to the issuer</li> <li>Clarified that the Medical Record Request Memo should not be submitted with the enrollee’s medical record as part of the IVA results submission</li> </ul>
16	<b>Inpatient cross-year medical record workpaper</b>	Section 9.8.6.1 (Inpatient Considerations)	P. 74	<ul style="list-style-type: none"> <li>Clarified guidance related to professional claims documented within inpatient medical records and a discharge date outside of the benefit year</li> <li>Guidance provided to allow issuers and IVA Entities to identify standalone professional service claims and how to identify and document these claims to allow diagnoses to be abstracted and considered within the current benefit year</li> </ul>
17	<b>Updated list of recommended documents for abstraction</b>	Section 9.8.9 (Recommended Documents for Medical Record Abstraction)	P. 80	<ul style="list-style-type: none"> <li>Added clarifying language to indicate that certain medical records on their own <b>cannot</b> be used to substantiate a diagnosis and that the listed reports in conjunction with a valid medical record can help substantiate a diagnosis</li> </ul>

**CMS RADV Protocols Updates Log – Major Updates**

Item	Subject	Protocols Section Reference	Page #	Summarized Update
18	<b>Electronically sent signature attestations</b>	Section 9.8.11.1 (Medical Record Attestations)	P. 82	<ul style="list-style-type: none"> <li>Updated guidance to indicate that signature attestation forms can be sent to a provider and electronically populated, signed, and returned to the IVA Entity, issuer or other party requesting the record on behalf of the issuer</li> </ul>
19	<b>Abstraction coding</b>	Section 9.8.12 (Abstraction Coding)	P. 83 – 86	<ul style="list-style-type: none"> <li>Explained that CMS cannot provide specific coding guidance beyond what is in the Protocols</li> <li>Added reference to Appendix D (ICD-10-CM Official Guidelines for Coding and Reporting) and Appendix E (Lifelong Permanent Conditions) for additional coding guidance and considerations</li> </ul>
20	<b>Key Considerations for Medical Record Abstraction</b>	Section 9.8.13 (Key Considerations for Medical Record Abstraction – New HCC Findings with Positive Risk Score Impact)	P. 86 – 89	<ul style="list-style-type: none"> <li>Updated to clarify the impact of new diagnosis codes on the calculation of an issuer's HCC group failure rates</li> </ul>
21	<b>Senior coder requirements to review primary coder records</b>	Section 10.3 (IRR Process)	P. 91 – 93	<ul style="list-style-type: none"> <li>Defined that CMS does not require one (1) senior coder to review all of a single primary coder's records for IRR purposes</li> <li>Clarified that multiple senior coders can be utilized to review a primary coder's IRR eligible records</li> </ul>
22	<b>Pairwise Test</b>	Section 11.2.1 (Pairwise Test between SVA and IVA)	P. 95 – 98	<ul style="list-style-type: none"> <li>Provided additional detail concerning pairwise means test results from incremental SVA subsample expansion</li> <li>Clarified that if the issuer is found to be an outlier, the results will also be used to calculate the issuer's risk score error rate, which will be applied to the issuer's RA covered plan data</li> </ul>

**CMS RADV Protocols Updates Log – Major Updates**

Item	Subject	Protocols Section Reference	Page #	Summarized Update
23	Exiting issuers	Section 11.3 (Error Estimation)	P. 98 – 100	<ul style="list-style-type: none"> <li>• Provided additional detail to describe positive and negative outlier status</li> <li>• Provided clarifying verbiage to define “exiting issuer” in accordance with 2020 Payment Notice. Indicated that if an issuer only exits some of the markets or risk pools in the state, but continues to sell or offer new plans in other states, then it would not be considered an exiting issuer</li> </ul>
24	Applying HHS-HCC Hierarchies	Section 11.3.1.1 (Applying HHS-HCC Hierarchies)	P. 101	<ul style="list-style-type: none"> <li>• Described the process of applying HHS-HCC hierarchies to all final diagnoses</li> </ul>
25	Error Estimation Example refresh	Section 11.3.4 (Illustration of the Pairwise and Error Estimation Processes)	P. 106 – 113	<ul style="list-style-type: none"> <li>• Updated the example with HCC data and aligned to example data to be consistent with the 2018 DIY software tables</li> </ul>
26	Discrepancy Reporting and Administrative Appeals	Section 12	P. 114 – 118	<ul style="list-style-type: none"> <li>• Updated guidance, timeline, and process details for the 2018 benefit year to align with payment year activities and requirements</li> <li>• Provided process detail for the 1<sup>st</sup> Discrepancy Window: <i>HHS-RADV SVA Findings Attestation and Discrepancy Reporting Process</i>. Clarified that only issuers who have insufficient agreement between the IVA and SVA pairwise means test analysis need to complete this attestation and discrepancy reporting process during the first discrepancy window</li> <li>• Provided process detail for the 2<sup>nd</sup> Discrepancy Window: <i>HHS-RADV Error Rate Calculation Attestation and Discrepancy Reporting Process</i>. Clarified that all issues must complete the attestation and discrepancy reporting process during the 2<sup>nd</sup> discrepancy window</li> <li>• Updated the Attestation and Discrepancy Reporting Process Table to describe the issuers eligible to participate and the action required by eligible issuers for each discrepancy window and major process</li> </ul>
27	D&E Documentation Examples	Appendix A (2018 Benefit Year D&E Documentation Examples)	P. 120 – 124	<ul style="list-style-type: none"> <li>• Provides D&amp;E documentation examples including mapping documentation, source system screenshot, and workpaper</li> </ul>

### CMS RADV Protocols Updates Log – Major Updates

Item	Subject	Protocols Section Reference	Page #	Summarized Update
28	<b>D&amp;E Subsample Data Elements</b>	Appendix B (D&E Subsample Data Elements)	P. 125 – 129	<ul style="list-style-type: none"> <li>Lists sampling D&amp;E subsample data elements listed in Section 5.5.1.1 (Validating Data Elements – Additional Detail) of the 2017 Benefit Year HHS-RADV Protocols</li> </ul>
29	<b>Final Drug Diagnosis Pairs for the 2018 RXC Adult Model</b>	Appendix C (Final Drug Diagnosis (RXC-HCC) Pairs for the 2018 Adult Model)	P. 130 – 131	<ul style="list-style-type: none"> <li>Provides drug diagnosis (RXC-HCC) pairs chosen for the hybrid RA Models</li> </ul>
30	<b>Lifelong Permanent Conditions</b>	Appendix E (Lifelong Permanent Conditions)	P. 133 – 136	<ul style="list-style-type: none"> <li>New for the 2018 benefit year HHS-RADV, CMS has provided specific guidance for the abstraction of lifelong permanent health conditions, and has eliminated the 'Chronic Condition HCC' list of the 2017 benefit year HHS-RADV Protocols</li> </ul>
31	<b>Guidance to Coders</b>	Appendix F (Guidance to Coders)	P. 137 – 142	<ul style="list-style-type: none"> <li>Expanded on acceptable medical record signature guidance from Table 6 - Allowable Provider Signature Types and Table 7 - Allowable Signature Types from Section 5.6.10 (Acceptable Medical Record Signature)</li> <li>Updated to remove National Provider Identifier (NPI) verbiage and update guidance for attesting the provider's credentials</li> </ul>
32	<b>Examples of Applying HHS-HCC Hierarchies</b>	Appendix G (Examples of Applying HHS-HCC Hierarchies)	P. 148	<ul style="list-style-type: none"> <li>New appendix providing examples of applying HHS-HCC hierarchies</li> </ul>
33	<b>Error Estimation Examples</b>	Appendix H (Error Estimation Examples)	P. 149 – 160	<ul style="list-style-type: none"> <li>Updated examples with HCC data and aligned to example data to be consistent with the HHS-RADV 2018 DIY table</li> </ul>
34	<b>IRR Scenarios</b>	Appendix I (IRR Scenarios)	P. 161 – 163	<ul style="list-style-type: none"> <li>Lists IRR scenarios from Section 6.5 (IRR Scenarios) from the 2017 Benefit Year HHS-RADV Protocols</li> </ul>
35	<b>Application of Risk Score Error Rates for Issuers Exiting the Market</b>	Appendix J (Application of Risk Score Error Rates for Issuers Exiting the Market)	P. 164	<ul style="list-style-type: none"> <li>New appendix providing examples explaining the impact on risk score adjustments for issuers exiting the market</li> </ul>
36	<b>Updates Log</b>	Appendix K (Updates Log)	P. 165 – 172	<ul style="list-style-type: none"> <li>New appendix providing a list of major updates in the 2018 Benefit Year HHS-RADV Protocols</li> </ul>

### CMS RADV Protocols Updates Log – Major Updates

Item	Subject	Protocols Section Reference	Page #	Summarized Update
37	<b>Provider Signature Attestation Date</b>	9.8.11.1 and Appendix F (Medical Record Attestation)	P. 82 & 137 – 147	<ul style="list-style-type: none"> <li>Clarified signature attestation date requirement</li> </ul>
38	<b>RXC Data Element</b>	9.7.4 RXC Validation Steps	P. 65 – 68	<ul style="list-style-type: none"> <li>Removed service code qualifier from the RADVMCE required data elements</li> </ul>
39	<b>Lifelong Permanent Conditions</b>	Appendix E	P. 133 – 136	<ul style="list-style-type: none"> <li>Clarified Lifelong Permanent Conditions requirement</li> </ul>
40	<b>Diagnosis Validation</b>	9.8.9 Recommended Documents for Medical Record Abstraction Submission	P. 80	<ul style="list-style-type: none"> <li>Clarified requirement</li> </ul>
41	<b>Medical Record and Chart Retrieval</b>	9.8.1 Medical Record and Chart Retrieval	P. 69 – 70	<ul style="list-style-type: none"> <li>Clarified requirement</li> </ul>
42	<b>Medical Record Signature</b>	9.8.11 Acceptable Medical Record Signature	p. 81 & 82	<ul style="list-style-type: none"> <li>Clarified requirement</li> </ul>

## Appendix L: Glossary of Terms, Acronyms and Definitions

Term	Acronym	Definition
Acceptable Risk Standards	ARS	CMS guidance to its contractors as to the minimum level of required security controls that they must implement to protect CMS information and information systems.
Advanced Premium Tax Credit	APTC	Eligible consumers may use an Advanced Premium Tax Credit through the Exchange to lower their monthly health insurance premium.
Agency for Healthcare Research and Quality	AHRQ	The Agency for Healthcare Research and Quality is the lead federal agency charged with improving the safety and quality of America's health care system.
American Academy of Professional Coders	AAPC	The American Academy of Professional Coders is a national medical coding training and certification association.
American Health Information Management Association	AHIMA	The American Health Information Management Association is an association of health information management professionals.
American Hospital Association	AHA	The American Hospital Association is the national organization that represents and serves all types of hospitals, health care networks, and their patients.
Center for Consumer Information and Insurance Oversight	CCIIO	The Center for Consumer Information and Insurance Oversight is charged with helping implement many reforms of the Affordable Care Act, the historic health reform bill that was signed into law March 23, 2010. CCIIO oversees the implementation of the provisions related to private health insurance. In particular, CCIIO is working with states to establish new Health Insurance Marketplaces. CCIIO works closely with the state regulators, consumers, and other stakeholders to ensure the Affordable Care Act best serves the American people.
Centers for Medicare & Medicaid Services	CMS	Centers for Medicare and Medicaid Services is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards.
Chief Executive Officer	CEO	A chief executive officer is the highest-ranking person in a company, organization or other institution that is ultimately responsible for managerial decisions.
Chief Financial Officer	CFO	A chief financial officer is a senior executive with responsibility for the financial affairs of a company, organization or other institution.
Chronic Obstructive Pulmonary Disease	COPD	Chronic Obstructive Pulmonary Disease is a medical condition involving the constriction of the airways and difficulty or discomfort in breathing.
Civil Money Penalties	CMP	A civil monetary penalty is a monetary penalty the Centers for Medicare & Medicaid Services may impose for noncompliance.

<b>Term</b>	<b>Acronym</b>	<b>Definition</b>
Coordinator	CO	Issuers and Initial Validation Audit Entities identify a representative within their organization to conduct certain HHS_RADV activities.
Conflict of Interest	COI	A situation that has the potential to undermine the impartiality of a person, company or organization because of the possibility of a clash between the person's self-interest and professional interest or public interest.
Confidence Level	CL	The confidence level is the probability that the value of a parameter falls within a specified range of values.
Congestive Heart Failure	CHF	Congestive Heart Failure is a medical condition involving weakness of the heart that leads to a buildup of fluid in the lungs and surrounding body tissues.
Cost-sharing Reduction	CSR	Cost-sharing Reductions are discounts for eligible consumers through the Exchange that lowers the dollar amount of health insurance deductibles, copayments, and coinsurance.
Current Procedural Terminology/ Healthcare Common Procedure Coding System	CPT/HCPCS	CPT/HCPCS® codes are the United States' standard for how medical professionals document and report medical, surgical, radiology, laboratory, anesthesiology, and evaluation and management (E/M) services.
Date of Birth	DOB	The month, day and year a person was born.
Date of Service	DOS	A medical record date of service defines when an enrollee received medical treatment from a physician, permitted provider, medical facility, or telehealth visit
Demographic & Enrollment	D&E	Demographic & Enrollment data describes an enrollee's demographics and enrollment status.
Diabetes Mellitus	DM	Diabetes Mellitus is a medical condition in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine.
Do It Yourself	DIY	The Do It Yourself Software is a tool that includes SAS software and the Department of Health and Human Services Developed RA Model Algorithm. The software instructs issuers how to simulate their enrollee populations' benefit year risk scores within the RA model. This software is only as supplemental guidance for issuers to better understand and simulate the calculation of plan liability risk scores for their enrollees.
Extensible Markup Language	XML	A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine readable.
External Data Gathering Environment	EDGE	Issuers in states where HHS operates a RA program are required to submit enrollment, pharmaceutical claims and medical claim information on enrollees from issuers' proprietary systems to an issuer-distributed data collection server (also known as an EDGE server). An EDGE server runs HHS-developed software designed to verify submitted data, execute RA processes and submit summary reports to CMS.
EDGE Server Business Rules	ESBR	The EDGE Server Business Rules defines the rules under which data is submitted to EDGE servers.

<b>Term</b>	<b>Acronym</b>	<b>Definition</b>
Finite Population Correction	FPC	The Finite Population Correction factor is used to define both the standard error of the mean and the standard error of the proportion.
Health and Human Services	HHS	The U.S. Department of Health & Human Services mission is to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services.
Health Insurance Oversight System ID	HIOS ID	ID assigned by HIOS to a validated insurance issuer. HIOS was created to facilitate several types of data collections from the Department of Insurance for states/territories as well as insurance issuers that sell health insurance coverage. The collected data is aggregated with other data sources and made public on the consumer-facing website.
Health Insurance Portability and Accountability Act	HIPPA	The Health Insurance Portability and Accountability Act is a federal law that was enacted in 1996 that protects continuity of health coverage when a person changes or loses a job, that limits health plan exclusions for preexisting medical conditions, that requires patient medical information be kept private and secure, that standardizes electronic transactions involving health information, and that permits tax deduction of health insurance premiums by the self-employed.
Hierarchical Condition Category	HCC	Hierarchical Condition Category coding is a payment model that identifies health conditions documented by health professionals and assigns a risk score factor.
History of Present Illness	HPI	The History of Present Illness refers to a detailed interview prompted by a presenting symptom that documents the history of that presenting symptom.
Human Immunodeficiency Virus	HIV	Human Immunodeficiency Virus is a medical condition that damages the immune system and can lead to acquired immunodeficiency syndrome.
Information Security	IS	Information security is the practice of preventing unauthorized access, use, disclosure, disruption, modification, inspection, recording or destruction of information. It is a general term that can be used regardless of the form the data may take (e.g. electronic, physical).
Initial Validation Audit	IVA	Validation audit of enrollment and health status data submitted by the issuer to HHS for RA-covered plans. This audit is conducted by an independent audit entity hired by the issuer. Findings from the IVA must be submitted to CMS for review during the Second Validation Audit.
International Classification of Diseases, Clinical Modification, Tenth edition	ICD-10-CM	The National Center for Health Statistics is a federal agency responsible for the use of The International Classification of Diseases, Clinical Modification, Tenth Edition and has developed a clinical modification of the classification for morbidity purposes.
Internal Revenue Service	IRS	The Internal Revenue Service is the nation's tax collection agency and administers the Internal Revenue Code enacted by Congress.
Inter-Rater Reliability	IRR	Inter-Rater Reliability is a process to determine the accuracy of the abstraction diagnoses by Primary Coders when compared to Senior Coders.

<b>Term</b>	<b>Acronym</b>	<b>Definition</b>
Medication Administration Record	MAR	The Medication Administration Record serves as a legal medical record of drugs administered to a patient.
National Center for Health Statistics	NCHS	The National Center for Health Statistics is a federal agency within the United States Centers for Disease Control.
National Drug Code	NDC	The National Drug Code or NDC is a unique numeric identifier given to each medication listed under the Drug Listing Act of 1972
Non-EDGE Claim	NEC	A claim that is not present in the RA Data Validation Medical Claim Extract Report generated by the EDGE server.
Office of Federal Contract Compliance Programs	OFCCP	The Office of Federal Contract Compliance Programs is part of the U.S. Department of Labor. OFCCP is responsible for ensuring that employers doing business with the federal government comply with the laws and regulations requiring nondiscrimination.
Office of Inspector General	OIG	The Office of Inspector General's protects the integrity of Department of Health & Human Services programs as well as the health and welfare of program beneficiaries.
Office of Management and Budget	OMB	The Office of Management and Budget serves the President of the United States in overseeing the implementation of his vision across the Executive Branch. Specifically, OMB's mission is to assist the President in meeting his policy, budget, management and regulatory objectives and to fulfill the agency's statutory responsibilities.
Past Medical History	PMH	In a medical encounter, a past medical history is the total sum of a patient's health status prior to the presenting problem.
Patient Protection and Affordable Care Act	PPACA	The PPACA reforms certain aspects of the private health insurance industry and public health insurance programs, including increasing insurance coverage of pre-existing conditions and expanding access to insurance to Americans.
Payment Error Rate Measurement	PERM	The Payment Error Rate Measurement program measures and reports a national improper payment rate for Medicaid and the Children's Health Insurance Program.
Personally Identifiable Information	PII	Personally Identifiable Information is information that identifies or describes an individual, including but not limited to name, address, telephone number, social security number, credit card number, and personal characteristics that make the individual's identity easily discoverable.
Portable Document Format	PDF	A Portable Document Format is a file format that provides an electronic image of text, or text and graphics that looks like a printed document and can be viewed, printed, and electronically transferred.
Protected Health Information	PHI	Any information about health status, provision of health care, or payment for health care that is created or collected by "Covered Entity" and can be linked to a specific individual.
Registration for Technical Assistance Portal	REGTAP	The Registration for Technical Assistance Portal is used by the Centers for Medicare & Medicaid Services to provide technical assistance and training related to Exchange and Premium Stabilization program guidance and operations.

<b>Term</b>	<b>Acronym</b>	<b>Definition</b>
Risk Adjustment	RA	The Risk Adjustment program is a premium stabilization program established by the Patient Protection and Affordable Care Act. The overall goal of RA is to eliminate premium differences among plans based solely on favorable or unfavorable risk selection in the individual and Small Group Markets both inside and outside of the Marketplace. RA accomplishes this by transferring funds from issuers with lower risk enrollees to plans with higher risk enrollees.
Risk Adjustment Default Charge	RADC	Under 45 CFR §153.740(b), if an issuer of a RA covered plan fails to establish an EDGE server or fails to provide HHS with access to the required data on the EDGE server, such that CMS cannot apply the federally certified RA methodology, a default risk adjustment charge will be assessed.
Risk Adjustment Data Validation	RADV	Risk Adjustment Data Validation is an HHS-established data validation process to validate a statistically valid sample of enrollment and health status data submitted by issuers of risk adjustment covered plans.
Risk Adjustment Risk Score Details	RARSD	The Risk Adjustment Risk Score Details Report contains the risk score result.
Risk Adjustment Data Validation Detailed Enrollee Report	RADVDE	Risk Adjustment Data Validation Detailed Enrollee Report contains enrollee-level data for each enrollee selected for the RADV IVA sample such as the sampled enrollee's risk score, demographic, and health status information.
Risk Adjustment Data Validation Enrollment Extract Report	RADVEE	Risk Adjustment Data Validation Enrollment Extract Report contains all active enrollment data that was submitted by the issuer for each enrollee included in the RADV IVA sample.
Risk Adjustment Data Validation Initial Validation Audit Statistics	RADVIVAS	The Risk Adjustment Data Validation Initial Validation Audit Statistics Report contains the sample statistics calculated at the strata-level for the enrollees selected for the Risk Adjustment Data Validation Initial Validation Audit sample. The report is similar in layout to the Risk Adjustment Data Validation Population Summary Statistics Report, but limited to the enrollees selected for the IVA sample.
Risk Adjustment Data Validation Medical Claims Extract Report	RADVMCE	The Risk Adjustment Data Validation Medical Claims Extract Report contains all active RA eligible and/or RXC eligible medical claims that were submitted by the issuer for each enrollee included in the RADV IVA sample. The report contains claim line information of the active RA eligible claims from sampled enrollees.
Risk Adjustment Data Validation Supplemental Extract	RADVSE	The Risk Adjustment Data Validation Supplemental Extract Report contains all active supplemental records for active Risk Adjustment eligible medical claims that were submitted by the issuer for each enrollee included in the Risk Adjustment Data Validation Initial Validation Audit sample.

<b>Term</b>	<b>Acronym</b>	<b>Definition</b>
Risk Adjustment Data Validation Population Summary Statistics	RADVPS	The Risk Adjustment Data Validation Population Summary Statistics Report contains population statistics for the issuer's total population separated into sub-categories, or "strata," based on enrollee age (infant, child, adult) and risk score (low, medium, high). The RADVPS Report provides issuer level data, including total enrollees and plans, number of enrollees in each risk pool market (individual, small group, catastrophic), strata-level data (including number of enrollees in each of the specific stratum), and summary statistics for each of the specific stratum, including mean (average), minimum (min), and maximum (max) risk scores for enrollees in the stratum.
Risk Adjustment Data Validation Population Summary Statistics Final	RADVPSF	The Risk Adjustment Data Validation Population Summary Statistics Final Report contains the same data elements as the Risk Adjustment Data Validation Population Summary Statistics Report (as listed above), but is generated by the Risk Adjustment Data Validation Report command after the RA transfer calculation and the Issuer Reference Table is populated with risk pool markets included in the RADV sampling logic (RADV population). The new report removes markets in which the issuer is the only issuer in that risk pool market within a state, limiting the report to risk pool markets that are included in the RADV population.
Risk Adjustment Data Validation Pharmacy Claims Extract	RADVPC	This report contains all active RA eligible pharmacy claims that were submitted by the issuer in the pharmacy claim XML for each enrollee included in the RADV IVA sample.
Risk Adjustment Prescription Drug Categories	RXC	Beginning with the 2018 benefit year, RXCs will be utilized in the risk adjustment (RA) program to calculate an adult enrollee's risk score. As a result, IVA Entities will be required to validate the RXCs of sampled enrollees.
Second Validation Audit	SVA	CMS contracts with an approved vendor which performs an independent, third-party audit for CMS of the IVA Entity Audit results.
Senior Official	SO	Issuers and Initial Validation Audit Entities identify a representative Senior Official within their organization to conduct certain HHS-RADV activities.
Subjective, Objective, Assessment, and Plan	SOAP	The SOAP note is an optional method for medical record documentation utilized by some clinicians.
Third-Party Administrator	TPA	A third-party administrator is an organization that processes insurance claims or certain aspects of employee benefit plans for a separate entity.
Unique Enrollee Identification	UID	The unique enrollee identification is a number associated with a specific enrollee to use as an identifier without sharing personally identifiable information.