HHS Risk Adjustment Data Validation (HHS-RADV) Introduction & Updates to RADV Reports, IVA Selection, and Conflict of Interest

March 13, 2019

HHS-RADV Webinar Series IV

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Session Agenda

- Session Guidelines
- Intended Audience
- Session Purpose
- HHS-RADV Timeline
- Summary of Risk Adjustment Data Validation (RADV) Reports
  - Risk Adjustment Data Validation Population Summary Statistics Final (RADVPSF) and Risk Adjustment Data Validation Initial Validation Audit Statistics (RADVIVAS) Report
  - Risk Adjustment Data Validation Detailed Enrollee (RADVDE) Report
  - Risk Adjustment Data Validation Enrollment Extract (RADVEE) Report
  - Risk Adjustment Data Validation Medical Claim Extract (RADVMCE) Report
  - New: Risk Adjustment Validation Pharmacy Claim Extract (RADVPCE) Report
- Initial Validation Audit (IVA) Entity Selection and Conflict of Interest
- Question and Answer (Q&A)
- Next Steps, Resources, and Closing Remarks

Session Guidelines

- This is a 90-minute webinar session
- For questions regarding content, please submit questions to the RADV team at the following email: CCIIOACARADatavalidation@cms.hhs.gov
- For questions regarding logistics and registration, contact the Registrar at: (800) 257-9520

Intended Audience

- Issuers subject to the HHS-RADV Audit requirements under 45 CFR 153.630
- IVA Entities
- Third Party Administrators (TPA) and support vendors

Session Purpose

- Provide the 2018 Benefit Year HHS-RADV Timeline
- Provide updates made to the HHS-RADV Reports
- Provide an overview of IVA Entity selection
- Provide an overview of issuer and IVA Entity conflict of interest guidance
- Provide next steps and upcoming trainings

HHS-RADV Timeline

HHS-RADV Timeline

To access the most HHS-RADV Timeline, please log in to REGTAP and visit the HHS-RADV Program Area page: www.REGTAP.info/hhsradv.php

or utilize the following web link: https://www.regtap.info/reg_librarye.php?i=2456

RADV Reports Updates

Summary of RADV Reports Updates

- **EDGE Server 30.0 Maintenance Release updates:**
  - **Risk Adjustment Data Validation Population Summary Statistics Final (RADVPSF) Report**
    - Updated to include pharmacy data elements
  - **Risk Adjustment Data Validation Initial Validation Audit Statistics (RADVIVAS) Report**
    - Updated to include pharmacy data elements
  - **Risk Adjustment Data Validation Detailed Enrollee (RADVDE) Report**
    - Updated to include pharmacy data elements

Summary of RADV Reports Updates (continued)

- **EDGE Server 30.0 Maintenance Release updates:**
  - **Risk Adjustment Data Validation Enrollment Extract (RADVEE) Report**
    - Update to include all enrollment periods for all enrollees in the IVA sample and added 'Market Type' data element to this report
  - **Risk Adjustment Data Validation Medical Claim Extract (RADVMCE) Report**
    - Update to include all Risk Adjustment (RA) eligible and/or RA prescription drug category (RXC) eligible medical claims and added 'RA eligible flag' and 'RXC eligible flag' data elements to this report
  - **Risk Adjustment Data Validation Pharmacy Claim Extract (RADVPCE) Report**
    - NEW report, RADVPCE which is generated with the RADV batch job

Summary of RADV Reports Updates (continued)

- The following resources have been updated to reflect the changes in this release:
  - Risk Adjustment and Reinsurance (RARI) - Interface Control Document (ICD) Addendum
  - XML/XSD Outbound Files
  - EDGE Server Test Schema Data Model
  - EDGE Server Production Schema Data Model
  - EDGE Server Production and Test Schema Data Dictionary
  - EDGE Server Common Schema Data Model
  - EDGE Server Common Schema Data Dictionary
  - EDGE Server Validation Schema Data Model
  - EDGE Server Validation Schema Data Dictionary
  - EDGE Server Common Validation Schema Data Model
  - EDGE Server Common Validation Schema Data Dictionary

Summary of RADV Documentation Updates

- The Risk Adjustment and Reinsurance (RARI) - Interface Control Document (ICD) Addendum is now five (5) separate documents and remains posted in the Registration for Technical Assistance Portal (REGTAP) Library
- The latest version can be found at the following link https://www.regtap.info/reg_librarye.php?i=2707

RADVPSF and RADVIVAS Reports Updates

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RADVPSF and RADVIVAS Reports Updates

- Total Pharmacy Claims
  - For all enrollees in the defined strata
  - This only includes RA eligible pharmacy claims
- Total Pharmacy Plan Paid Amount
  - Total plan paid amount from all RA eligible pharmacy claims for enrollees belonging to the stratum
- Total Number of RA National Drug Codes (NDCs)
  - Total number of RA NDC codes that map to an RXC for all enrollees in the defined strata contained on RA eligible pharmacy claims
  - Duplicate codes are counted for an individual enrollee

RADVPSF and RADVIVAS Reports Updates (continued)

- Total Unique Number of RA NDC Codes
  - Total number of RA NDC codes de-duplicated for each enrollee, that map to an RXC for all enrollees in the defined strata contained on RA eligible pharmacy claims
  - Duplicate codes are counted once for an individual enrollee
- Total Number of Payment RXCs
  - Total number of RXCs de-duplicated for each enrollee within the strata after the RXC hierarchy is applied

RADVPSF and RADVIVAS Reports Updates (continued)

- Total Unique Healthcare Common Procedure Coding System (HCPCS) That Created Payment RXCs
  - Total number of total service codes from medical claims de-duplicated for each enrollee within the strata that created RXCs for enrollees in the defined strata
- Total Unique Payment RXCs Created By HCPCS
  - Total number of RXCs de-duplicated for each enrollee within the strata after the RXC hierarchy is applied, that are created by a HCPCS service code on a medical claim mapping to the RXC

RADVPSF and RADVIVAS – ICD

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Pharmacy Claims	Total pharmacy claims for all enrollees in the defined strata. This only includes RA eligible pharmacy claims.	Stratum Type	1	totalRxClaims	Integer	minInclusive = 0; maxInclusive = 999999999
Total Pharmacy Plan Paid Amount	Total plan paid amount from all RA eligible pharmacy claims for enrollees belonging to the stratum.	Stratum Type	1	totalRxPlanPaidAmount	Decimal	minInclusive = 0; maxInclusive = 9999999999.99

RADVPSF and RADVIVAS – ICD (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Number of RA NDC Codes	Total number of RA NDC Codes that map to an RXC for all enrollees in the defined strata contained on RA eligible pharmacy claims. Duplicate codes are counted for an individual enrollee.	Stratum Type	1	totalRANdcCodes	Integer	minInclusive = 0; maxInclusive = 999999999
Total Unique Number of RA NDC Codes	Total number of RA NDC Codes, de-duplicated for each enrollee, that map to an RXC for all enrollees in the defined strata contained on RA eligible pharmacy claims.	Stratum Type	1	totalUniqueRANdcCodes	Integer	minInclusive = 0; maxInclusive = 999999999

RADVPSF and RADVIVAS – ICD (continued)

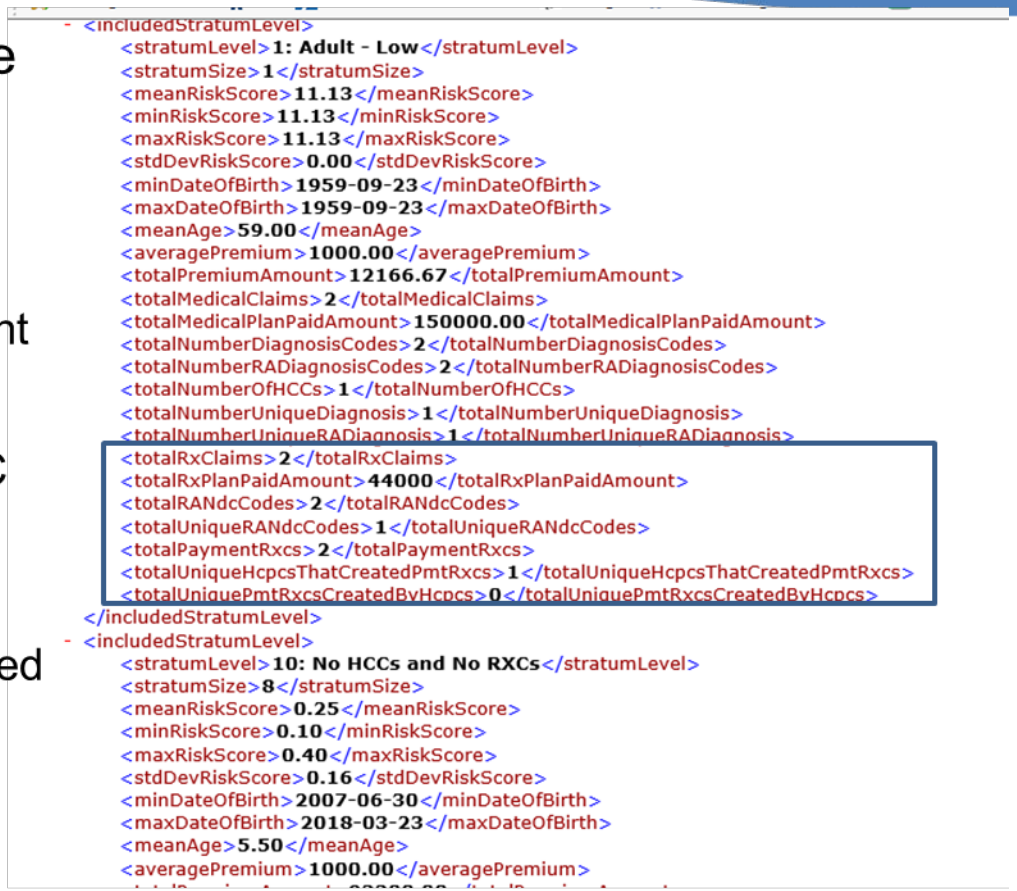
Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Number of Payment RXCs	Total number of RXCs de-duplicated for each enrollee within the strata after the RXC hierarchy is applied.	Stratum Type	1	totalPaymentRxcs	Integer	minInclusive = 0; maxInclusive = 999999999
Total Unique HCPCS That Created Payment RXCs	Total service codes from medical claims, de-duplicated for each enrollee within the strata that created RXCs for enrollees in the defined strata.	Stratum Type	1	totalUniqueHcpcsThatCreatedPmtRxcs	Integer	minInclusive = 0; maxInclusive = 999999999

RADVPSF and RADVIVAS – ICD (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Unique Payment RXCs Created By HCPCS	Total number of RXCs de-duplicated for each enrollee within the strata after the RXC hierarchy is applied, that are created by a HCPCS service code on medical claim mapping to the RXC.	Stratum Type	1	totalUniquePmtRxcsCreatedByHcpcs	Integer	minInclusive = 0; maxInclusive = 999999999

RADVPSF and RADVIVAS XML Updates

- Added the following fields to the RADVPSF and RADVIVAS Reports:
  - Total Pharmacy Claims
  - Total Pharmacy Plan Paid Amount
  - Total Number of RA NDC Codes
  - Total Unique Number of RA NDC Codes
  - Total Number of Payment RXCs
  - Total Unique HCPCS That Created Payment RXCs
  - Total Unique Payment RXCs Created By HCPCS



RADVDE Report Updates

RADVDE Report Update

- Total Pharmacy Claims
  - Count of active, RA eligible pharmacy claims selected for the audit sample for the enrollee
- Total Payment RXCs
  - Count of unique payment RXCs for the enrollee, after the hierarchy is applied
- Total Number of RA NDC Codes
  - Total number of unique RA NDC Codes on any active, RA eligible pharmacy claims and their associated supplemental records for the benefit year

*Note: For new pharmacy data elements, only the adult RA model includes data. As a result only the adult strata 1-3 will have numbers >0

RADVDE Report Update (continued)

- RXC
  - Payment RXC assigned to the enrollee
  - This includes all RXCs identified after the RXC hierarchy is applied
- Unique RA NDC Code
  - All unique RA eligible NDC codes included for the enrollee on any active, RA eligible pharmacy claims for the benefit year
  - An RA NDC code is an NDC code that maps to RXC for the enrollee

*Note: For new pharmacy data elements, only the adult RA model includes data. As a result only the adult strata 1-3 will have numbers >0

RADVDE – ICD

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Pharmacy Claims	Count of active, RA eligible pharmacy claims selected for the audit sample for the enrollee.	Enrollee Detail	1	totalRxClaims	Integer	minInclusive = 0; maxInclusive = 999999999
Total Payment RXCs	Count of payment RXCs for the enrollee. This is the count of unique payment RXCs for the enrollee, after the hierarchy is applied.	Enrollee Detail	1	enrolleePaymentRxcs	Integer	minInclusive = 0; maxInclusive = 999999999

RADVDE – ICD (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Number of RA NDC Codes	Total number of unique RA NDC Codes on any active, RA eligible pharmacy claims and their associated supplemental records for the benefit year. An RA Diagnosis Code is a Diagnosis Code that mapped to a condition category (CC) for the enrollee.	Enrollee Detail	1	totalNumber RANdcCodes	Integer	minInclusive = 0; maxInclusive = 999999999

RADVDE – ICD (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
RXC	Payment RXC assigned to the enrollee. This includes all RXCs identified after the RXC hierarchy is applied.	Enrollee Detail	1 or more	enrolleePaymentRXC	String	minLength = 0; maxLength = 10
Unique RA NDC Code	All unique RA eligible NDC codes included for the enrollee on any active, RA eligible pharmacy claims for the benefit year. An RA NDC code is an NDC code that maps to an RXC for the enrollee.	Enrollee Detail	1 or more	uniqueRANDCCode	String	minLength = 0; maxLength = 30

RADVDE XML Updates

- Added the following fields to the RADVDE:
  - Total Pharmacy Claims
  - Total Payment RXCs
  - Total Number of RA NDC Codes
  - RXC assigned to the Enrollee
  - Unique RA NDC Code

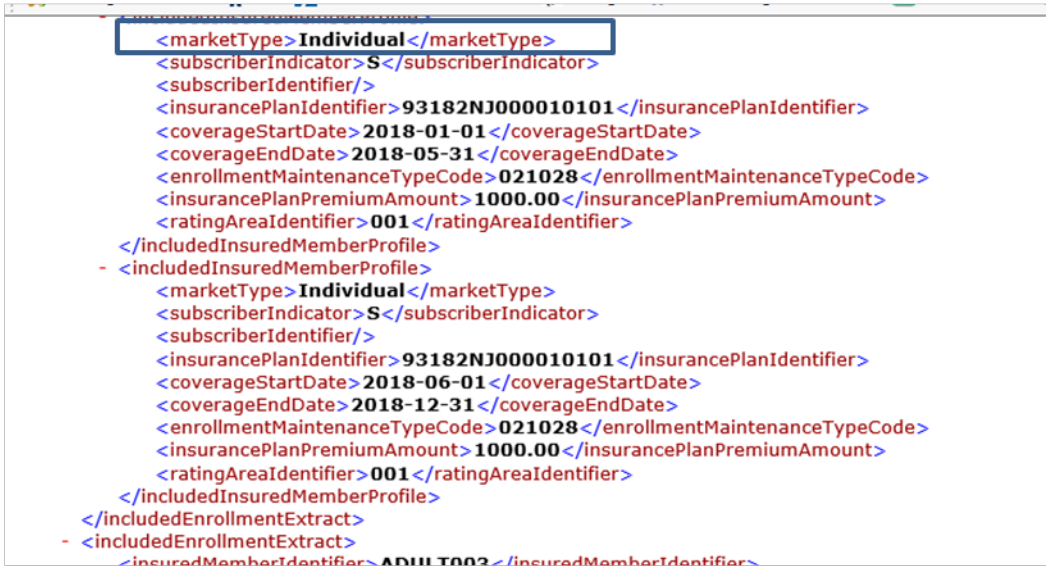
RADVEE Report Updates

RADVEE Report – ICD

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Market Type	Indicates the market that the extracted enrollment period belongs to. Note: The market type for the enrollment period is identified as catastrophic if the market type used for the plan by RA is Individual and the metal level used is Catastrophic. Note: Market type for the extracted issuer submitted or system generated enrollment period should be the same as the market type used by RA for that enrollment period.	Enrollment Period	1	marketType	String	minLength = 0; maxLength = 80 "Individual" OR "Small Group" OR "Catastrophic"

RADVEE Report Updates

- The RADVEE report will now include all enrollment periods for enrollees that are in the IVA sample
- Added the following field to the RADVEE:
  - Market Type



RADVMCE Report Updates

RADVMCE Report – ICD

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
RA Eligible Flag	Indicates whether the medical claim is RA eligible or not.	Claim Header	1	raEligibleFlag	String	Length = 1; Enumeration Values: "Y","N" Enumeration Values Description: "Y": RA Eligible "N": Not RA Eligible
RXC Eligible Flag	Indicates whether the medical claim is RXC eligible or not.	Claim Header	1	rxcEligibleFlag	String	Length = 1; Enumeration Values: "Y","N" Enumeration Values Description: "Y": RXC Eligible "N": Not RXC Eligible

RADVMCE Report Updates

- Added the following field to the RADVMCE report
  - RA Eligible Flag
  - RXC Eligible Flag

```
<billTypeCode/>
<voidReplaceCode/>
<diagnosisTypeCode>02</diagnosisTypeCode>
<diagnosisCode>E0800</diagnosisCode>
<dischargeStatusCode/>
<statementCoverFromDate>2018-01-01</statementCoverFromDate>
<statementCoverToDate>2018-10-01</statementCoverToDate>
<billingProviderIDQualifier>99</billingProviderIDQualifier>
<billingProviderIdentifier>808401234567893</billingProviderIdentifier>
<issuerClaimPaidDate>2016-03-05</issuerClaimPaidDate>
<allowedTotalAmount>6050000.02</allowedTotalAmount>
<policyPaidTotalAmount>605001.52</policyPaidTotalAmount>
<derivedServiceClaimIndicator>N</derivedServiceClaimIndicator>
<raEligibleFlag>N</raEligibleFlag>
<rxcEligibleFlag>Y</rxcEligibleFlag>
- <includedMedicalClaimExtractServiceLine>
    <serviceLineNumber>131</serviceLineNumber>
    <serviceFromDate>2018-01-01</serviceFromDate>
    <serviceToDate>2018-10-01</serviceToDate>
    <revenueCode/>
    <serviceTypeCode>03</serviceTypeCode>
    <serviceCode>J1324</serviceCode>
    <serviceModifierCode>A1</serviceModifierCode>
    <serviceFacilityTypeCode>57</serviceFacilityTypeCode>
    <renderingProviderIDQualifier>99</renderingProviderIDQualifier>
    <renderingProviderIdentifier>808401234567893</renderingProviderIdentifier>
    <allowedAmount>3025000.01</allowedAmount>
    <policyPaidAmount>302500.76</policyPaidAmount>
    <derivedServiceClaimIndicator>N</derivedServiceClaimIndicator>
</includedMedicalClaimExtractServiceLine>
- <includedMedicalClaimExtractServiceLine>
    <serviceLineNumber>132</serviceLineNumber>
    <serviceFromDate>2018-01-01</serviceFromDate>
    <serviceToDate>2018-10-01</serviceToDate>
    <revenueCode/>
    <serviceTypeCode>03</serviceTypeCode>
    <serviceCode>0038U</serviceCode>
```

New RADVPCE Report

New Report: RADVPCE Report

- The RADVPCE 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
- The RADVPCE Report will be generated with the RADV batch job
- Details of the new RADVPCE Report can be found in the RARI_ICD_RADV Addendum

New Report: RADVPCE Report XML

```
<?xml version="1.0"?>
- <radvPharmacyClaimExtract xmlns="http://vo.edge.fm.cms.hhs.gov">
  - <includedFileHeader>
      <outboundFileIdentifier>36228137-c3e3-4511-b344-8d2ae1c4f9da</outboundFileIdentifier>
      <cmsBatchIdentifier>RVP-2018-00001</cmsBatchIdentifier>
      <cmsJobIdentifier>136044</cmsJobIdentifier>
      <snapShotFileName>93182.BACKUP.D12202018T114821.dat</snapShotFileName>
      <snapShotFileHash>e96905cfbee75e8b0a4b57115616715484e2468b</snapShotFileHash>
      <outboundFileGenerationDateTime>2018-12-20T23:48:26</outboundFileGenerationDateTime>
      <interfaceControlReleaseNumber>05.00.21</interfaceControlReleaseNumber>
      <edgeServerVersion>EDGEServer_30.00_00_b0211</edgeServerVersion>
      <outboundFileTypeCode>RADVPCE</outboundFileTypeCode>
      <edgeServerIdentifier>13100124</edgeServerIdentifier>
      <issuerIdentifier>93182</issuerIdentifier>
    </includedFileHeader>
```

RADVPCE Report Data Elements

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
In-Network or Out-of-Network Indicator	Indicator to identify if a service was provided by an In-Network or Out-of-Network dispensing provider.	Claim	1	pharmacyNetworkIndicator	String	Enumeration Values: 'I','O' Enumeration Values Description: "I" = In-Network "O" = Out-of-Network
Claim Processed Date Time	The date and time when the claim was adjudicated and resulted in a paid amount or reported encounter.	Claim	1	claimProcessedDateTime	String	Strict YYYY-MM-DDTHH:mm:SS Note: A default of 00:00:00 for time can be used if no timestamp is available.
Fill Date	Indicates the date that the prescription was dispensed by the dispensing pharmacy.	Claim	1	prescriptionFillDate	String	Strict YYYY-MM-DD

RADVPCE Report Data Elements (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Dispensing Provider ID Qualifier	Identifies the type of dispensing provider ID being submitted in the Dispensing Provider ID field.	Claim	1	dispensing ProviderID Qualifier	String	Length = 2 Enumeration Values: 'XX', '99' • XX - National Provider Identifier (NPI) –• 99 - Other –Different from those implied or specified.
Dispensing Provider ID	The dispensing provider's identification number [National Provider Identifier (NPI) or unique issuer assigned provider ID].	Claim	1	dispensing ProviderId entifier	string	minLength = 1; maxLength = 15

RADVPCE Report Data Elements (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Fill Number	Code identifying whether the prescription is an original (0) or refill (1-999).	Claim	1	prescriptionFillNumber	integer	minInclusive = 0; maxInclusive = 999
Dispensing Status	Indicates if the prescription was a partial fill (P) or the completion of a partial fill (C).	Claim	1	dispensingStatusCode	string	minLength = 0; maxLength 1 Enumeration Values: ‘ ’, ‘P’, ‘C C – Completion of a partial Fill; P = Partial Fill A blank implies a complete fill

RADVPCE Report Data Elements (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Total Allowed Cost	Represents the sum of allowed charges for ingredient cost, dispensing fee, and sales tax.	Claim	1	allowedTotalCostAmount	decimal	minExclusive = -9999999999999999.99; maxInclusive = 9999999999999999.99 decimal required
Prescription/ Service Reference Number	Unique number assigned by the pharmacy to the dispensed prescription.	Claim	1	prescriptionServiceReferenceNumber	string	minLength=7; maxLength=12
Product/Service ID Qualifier	Identifies whether the Product/Service ID is an National Drug Code or not.	Claim	1	nationalDrugCodeQualifier	string	Length = 2 Enumeration Values: • 01 Product/Service ID other than National Drug Code • 02 Product/Service ID is a NDC

RADVPCE Report Data Elements (continued)

Business Data Element	Description	Data Category	Frequency of Occurrence	XML Element Names	Data Type	Restrictions
Product/Service ID	Unique ID of the product or service dispensed [National Drug Code (NDC)].	Claim	1	nationalDrug Code	string	minLength=1; maxLength=11
Days of Supply	Number of days of supply for the product or service dispensed.	Claim	1	daysSupply	Integer	minInclusive = 1, maxInclusive = 999

IVA Entity Selection Regulatory Requirements

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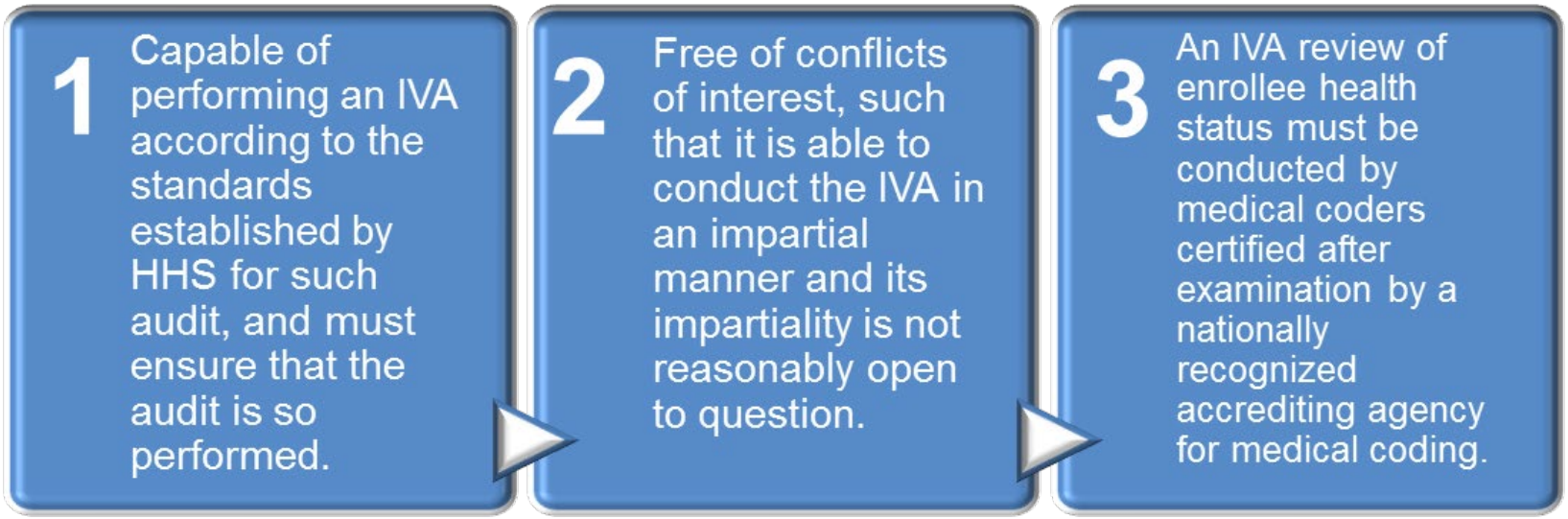
HHS-RADV Regulatory Requirements for Selecting an IVA Entity

- Per 45 C.F.R. §153.630, issuers must ensure that the designated IVA Entity meets the following criteria:



CMS may not accept an issuer's IVA Entity designation if the designated IVA Entity does not meet the regulatory requirements

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

Regulatory requirement for the IVA Entity Selection:

1 Capable of performing an IVA according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

- Issuers must retain documentation from the selection and review process that demonstrates the IVA Entity meets the regulatory requirements
- CMS may request documentation regarding the issuer's IVA Entity selection process and the IVA Entity's compliance with applicable requirements

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

Regulatory requirement for the IVA Entity Selection:

2 Free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question.

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

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

Regulatory requirement for IVA the Entity Selection:

2 Free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question.

- Issuers must verify 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 Office of Inspector General (OIG) exclusion list or, to its knowledge, are under investigation with respect to any HHS programs
- Issuers must perform a reasonable investigation to verify there are no material or financial ownership interests between the issuer, the IVA Entity, or any member of either management team (or any member of the immediate family of such member) such that the financial success of the issuer or IVA Entity could be seen as materially affecting the success of the other entity, calling into question the impartiality of the IVA process, and/or could reasonably be seen as having the ability to influence the decision making of the other entity

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

Regulatory requirement for the IVA Entity Selection:

3 An IVA review of enrollee health status must be conducted by medical coders certified after examination by a nationally recognized accrediting agency for medical coding.

- The IVA Entity must use medical coders with relevant skills as demonstrated through certification after examination by a nationally recognized accrediting agency for medical coding, such as the American Health Information Management Association (AHIMA) or the American Academy of Professional Coders (AAPC), and in good standing
- A senior reviewer is required to confirm any finding of an RA error discovered during the IVA
  - A senior reviewer is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least five (5) years of experience in medical coding

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

- **Additional Regulatory Requirements**
  - **The issuer Chief Executive Officer (CEO)/Chief Financial Officer (CFO) or a person who is authorized to legally and financially bind the organization will be required to attest to the following:**
    - There are no conflicts of interest between the IVA Entity (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation
    - That the issuer has obtained an equivalent representation from the IVA Entity and
    - That no key individual involved in supervising or performing the IVA appears on the Office of the Inspector General List of Excluded Individuals and Entities or, to the issuer's knowledge, are under investigation with respect to any HHS program

HHS-RADV Regulatory Requirements for Selecting an IVA Entity (continued)

- **Non-Compliance Implications of Not Engaging an IVA Entity**
  - Issuers are required to engage and have the Centers for Medicare & Medicaid Services (CMS) accept an IVA Entity before the IVA process begins
  - If an issuer of an RA covered plan fails to engage an IVA Entity and an HHS-RADV exemption does not apply, CMS will impose a Default Data Validation Charge (DDVC)*
  - In the 2020 Payment Notice Proposed Rule, we propose, beginning with the 2018 benefit year, to calculate the DDVC using enrollment data for the current benefit year being audited

* We use the DDVC acronym to more clearly distinguish it from the RADC under 45 C.F.R § 153.740(b). In the 2020 Payment Notice Proposed Rule, we propose to update §153.630(b)(10) to formally adopt the DDVC language

Issuer and IVA Entity Conflict of Interest Examples

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HHS-RADV Conflict of Interest

Example	Background	Question	Answer	Regulatory Reference
Example 1	Issuer A contracts with IVA Entity B to conduct the HHS-RADV IVA. IVA Entity B's Director, John, is an owner of issuer A.	Does a conflict of interest exist?	YES	Owners, directors, and officers of the issuer may not be owners, directors, or officers of the initial validation auditor, and vice versa.
Example 2	Issuer A contracts with IVA Entity B to conduct the HHS-RADV IVA. IVA Entity B's management team member, John, has a material financial interest in issuer A. John is married to Susan, who is a part owner of issuer A.	Does a conflict of interest exist?	YES	Neither the initial validation auditor nor any member of its management team or data validation audit team (or any member of the immediate family of such a member) may have any material financial or ownership interest in the issuer, such that the financial success of the issuer could be reasonably seen as materially affecting the financial success of the initial validation auditor or management team or audit team member (or immediate family member) and the impartiality of the initial validation audit process could reasonably be called into question, or such that the initial validation auditor or management or audit team member (or immediate family member) could be seen as having the ability to influence the decision making of the issuer.

HHS-RADV Conflict of Interest (continued)

Example	Background	Question	Answer	Regulatory Reference
Example 3	Issuer A contracts with IVA Entity B to conduct the HHS-RADV IVA. IVA Entity B hires five (5) medical coders to work as members of the data validation audit team. New medical coder employee, Gerry, has no material financial interest or ownership interest in issuer A. However, Gerry's brother is a director of issuer A.	Does a conflict of interest exist?	YES	Members of the data validation audit team of the initial validation auditor may not be married to, in a domestic partnership with, or otherwise be in the same immediate family as an owner, director, officer, or employee of the issuer.
Example 4	Issuer A contracts with IVA Entity B to conduct the HHS-RADV IVA. IVA Entity B hires Kate to participate on the data validation audit team. Kate has no material financial interest or ownership interest in issuer A. Kate's husband is employed in a non-management position for issuer A.	Does a conflict of interest exist?	YES	Members of the data validation audit team of the initial validation auditor may not be married to, in a domestic partnership with, or otherwise be in the same immediate family as an owner, director, officer, or employee of the issuer.

HHS-RADV Conflict of Interest (continued)

Example	Background	Question	Answer	Regulatory Reference
Example 5	Issuer A has contracted with Organization Z to act as a TPA during the HHS-RADV process. Issuer A then contracts with Organization Z to serve as their IVA Entity.	Does a conflict of interest exist?	YES	The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the RA data validation process when HHS is operating RA on behalf of a State, or serve in any capacity as an advisor to the issuer regarding the initial validation audit.
Example 6	Issuer A has contracted with Organization X to provide consultation services and assist in preparing issuer A for the HHS RA and RADV processes. Organization X has assisted in the establishment of internal controls over enrollee files and medical record documentation, as well as the upload of documentation to the EDGE server. Because of their familiarity with issuer A's organizational structure, and having demonstrated excellent quality of work products, issuer A contracts with Organization X to serve as their IVA Entity.	Does a conflict of interest exist?	YES	The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the RA data validation process when HHS is operating RA on behalf of a State, or serve in any capacity as an advisor to the issuer regarding the initial validation audit.

HHS-RADV Conflict of Interest (continued)

Example	Background	Question	Answer	Regulatory Reference
Example 7	Issuer A contracts with IVA Entity B to conduct the HHS-RADV IVA. IVA Entity B hires Amy, a senior medical coder, to serve on the data validation audit team and act in a supervisory role on the HHS-RADV process. The previous year, Amy was barred from working with the Medicare program, and was placed on the OIG exclusion list.	Does a conflict of interest exist?	YES	No key individuals involved in supervising or performing the initial validation audit have been excluded from working with either the Medicare or Medicaid program, are on the OIG exclusion list or, to its knowledge, are under investigation with respect to any HHS programs.
Example 8	TPA Y only performs the HR functions for issuer A. TPA Y will also perform the IVA for issuer A.	Does a conflict of interest exist?	NO, since the human resource function was not related to the establishment of internal controls around RA data of the HHS-RADV process, it is not a conflict of interest.	The initial validation auditor may not have had a role in establishing any relevant internal controls of the issuer related to the RA data validation process when HHS is operating RA on behalf of a State, or serve in any capacity as an advisor to the issuer regarding the initial validation audit.

Issuer's Assessment of an IVA Entity's Capabilities

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Assessing IVA Entity Capabilities

1 Capable of performing an IVA according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

- **IVA Technical capabilities should include:**
  - The IVA Entity must have a method of receiving claims and encounter data, as well as medical record documentation, from the issuer
  - The IVA Entity must be able to validate medical records according to the standards for coding and reporting approved by AHIMA, American Hospital Association, CMS and the National Center for Health Statistics (NCHS)
  - The IVA Entity must be able to measure and report its Inter-rater Reliability (IRR) among its reviewers to ensure the reviewers meet consistency measures as required in regulation
  - The IVA Entity must be able to comply with privacy and security standards for Protected Health Information (PHI) in connection with the IVA
  - The IVA Entity must submit reports and data to CMS through the Audit Tool

Assessing IVA Entity Capabilities
(continued)

- **IVA Personnel Qualifications include the following:**
  - The IVA Entity and/or key personnel cannot be on the HHS OIG List of Excluded Individuals and Entities or under investigation with respect to any HHS program
  - The IVA Entity must have 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
  - The IVA Entity must have at least two (2) coders to perform medical record reviews, with one (1) being a senior coder having five (5) years of experience
  - The IVA Entity must have knowledge of reviewing financial, enrollment, and insurance premiums

Assessing IVA Entity Capabilities
(continued)

Issuer Assessment of IVA Entity's Capabilities

- Issuer will ensure that the IVA Entity is capable of conducting the audit in the following manner:
  - Once the audit sample is selected by CMS, the issuer would provide the IVA Entity with source enrollment and source medical record documentation, as well as claims and encounter data, to validate issuer submitted RA data for each sampled enrollee
  - The issuer and IVA Entity would determine a timeline and information-transfer methodology that satisfies data security and privacy requirements, including the applicable provisions of Health Insurance Portability and Accountability Act (HIPAA), and enables the IVA Entity to meet HHS established timelines

Assessing IVA Entity Capabilities
(continued)

Issuer Assessment of IVA Entity's Capabilities

- Issuer will ensure that the IVA Entity is capable of conducting the audit in the following manner:
  - The IVA Entity would validate the health status of each enrollee in the sample in accordance with the standards established by HHS
  - **The issuer discusses** IVA findings with IVA Entity prior to submission and signoff in the HHS-RADV Audit Tool
    - Resolve disputes while maintaining the integrity of the IVA Entity's independence
  - The IVA Entity would provide CMS with the final results from the IVA and all requested information for the Second Validation Audit (SVA)

IVA Entity Solicitation

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HHS-RADV IVA Entity Solicitation

- The issuer must document that the IVA Entity's capability of performing an IVA will be considered during the solicitation and review process
- The issuer must document that the issuer and IVA Entity do not have any conflicts of interest and the issuer has obtained equivalent representation from the IVA Entity regarding conflict of interest
  - This will be done via an attestation within the Audit Tool
  - Details about this process will be provided at a later date in an upcoming webinar
- The issuer must provide CMS with information regarding the IVA Entity for CMS review via the Audit Tool
- The IVA Entity will detail for the issuer its technical capabilities and approach to performing the IVA and submitting its findings in the timeframe specified by CMS

IVA Entity Election

IVA Entity Election

- The IVA Entity election requires IVA Entities to declare their intent to participate as an IVA Entity for the 2018 benefit year HHS-RADV
- IVA Entities submit their election to CMS before an issuer is able to designate their IVA Entity
- This is an annual process that must be completed by new and returning IVA Entities

IVA Entity Election Process

IVA Entity receives a link to the web form in an invitation email. If a new IVA Entity does not receive an email with the link to the IVA Entity Election web form, they should email CCIIOACARADataValidation@cms.hhs.gov and the link can be sent to them

IVA Entity accesses the web form, submits election as an IVA Entity, and identifies IVA Entity SOs, if necessary

CMS reviews submission and determines if the IVA Entity is on the OIG exclusion list

IVA Entity receives an email from CMS indicating whether the election was accepted or not accepted

CMS publishes a list of IVA Entities who have completed the election process and are registered for the applicable benefit year

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IVA Entity Election Web Form

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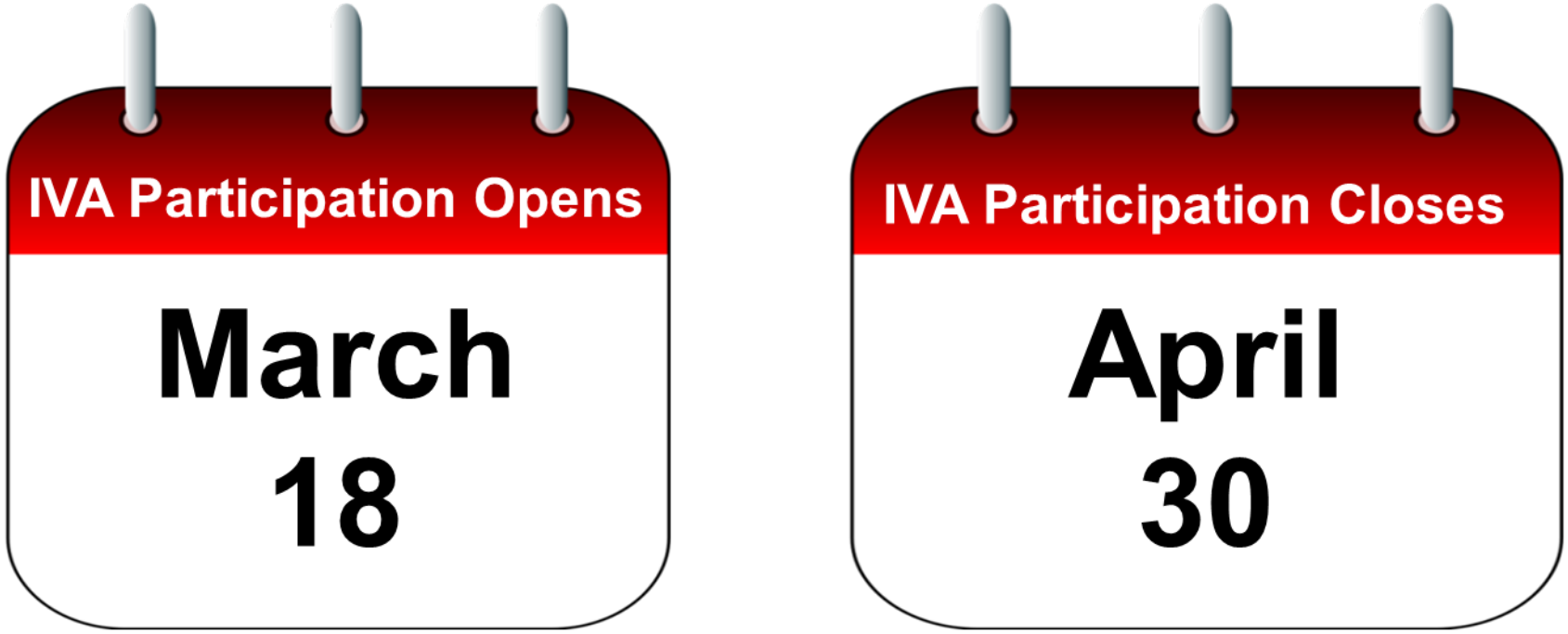
Web Form Overview

- The 2018 Benefit Year HHS-RADV IVA Entity Election web form allows organizations to declare their intent to participate as an IVA Entity and to identify two (2) individuals from their organization, who will serve in the IVA Entity Senior Official (SO) role, if necessary

The web form must be completed in a single session and must only be completed once per organization

Web Form Availability

- The web form will be available **March 18, 2019.** The last day for an **IVA Entity** to elect to participate in the 2018 benefit year HHS-RADV is **April 30, 2019.**



Before You Begin the Web Form

- Understand that your organization will only be allowed to complete the web form once
- Decide who from your organization will be completing the web form
- Determine who from your organization will be the Alternate Contact; if you have participated previously, you will not need to provide this information
- Determine if you wish to share the tax identification number (TIN) for your organization

An IVA Entity may only complete the web form **one (1) time**

Before You Begin the Web Form

- Determine the address for the location at which you conduct your audit
- Determine the individuals from your organization who will act as IVA Entity SOs; if you have participated previously, you will not need to provide this information
  - You must maintain a minimum of two (2) SOs with a current effective date
- Ensure you have the accurate business name of your organization

An IVA Entity may only complete the web form **one (1) time**

Before You Begin the Web Form
(continued)

- If you represent an organization that has not participated as an IVA Entity for HHS-RADV previously, gather the following information before you begin the 2018 Benefit Year HHS-RADV IVA Entity Election web form:

Contact Information Data

- Contact information for the Submitter and Alternate Contact
  - Name
  - Email Address
  - Job Title
  - Phone Number
  - Phone Extension (optional)

IVA Entity and IVA Entity SO Data

- IVA Entity Name
- IVA Entity SOs information
  - Effective Date
  - Name
  - Email Address
  - Job Title
  - Phone Number
  - Phone Extension (optional)

Before You Begin the Web Form
(continued)

- If you represent an organization that has participated as an IVA Entity for HHS-RADV previously, gather the information of a current IVA Entity Senior Official or current IVA Entity RADV Coordinator to enter as the Submitter Contact:

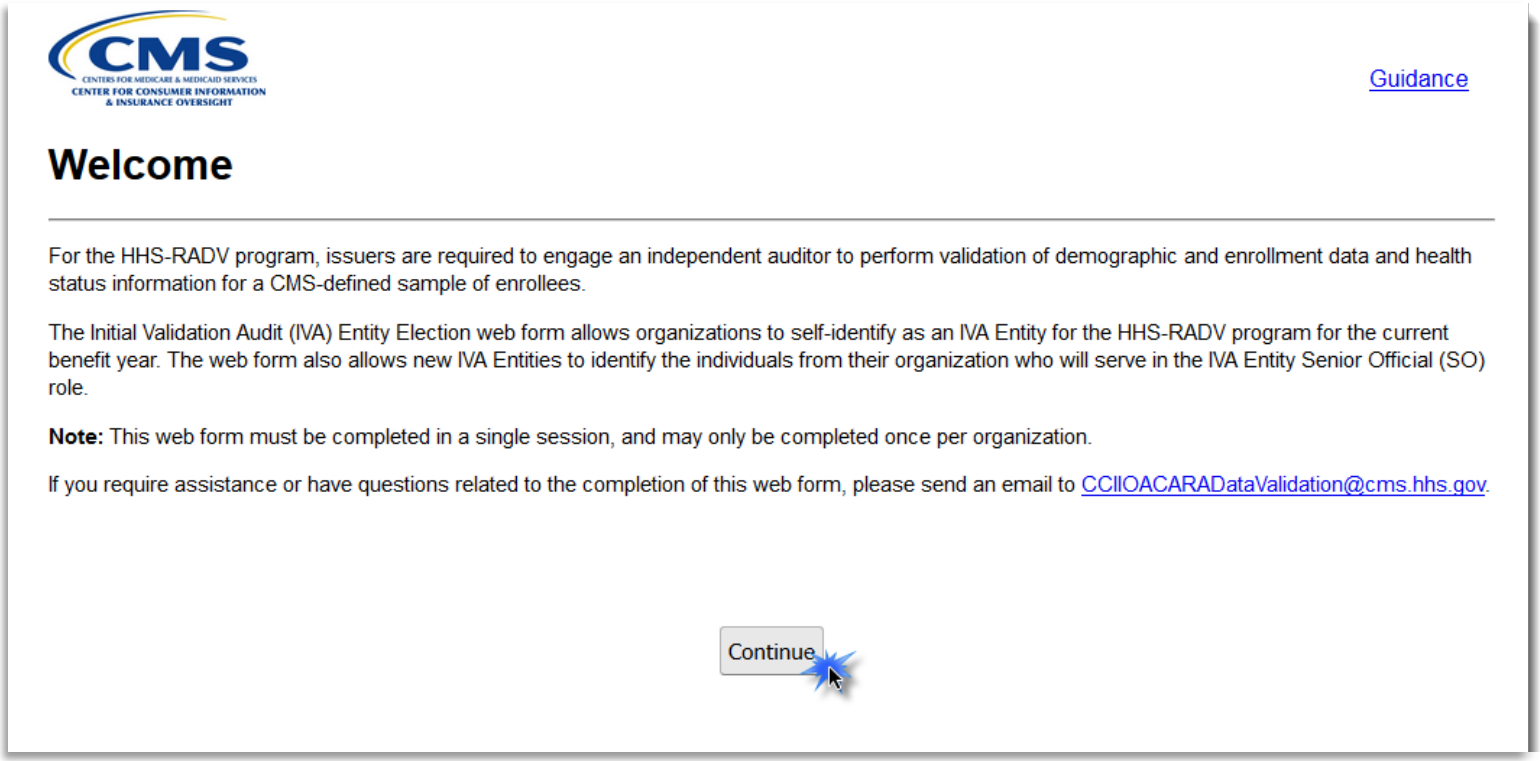
Contact Information Data

- Contact information for a IVA Entity SO or IVA Entity RADV Coordinator Contact
  - Name
  - Email Address
  - Job Title
  - Phone Number
  - Phone Extension (optional)

Completing the Web Form

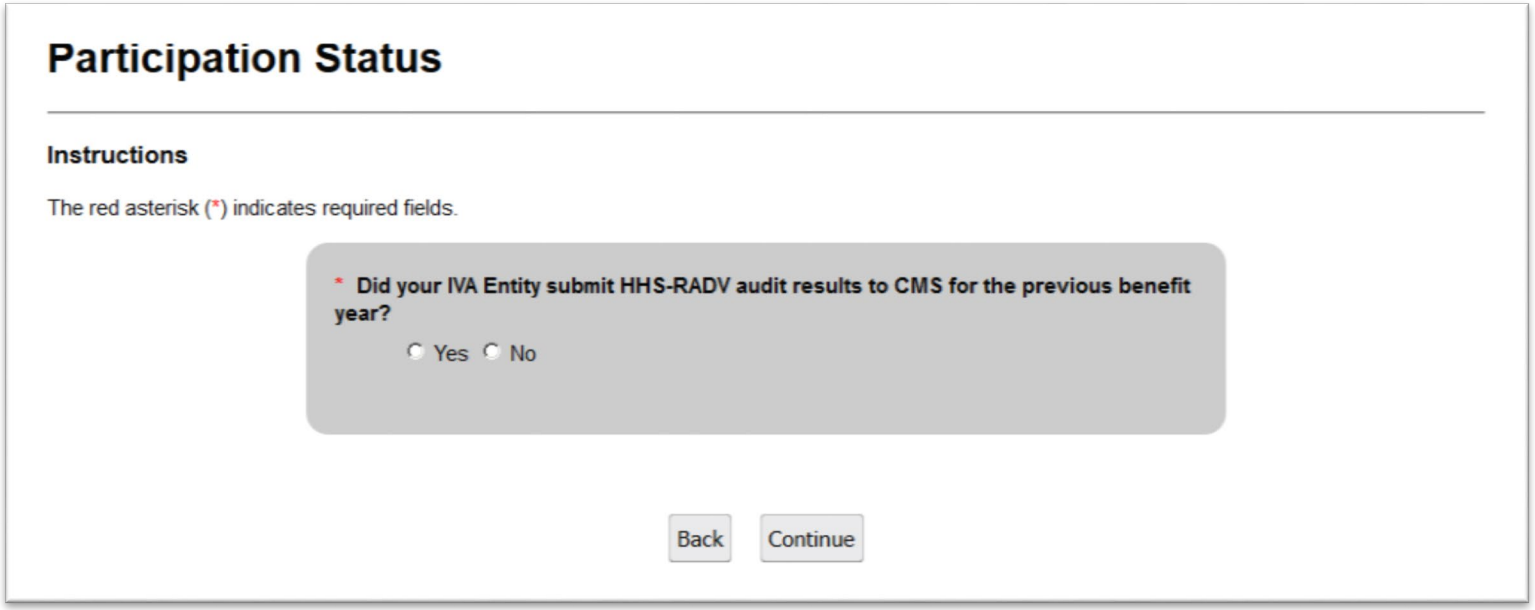
Welcome Page

- Review the instructions for electing to act as an IVA Entity



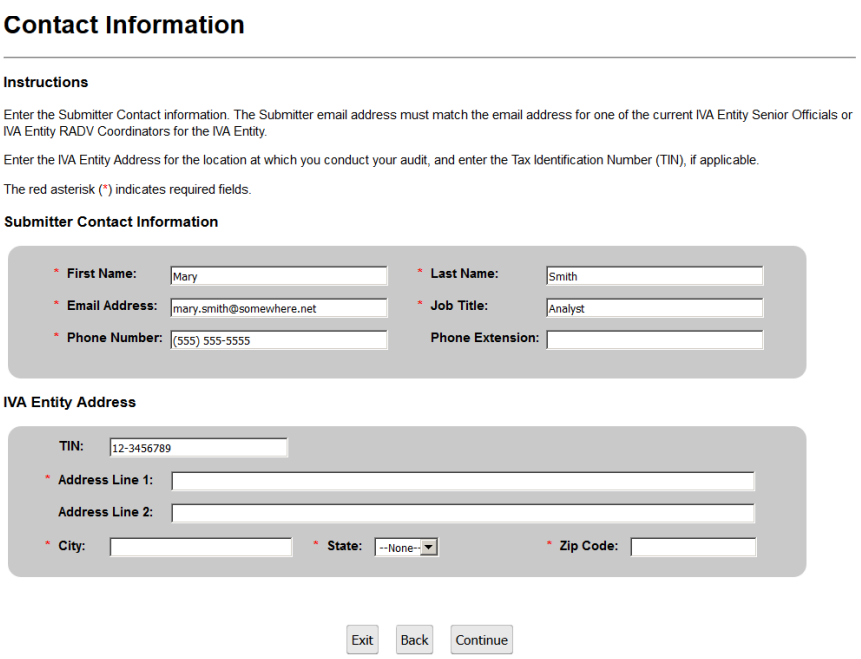
Participation Status Page

- Respond to the question: Did your IVA Entity submit HHS-RADV audit results to CMS for the previous benefit year?
  - The response to this question means that you will provide different information on the subsequent pages of the web form



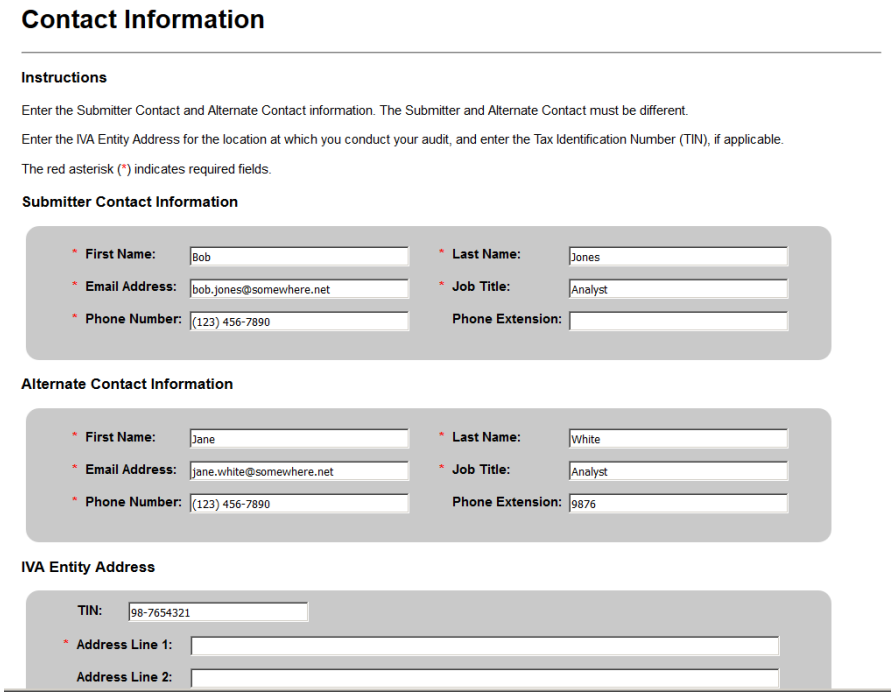
Contact Information Page – Existing IVA Entity

- Enter a Submitter contact, which must be one (1) of the current IVA Entity SOs or IVA Entity RADV Coordinators
  - If an existing IVA Entity needs to update its SO(s),you must access the Audit Tool and use the IVA Entity Senior Official Maintenance Form, located under the Forms tab, to make updates
- Enter the IVA Entity TIN, if available, and the address for where the IVA is being conducted
- After completing this page, you will be directed to the Summary page



Contact Information Page – New IVA Entity

- Enter contact information for the Submitter and an Alternate Contact
  - Submitter and Alternate Contacts must be different
- Enter the IVA Entity TIN, if available, and the address for where the IVA is being conducted



Contact Information

Instructions

Enter the Submitter Contact and Alternate Contact information. The Submitter and Alternate Contact must be different.

Enter the IVA Entity Address for the location at which you conduct your audit, and enter the Tax Identification Number (TIN), if applicable.

The red asterisk (*) indicates required fields.

Submitter Contact Information

* First Name:	Bob	* Last Name:	Jones
* Email Address:	bob.jones@somewhere.net	* Job Title:	Analyst
* Phone Number:	(123) 456-7890	Phone Extension:	

Alternate Contact Information

* First Name:	Jane	* Last Name:	White
* Email Address:	jane.white@somewhere.net	* Job Title:	Analyst
* Phone Number:	(123) 456-7890	Phone Extension:	9876

IVA Entity Address

TIN:	98-7654321
* Address Line 1:	
Address Line 2:	

New IVA Entity and IVA Entity SOs Page

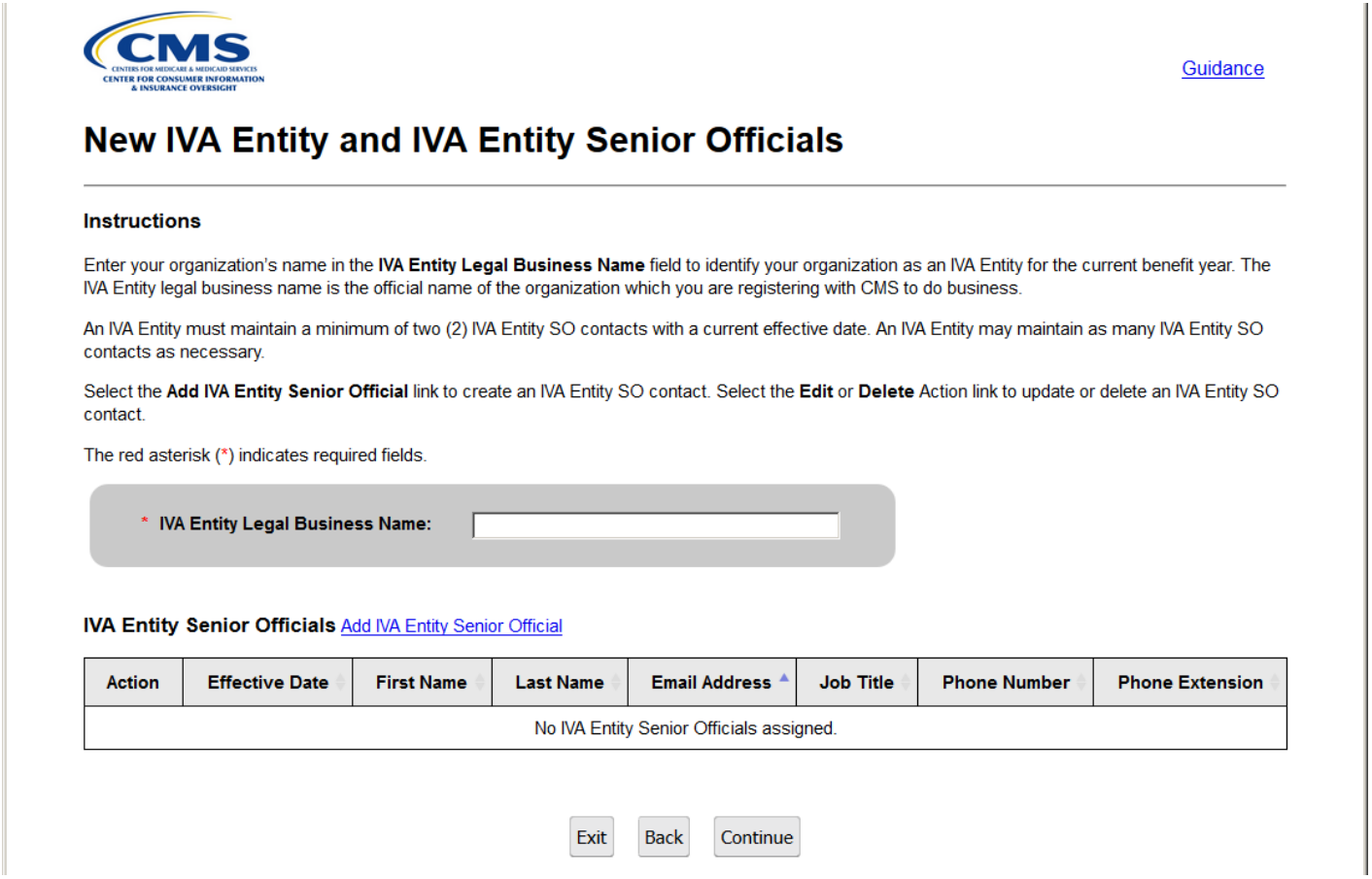
- First, enter the IVA Entity Legal Business Name

The IVA Entity entered should be the official name of the organization registering as an IVA Entity. Each IVA Entity is only entered through this page one (1) time

- Second, identify the IVA Entity SOs

It is possible to enter as many IVA Entity SOs as desired, but a minimum of two (2) must be entered

New IVA Entity and IVA Entity SOs Page (continued)



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Guidance

New IVA Entity and IVA Entity Senior Officials

Instructions

Enter your organization's name in the **IVA Entity Legal Business Name** field to identify your organization as an IVA Entity for the current benefit year. The IVA Entity legal business name is the official name of the organization which you are registering with CMS to do business.

An IVA Entity must maintain a minimum of two (2) IVA Entity SO contacts with a current effective date. An IVA Entity may maintain as many IVA Entity SO contacts as necessary.

Select the **Add IVA Entity Senior Official** link to create an IVA Entity SO contact. Select the **Edit** or **Delete** Action link to update or delete an IVA Entity SO contact.

The red asterisk (*) indicates required fields.

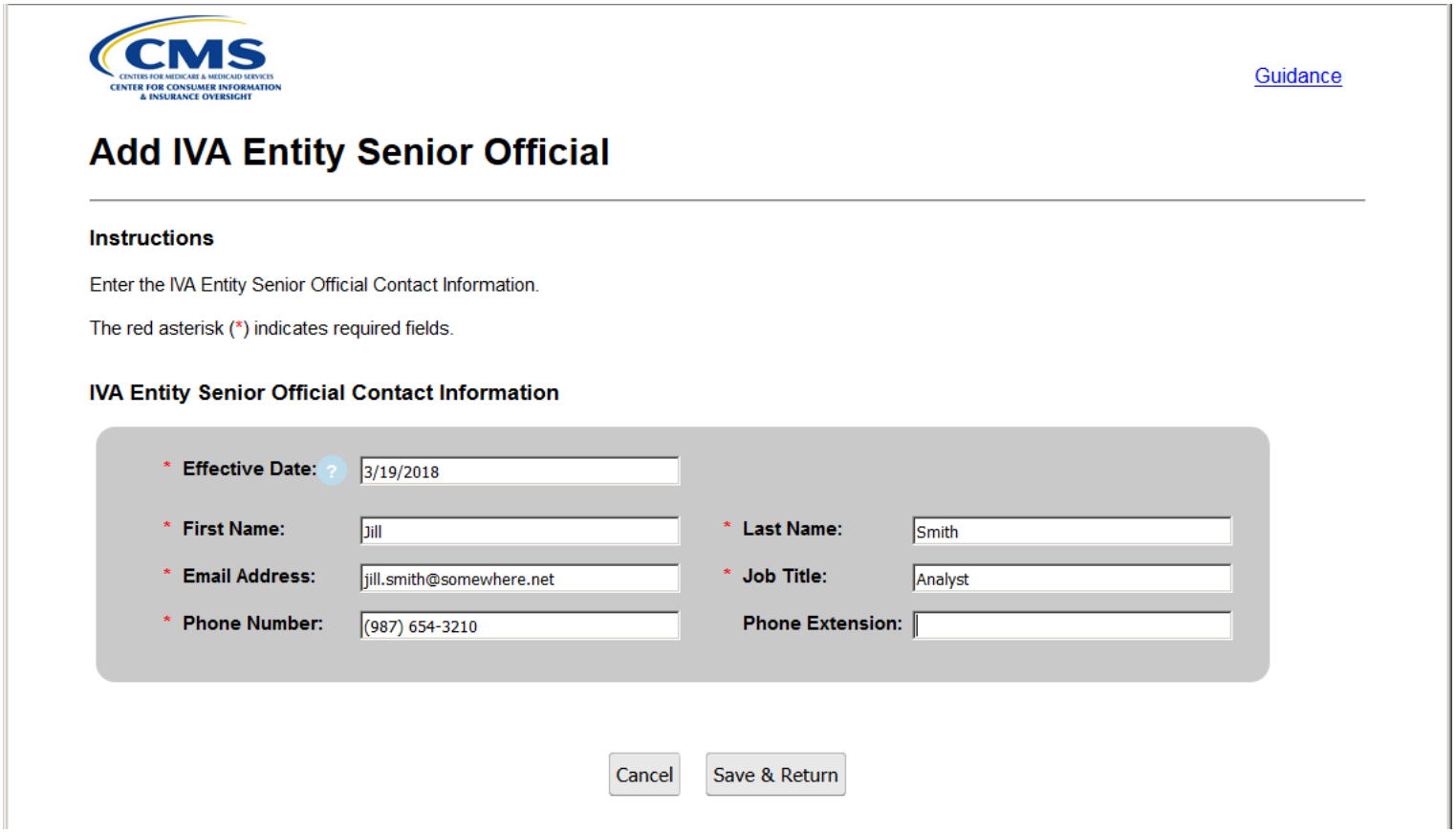
* **IVA Entity Legal Business Name:**

IVA Entity Senior Officials Add IVA Entity Senior Official

Action	Effective Date	First Name	Last Name	Email Address	Job Title	Phone Number	Phone Extension
No IVA Entity Senior Officials assigned.							

Exit Back Continue

Add IVA Entity SO Page



Summary Page

- Review the IVA Entity Legal Business Name and the response to the Participation Status question
- If necessary, review the IVA Entity SOs information for accuracy
- Review contact information for accuracy
- Review TIN and IVA Entity Address for accuracy
- Select the checkbox next to the statement “By submitting this form, my IVA Entity is electing to self-identify as an IVA Entity for the current benefit year”
- Select Submit button to complete the web form

Confirmation Page

- Submission End Time – date and time the form was submitted
- An email acknowledgement of submission will be sent to the Submitter, Alternate Contact, and IVA Entity SOs (if a new IVA Entity)
- An email acknowledgement of submission will be sent to active IVA Entity SOs and Coordinators (if an existing IVA Entity)
- Button to generate a PDF containing the election information submitted

It is recommended that you print and save a copy of the PDF for your records, as it is not included in the acknowledgement email

Issuer - IVA Entity Designation

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Issuers to Designate IVA Entity

- After an IVA Entity registers and elects to participate in HHS-RADV, issuers can designate the IVA Entity
- The issuer will review the list of registered IVA Entities within the Audit Tool and make their designation
- Only the issuer's HHS-RADV SO or Back-up SO are able to designate their IVA Entity within the Audit Tool for CMS to review
- This form will be available within the Audit Tool starting **April 15, 2019**

Issuers to Designate IVA Entity (continued)

- Issuers who do not find their contracted IVA Entity on the list of registered IVA Entities, should contact the IVA Entity and advise them to complete the HHS-RADV IVA Entity Election form
  - If an IVA Entity needs the link to the IVA Entity Election web form, they should email CCIIOACARADataValidation@cms.hhs.gov and the link can be sent to them

Issuers to Designate IVA Entity (continued)

- CMS accepts or rejects the issuer's IVA Entity designation in the Audit Tool
- Accepted IVA Entity is linked to designating issuer in the Audit Tool
- Please refer to the Audit Tool user manual for additional step-by-step details
- Additional details about this process will be shared during the HHS-RADV Series IV webinar taking place April 3, 2019

Q&A

- Type your question in the text box under the “Q&A” tab located to the left-hand panel of your screen
  - To submit your question, click “Submit”

If your question does not receive a response during this webinar session, please submit your question to the HHS-RADV team at CCIIOACARADataValidation@cms.hhs.gov

Next Steps

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Next Steps: Training Sessions

Topic	Date
2017 RADV SVA Findings Report Discrepancy Reporting Window 1	**March 20, 2019**

Resources

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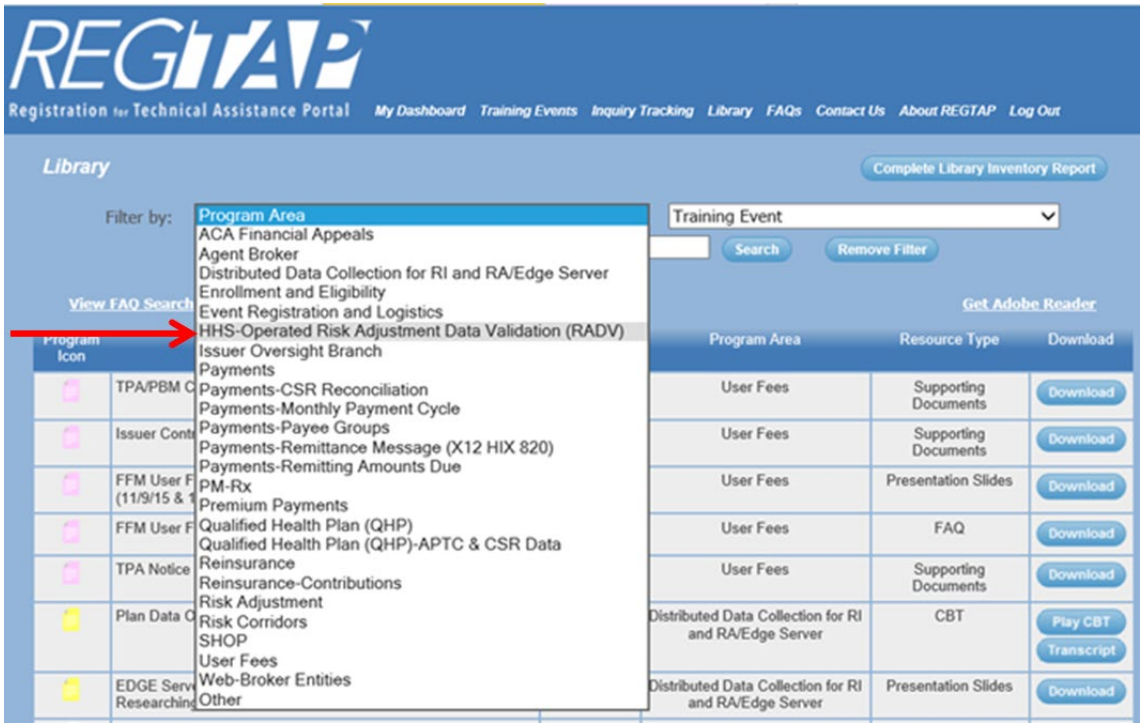
HTTPS://WWW.REGTAP.INFO

Locating HHS-RADV Documents in REGTAP

Stakeholders can access additional documents at https://www.REGTAP.info in the REGTAP Library.

Under Program Area, select "**HHS Risk Adjustment Data Validation (HHS-RADV)**"



Resources: Links

Resource	Resource Link
U.S. Department of Health & Human Services (HHS)	http://www.hhs.gov/
Centers for Medicare & Medicaid Services (CMS)	http://www.cms.gov/
The Center for Consumer Information & Insurance Oversight (CCIIO) web page	http://www.cms.gov/cciio
Consumer website on Health Reform	http://www.healthcare.gov/
Registration for Technical Assistance Portal (REGTAP)	https://www.REGTAP.info
Patient Protection and Affordable Care Act (PPACA)	http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/content-detail.html

Resources: Links (continued)

Resource	Resource Link
HHS Notice of Benefit and Payment Parameters for 2014	http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf
HHS Notice of Benefit and Payment Parameters for 2015	http://www.gpo.gov/fdsys/pkg/FR-2014-03-11/pdf/2014-05052.pdf
HHS Notice of Benefit and Payment Parameters for 2016	http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf
HHS Notice of Benefit and Payment Parameters for 2017	https://www.gpo.gov/fdsys/pkg/FR-2016-03-08/pdf/2016-04439.pdf
HHS Notice of Benefit and Payment Parameters for 2018	https://www.gpo.gov/fdsys/pkg/FR-2016-12-22/pdf/2016-30433.pdf

Resources: Links (continued)

Resource	Resource Link
HHS Notice of Benefit and Payment Parameters for 2019	https://www.govinfo.gov/content/pkg/FR-2018-04-17/pdf/2018-07355.pdf
Proposed HHS Notice of Benefit and Payment Parameters for 2020	https://www.govinfo.gov/content/pkg/FR-2019-01-24/pdf/2019-00077.pdf

Resources: Contact Information

Resource	Contact Information
For RADV policy questions, contact the RADV Team.	CCIIOACARADataValidation@cms.hhs.gov
For EDGE server questions, please contact your Financial Management (FM) Service Representative directly and copy the Centers for Medicare & Medicaid Services (CMS) Help Desk.	EDGE_server_data@cms.hhs.gov and copy CMS_FEPS@cms.hhs.gov
HHS-RADV Audit Tool	To contact us within the HHS-RADV Audit Tool, use the Inquiries tab and select “Submit Inquiry”

Closing Remarks