



Payment Year 2021
Medicare Advantage Contract-Specific
Risk Adjustment Data Validation (RADV)

Audit Methods and Instructions

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Payment Year 2021 Medicare Advantage Contract-Specific
RADV Audit Methods and Instructions

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1 Purpose

This document communicates the Centers for Medicare & Medicaid Services' (CMS) audit methods and instructions to a Medicare Advantage (MA) organization selected for a payment year (PY) 2021 contract-specific RADV audit. The MA organization should closely review this document to understand the full scope and requirements for the audit.

2 Background

Section 1853(a)(1)(C) of the Social Security Act requires that CMS risk adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that appropriate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries. MA organizations submit enrollee diagnosis data to CMS until the final risk adjustment data submission deadline to receive risk adjusted payments from CMS. CMS published information about how PY 2021 MA risk adjusted payments were calculated in the Announcement of Calendar Year (CY) 2021 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (April 06, 2020).¹ Risk adjustment factors and hierarchical condition categories (HCCs) for the 2017 (V22) CMS-HCC risk adjustment model can be found in the Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 4, 2016).² Risk adjustment factors and HCCs for the 2020 (V24) CMS-HCC risk adjustment model can be found in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 1, 2019).³

CMS conducts RADV audits pursuant to 42 C.F.R. § 422.310(e), which requires MA organizations to submit a sample of medical records (MRs)⁴ to CMS for validation of risk adjustment data. Contract-specific RADV audits are CMS' main corrective action to identify overpayments made to MA organizations when there is a lack of documentation in MRs to support the diagnoses reported by MA organizations for risk adjusted payments. In 2023, CMS published a rule concerning the use of statistical

¹ <https://www.cms.gov/files/document/2021-announcement.pdf>

² <https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/downloads/announcement2017.pdf>

³ <https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/downloads/announcement2020.pdf>

⁴ Chapter 7 of the CMS Medicare Managed Care Manual indicates that all diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf>

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sampling and extrapolation in its MA contract-specific RADV audits.⁵ That rule was vacated by a federal district court in 2025,⁶ in a decision that is currently under appeal.

CMS publishes audit methods and instructions describing the statistical sampling and extrapolation methods that it intends to use for each MA contract-specific RADV audit. As discussed in greater detail below, CMS has designed its PY 2021 MA contract-specific RADV audits to calculate extrapolated overpayments. CMS has not yet decided whether it will collect extrapolated overpayment amounts or only overpayments associated with the sampled enrollees for these audits but will notify MA organizations with contracts selected for audit of the final decision at a later date. Each MA contract-specific RADV audit includes:

- Planning: CMS defines a sample unit, sampling frame, and sample selection method.
- Initiation: CMS sends an Audit Notice, provides audit methods and instructions, and makes an enrollee data list (EDL) available for download in the RADV secure system, the Centralized Data Abstraction Tool (CDAT).
- MR Submission: The MA organization submits MRs to CMS during a MR submission window for enrollees selected in the audit sample.
- Analysis and Issuance of an Audit Report Package: CMS analyzes the output from MR reviews, calculates payment errors, and issues an Audit Report Package to the MA organization.⁷

3 Important Dates to Remember

The following are important dates to remember for the PY 2021 MA contract-specific RADV audits:

- EDL available in CDAT for viewing and downloading: June 12, 2026
- MR submission window opens: June 22, 2026
- MR Submission Deadline (window closes): November 06, 2026, at 11:59pm EST
- Hardship Exception Request Deadline: November 20, 2026, at 11:59pm EST

4 Statistical Sampling Methodology

This section describes the sampling frame, sample unit definition, sample design, and sample selection method for this audit.

⁵ 88 Fed. Reg. 6650 (Feb. 1, 2023).

⁶ *Humana Inc. v. Becerra*, 801 F. Supp. 3d 624 (N.D. Tex. 2025).

⁷ MA organizations have appeal rights pursuant to 42 C.F.R. § 422.311(c).

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4.1 Sampling Frame

CMS defined the sampling frame for this MA contract-specific RADV audit by identifying enrollees who:

1. Were continuously enrolled in the audited MA contract from January of the data collection year (DCY) 2020 through January of the PY 2021;
2. Were enrolled in Medicare Part B coverage for 12 months during DCY 2020;
3. Had at least one risk adjustment diagnosis in the International Classification of Diseases, Clinical Codes with a 2020 date of service that led to at least one HCC assignment for PY 2021;
4. Were not in an End Stage Renal Disease status from January of the DCY 2020 through January of the PY 2021;
5. Were not in a hospice status from January of the DCY 2020 through January of PY 2021;
6. Were not part of an Office of Inspector General (OIG) audit or other pertinent settlement that included data from January of the DCY 2020 through January of the PY 2021;
7. Were not enrolled in a Chronic Condition Special Needs Plan (C-SNP), an Institutional Special Needs Plan (I-SNP) or a Fully Integrated Dual Eligible Special Needs Plan (FIDE-SNP) from January of the DCY 2020 through January of PY 2021; and
8. Were ranked in the top quartile of PY 2021 RADV-eligible enrollees across all RADV-eligible MA contracts⁸ by one or both of CMS's PY 2021 MA improper payment prediction models and, therefore, predicted to have the greatest reduction in their risk score as a result of a RADV audit.⁹

4.2 Sample Unit Definition

The sample unit is an MA contract enrollee that meets the sampling frame criteria.

4.3 Sample Selection Method

CMS selected a statistically valid random sample of enrollees¹⁰ from the sampling frame by:

1. Establishing a seed number using a random number generator,¹¹

⁸ Types of entities considered for contract-specific RADV audits included Coordinated Care Plans (CCPs), local Health Maintenance Organizations (HMOs), local preferred provider organizations (PPOs), Regional PPOs, Provider-Sponsored Organizations (PSOs), Special Needs Plans (SNPs) Demonstrations, Medical Savings Accounts (MSAs) Contracts, Private Fee for Service Contracts, and Employer/Union Only Direct Contract PFFS plans.

⁹ CMS required a minimum of 30 such enrollees to establish a sampling frame.

¹⁰ The MA Organization is required to submit medical record documentation to support HCCs, associated with sampled enrollees, identified in the Enrollee Data List made available by CMS at the beginning of the audit.

¹¹ The seed number was generated using the SAS CALL routine random number generator.

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2. Sorting enrollees (i.e., sample units) included in the sampling frame by CMS' unique identifier for each enrollee, and
3. Using a statistical software tool¹² to select a simple random sample (without replacement) to randomly select 35, 50, 100, or 200 enrollees.¹³

5 Audit Initiation

CMS initiates an MA contract-specific audit by sending the MA organization an Audit Notice. Upon receiving the letter, the MA organization should begin taking steps to assign a Lead Point of Contact (POC), review audit instructions, access available audit data and begin gathering MRs.

5.1 Audit Notice

CMS sends an Audit Notice to the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO), and Medicare Compliance Officer (MCO) to initiate the MA contract-specific RADV audit. The letter provides important information about the audit, including instructions for designating a Lead POC, important dates, and reminders about if/when to report plan-identified overpayments.

5.2 Points of Contact

The CEO, CFO, COO, and/or MCO must establish a Lead POC for each audited MA contract. Lead POC contact information must be provided to CMS on the *Lead POC Form* for each audited MA contract. Only the CEO, CFO, COO, or MCO may submit the completed *Lead POC Form* to RADVCONTechSupport@radvcdat.com.

The designated Lead POC will receive an email from RADVCONTechSupport@radvcdat.com. The email will instruct the Lead POC to use the CMS secure RADV system, called the Centralized Data Abstraction Tool (CDAT), to register. Once registered, the Lead POC will be able to access CDAT to view/download RADV audit data (including the EDL) and the Point of Contact Management tool to add or remove other POCs for the audited MA contract. For detailed instructions on using this feature, refer to the "Point of

¹² The software tool used was the SAS PROC SurveySelect function.

¹³ The number of enrollees sampled was determined by the size of the audited MA contract's sampling frame. To establish the sampling structure, CMS sorted all RADV-eligible contracts in descending order according to their sampling frame sizes and assigned them into four strata. Stratum 1 comprised the ten contracts with the largest sampling frame sizes. The remaining RADV-eligible contracts not included in Stratum 1 were then divided into Strata 2, 3, and 4, representing the top, middle, and bottom thirds (each approximately 33%), respectively, of those remaining contracts. The enrollee sample sizes assigned to each stratum were 200 for Stratum 1, 100 for Stratum 2, 50 for Stratum 3, and 35 for Stratum 4. An MA organization should refer to the EDL in CDAT to identify the applicable sample size for an audited contract. When the number of enrollees in an audited MA contract's sampling frame is equal to or less than the minimum sample size designated for its stratum, all enrollees within that sampling frame shall be audited.

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Contact Management" section in the CDAT User Guide, located in the CDAT Plan Library. A maximum of five individuals per contract (including the Lead POC) may be designated as POCs.¹⁴

Information about the RADV audit is only provided to designated POCs. CMS urges MA organizations to submit their *Lead POC Forms* as soon as possible, because it may take up to 5 business days to process during peak submission times (e.g., at the beginning of an audit cycle).

5.3 Enrollee Data List

CMS will make an enrollee data list (EDL) available in the audited MA contract's secure portal within CDAT to communicate the enrollees and HCCs selected for audit. A POC for the MA organization should access the EDL as soon as it is available to give the MA organization the maximum amount of time available to gather and submit the necessary MRs for the audit.

The EDL is a Microsoft Excel file with three worksheets (or tabs):

1. Data Dictionary – Describes each column in the EDL.
2. Sampled Enrollee List – Includes the sampled enrollees, HCCs, and associated diagnosis codes that the MA organization submitted to the Risk Adjustment Processing System (RAPS) and/or Encounter Data Processing System (EDPS) for which the MA organization must submit MRs to CMS via CDAT.
3. Sampling Frame – Includes identifiers for all enrollees included in the sampling frame and a flag indicating which enrollees are selected in the sample, for reference only.¹⁵

6 MR Requirements and Submission Instructions

The audited MA organization must submit at least one valid MR and MR coversheet to CMS to support each audited HCC included in the EDL. A valid MR for RADV purposes is a legibly signed and dated

¹⁴ CMS recommends that at least one individual in the CEO, CFO, COO, or MCO role be designated as a POC to access CDAT and timely information about the audit.

¹⁵ See Section 11 for important information about when to suspend the reporting of overpayments to the Risk Adjustment Overpayment Reporting (RAOR) module in the Health Plan Management System (HPMS) and the submission of data corrections in RAPS and/or EDPS.

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medical record¹⁶ that documents diagnoses and services provided during a face-to-face visit¹⁷ and conducted by an appropriately credentialed provider within the designated data collection period.¹⁸

The MA organization must submit MRs and MR coversheets within CDAT while the MR submission window is open. For instructions on how to submit an MR and MR coversheet within CDAT, review the *CDAT User Guide* in the Plan Library within CDAT. The MA organization must request MRs from hospitals and physicians/practitioners who provided services to enrollees and documented diagnoses associated with audited HCCs during the appropriate data collection period.¹⁹ The data collection period for PY 2021 is January 1, 2020, through December 31, 2020.

For each sampled enrollee, the MA organization may submit a maximum number of MRs equal to twice the number of audited HCCs. For example, if a sampled enrollee has three audited HCCs in the EDL, the maximum number of MRs an MA organization can submit for that enrollee is six (3 HCCs multiplied by 2 = 6 MRs maximum). An MA organization may submit up to six MRs in any combination for the three audited HCCs.

The MR submission process includes two parts, MR intake and diagnosis code abstraction. Each submitted MR will be reviewed during the MR intake process to ensure it is valid. Only valid MRs and acceptable MR coversheets will move forward to the diagnosis code abstraction step. See Appendix A: Invalid MR Reason Codes for a list of reasons (i.e., reason codes) why an MR (and its associated MR coversheet) may be deemed invalid. CMS encourages MA organizations to submit MRs as soon as possible in the MR submission window.

6.1 Completing the MR Coversheet

This section includes guidance for completing the MR coversheet during the submission process in CDAT. For step-by-step instructions for accessing an electronic version of the MR coversheet template, please refer to the *CDAT User Guide* in the CDAT Plan Library. Hardcopy or “printable” coversheets are not provided. The MR coversheet allows CDAT users to submit documents (MR only or MR and attestation [MR+ATT]) or confirm no documents (No MR) for a specific sampled enrollee and audited HCC. The system will only allow the MR file to be uploaded as a PDF file to a coversheet.

¹⁶ The signature on the medical record must be the signature of the credentialed provider that conducted the face-to-face visit.

¹⁷ For dates of service (DOS) March 6, 2020, through December 31, 2020, within Payment Year 2021 (PY21), medical records substantiating diagnoses resulting from telehealth services may satisfy the risk adjustment face-to-face requirement, consistent with the April 10, 2020, Health Plan Management System (HPMS) memo. This applies when services are delivered via an interactive audio and video telecommunications system that enables real-time, two-way communication between the provider and the beneficiary.

¹⁸ Chapter 7 of the CMS Medicare Managed Care Manual indicates that all diagnosis codes submitted must be documented in the medical record, a result of a face-to-face visit, and coded according to International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf>

¹⁹ 42 C.F.R. § 422.310(d)(3)

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The MR coversheet template displays submission information in five sections:

Section I: MA Contract Information. Displays the Contract Name, Current Contract ID, and Sample Year Contract ID for the selected enrollee.

Section II: Enrollee Information. Displays details about the selected enrollee, including the Enrollee ID, Medicare Beneficiary Identifier (MBI), Date of Birth (DOB), Last Name, and First Name. Note: When completing the submission process, the MA organization must ensure the enrollee on the coversheet matches the enrollee on the MR. Submitting a MR for the wrong enrollee may lead to a Protected Health Information (PHI)/Personally Identifiable Information (PII) issue and will result in an invalid submission.

Section III: Document to be Attached. Indicates the type of MR uploaded. The uploaded file should contain one MR only. When completing the MR coversheet in CDAT, the MA organization is required to select a document type for the submission. The document type determines which coding guidelines (Inpatient or Outpatient) should be applied.

- **One Physician Specialist/Hospital Outpatient Record:** This type of record is submitted for one date of service and can be a physician office visit; a standalone hospital outpatient visit (for example, an emergency room visit or outpatient procedure report); a standalone document from an inpatient stay (Consult, Progress Note, History & Physical, Emergency Room or Operative Report); a Health Risk Assessment (HRA); or a visit with a physical therapist, occupational therapist, or speech language pathologist (not occurring in an inpatient setting). For an outpatient record, enter the one date of service documented in the record. A credentialed provider's standalone inpatient documentation, such as a progress note or a consult form, can be added to this record and submitted as an outpatient record if the date of service is within the data collection period and the MR has a valid signature and credentials.
- **One Hospital Inpatient Record:** This type of record can be a full inpatient hospital record or an inpatient rehabilitation record and must include an admission date, a discharge date, and a signed discharge summary. Enter a date range using both the admission date and the discharge date documented in the record. The discharge date must be in the DCY for the MR to be accepted as an inpatient record.

Section IV: Designated HCCs for this MR. This section displays which audited HCC(s) is designated for this MR. HCC numbers are displayed according to the CMS-HCC risk adjustment model version, e.g., V22HCC19. A MR with multiple HCCs will have each HCC in a separate row with the accompanying ICD codes for each. All the enrollee's audited HCCs are available for designation on each MR coversheet. Note: If the MR documents more than one of the audited HCCs for the enrollee, the MA organization should select all applicable HCCs when completing the MR coversheet and submit the MR only once. The MA organization should avoid submitting the same MR multiple times for the same or different HCC(s).

Section V: File Content/Coding Guidelines. This includes Provider Type (Inpatient or Outpatient), Admission and Discharge Dates for Inpatient Record, and Date of service for Outpatient Record.

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CMS includes pre-populated MA contract information and enrollee identifiers. All other information is supplied by the MA organization.

The MR coversheet should be completed according to the *CDAT User Guide* and reviewed for accuracy prior to submitting in CDAT. The following information should be verified prior to submitting each coversheet:

1. MR coversheet is correctly labeled “CY 2021 Contract-Level RADV” on all pages.
2. All data fields in Section I contain data.
3. All data fields in Section II contain enrollee data that matches the name on the MR submitted. The birth date may be used as a secondary identifier for common shortened names if it is present on the MR. The MA organization can note on the coversheet reasons that explain any name variance.
4. Section III, IV, and V are populated as directed with at least one HCC indicated. If any unusual format or population issues are noted, the automated intake process may be routed to a manual process for confirmation.
5. Year of Review field must be “2020”. For a hospital inpatient record, the Discharge Date Year of Review field is populated with “2020”. For a physician/specialist/hospital outpatient/observation record, the Year of Review field is populated with “2020”.
6. All fields in the MR Submission Information section (File Name, Submitted By, and Submission Date) must contain data.

6.2 Preparing the MR File

The MA organization must submit MR documentation for each audited HCC. To do so, the MA organization must create an MR file that contains one MR and, if applicable, one completed CMS-generated attestation. Please note that if the MA organization intends for the MR documentation to substantiate more than one audited HCC for the enrollee, then it must indicate all applicable HCCs on the MR coversheet and submit the MR only once to validate multiple HCCs. The MA organization should avoid submitting the same MR documentation multiple times. The MA organization must attach each MR file to an electronic MR coversheet for submission into CDAT. An MR file submitted to CDAT cannot exceed 100MB.

Although CMS does not review MRs based on the naming convention, CMS encourages the MA organization to name the MR file using the following:

1. Use the enrollee ID as provided in the sample list (e.g. 12345678),
2. Include at least one of the HCC model numbers used for 2020 dates of service (e.g., V22) on the coversheet, and
3. Include one HCC in your naming convention (e.g., HCC017).

In this example, the file name would be: 12345678_V22_HCC017. The MA organization should avoid duplicate file names when submitting multiple MRs for the same HCC(s). Use unique file names for each MR. If multiple MRs are submitted for the same set of HCCs, add a Version number at the end (_v1, _v2).

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MRs lacking the necessary provider signature and/or credentials require a signed attestation to be considered valid and eligible for RADV review. If a completed CMS-generated attestation is submitted, it must appear on the first page of the MR file. For additional information on the CMS-generated attestation, see Section 6.4. If applicable, the MA organization should prepare each MR file containing one completed CMS-generated attestation and one MR in a PDF format.

6.3 Checking the MR File before Submission

After the MR file has been prepared according to these instructions, the MA organization must complete the MR coversheet and upload the MR file in CDAT following instructions in the *CDAT User Guide*. When attaching the MR file to the MR coversheet in CDAT, the MA organization must identify the type of record being submitted. If “One Physician Specialist/ Hospital Outpatient Record” or “One Observation Record” is selected, only outpatient coding guidelines will apply. If “One Hospital Inpatient Record” is selected, only inpatient coding guidelines will apply. Ensure the conditions in the inpatient MR are documented and authenticated by an acceptable risk adjustment physician specialty.

Check the MR file to ensure that:

- The MR contained in the file corresponds with the MR coversheet for which it is being submitted.
- It does not contain multiple MRs.
- All text and images are legible.
- It does not exceed 100MB.

All MR coversheets and associated MR files must be submitted by the MR Submission Deadline (see Important Dates to Remember). The MA organization will receive feedback on the validity of submitted MRs via the Intake Feedback Report in CDAT.

6.4 MR Attestation

MRs submitted for this audit that do not contain physician/practitioner signatures or credentials (i.e. Physician Assistant) will result in errors under the MR review process. If an MR lacks the necessary physician/practitioner signature and/or credentials, CMS allows the MA organization to submit a CMS-generated attestation form (PDF file) with the MR. CMS-generated attestations are accepted only for physician and hospital outpatient MRs (i.e., not for inpatient hospital MRs).

A CMS-generated attestation must be signed by a physician/practitioner who attests responsibility for conducting and documenting the health services in the accompanying physician or outpatient MR that the MA organization submits. By signing and documenting credentials on the attestation and identifying the date of service, physicians/practitioners are attesting to the MR entry being submitted for this audit.

CMS-generated attestations will be accepted only for MRs that the MA organization indicates on the coversheet and should be coded accordingly. Attestations are only acceptable for physician/outpatient sites for dates of service between January 1, 2020, to December 31, 2020.

Elements of the CMS-generated attestation are pre-populated by CMS (e.g., name, date of birth, Medicare identifiers, contract name and ID) for data integrity purposes. Because it contains PHI/PII, this document will only be made available to the MA organization’s POCs via the plan portal within CDAT.

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For point-and-click instructions on how to submit a CMS-generated attestation form in CDAT, the MA organization should review the *CDAT User Guide*. CMS-generated attestation forms for sampled enrollees are available in the CDAT plan portal.

CMS reviews each submitted attestation form for validity. Attestations will be found valid if they meet the following criteria:

1. Attestation is a CMS-generated attestation form only.
2. The CMS-generated attestation is completed in its entirety, signed, and dated by the physician/practitioner who provided those services.
3. The completed fields include the printed physician/practitioner's name, the date of service of the MR to which they are attesting, the physician/practitioner's specialty or credential (i.e. Physician Assistant), and the signature and date by the physician/practitioner that conducted the face-to-face visit.

Attestations will be deemed invalid if one (or more) of the following conditions is true:

1. The CMS-generated attestation form is altered.
2. The attestation is incomplete.
3. Date of service on the attestation form does not match the MR.
4. Enrollee name does not match both coversheet and MR.
5. The attestation form is not CMS-generated (only a CMS Generated Attestation Form is acceptable).
6. Unacceptable provider credentials.
7. Unacceptable signature(s), including an attestation that is signed by someone other than the physician/practitioner with or without explanation (retired, expired, Power of Attorney, etc.).

Attestations are accepted only for physician and hospital outpatient MRs. Also, inpatient records that indicate a specific date of service and progress note are considered outpatient records and can include an attestation.

Valid attestations move forward through the MR intake process to the diagnosis code abstraction process. Attestations that are deemed invalid will result in an error and the associated MR will be considered invalid.

6.5 Hardship Exception Request

CMS recognizes there may be extraordinary circumstances preventing an audited MA organization from providing MRs to CMS and complying with audit requirements. If an MA organization faces such circumstances, it may request that a hardship exception be granted for an entire contract, one or more specific sampled enrollees, or for specific audited HCCs. The request must include comprehensive documentation and a robust justification detailing the extraordinary circumstances, such as natural disasters, law enforcement actions, or other significant events making it impossible to comply with audit requirements. Please note, a change of ownership (CHOW) does not exclude an MA organization from an audit. The MA organization must include the applicable documentation, for example the novation,

highlighting the audited MA organization is not responsible for the specific audit. Please see Appendix B: Hardship Exception Request Process for additional information on the hardship exception request process.

7 MR Intake and Feedback Process

CMS reviews all submitted MR files and coversheets during the MR intake process to determine which ones are valid and invalid. Each submitted MR file and coversheet combination are assigned a unique Coversheet ID. When an MR file and coversheet combination is determined to be invalid, the MA organization may submit another one to replace it if the MR submission window is still open. Accordingly, CMS encourages the MA organization to submit coversheets and MRs as accurately and as early as possible. CMS continues the MR intake process until all submissions are reviewed.

CMS will provide feedback about each submitted MR file and coversheet throughout the MR intake process. An MA organization's POC may access an Intake Feedback Report (IFR) within CDAT. The IFR provides the status of intake processing for each MR submitted during the MR submission window.²⁰ Once intake processing is complete for a given MR, the IFR is updated to indicate if the MR passed all intake validity checks. If it did not, then the IFR will list the reason(s) why it did not pass. Instructions for how to access the IFR are included in the *CDAT User Guide* in the Plan Library within CDAT. The IFR will be available to the MA organization's POCs throughout the audit lifecycle.

Only MR files and coversheets that pass all MR intake checks and are determined to be valid will be forwarded to the diagnosis code abstraction process. Furthermore, only valid MRs are eligible to be used as a basis for medical record review determination (MRRD) appeal, if applicable. Important Dates to Remember

8 Diagnosis Code Abstraction

From all valid MRs that pass MR intake, CMS abstracts diagnosis codes in accordance with International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Guidelines for Coding and Reporting²¹, and *Coding Clinic for ICD-10-CM and ICD-10-PCS*²² quarterly newsletters published by the American Hospital Association's Central Office on ICD-10-CM and ICD-10-PCS. An MA organization must also follow these guidelines and newsletters; instructions in this document; requirements set forth in Chapter 7 of the *CMS Medicare Managed Care Manual*; and all requirements set forth in Medicare regulations, Parts C and D contracts, and Electronic Data Interchange Agreements.

Each submitted valid MR may be subjected to up to three independent reviews by certified MR coders. An initial MR review to abstract ICD-10-CM codes is conducted on all submitted valid MRs. MRs that do

²⁰ The IFR within CDAT does not provide the results of diagnosis coding abstraction activities. Instead, CMS will provide diagnosis coding abstraction results when it issues an Audit Findings Report at the end of an audit.

²¹ ICD-10-CM Coding Guidelines: <https://www.cms.gov/medicare/coding-billing/icd-10-codes>

²² Coding Clinic Advisor: <https://www.codingclinicadvisor.com/aha-central-office>

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not substantiate one or more audited HCCs for which they were submitted will undergo a second review. A third and final review is conducted on each MR where there is disagreement between the first and second MR review about whether, or to what degree, an audited HCC(s) is discrepant.

9 Payment Error Calculation Methodology

RADV audits confirm the presence of diagnoses, that map to HCCs used for risk adjustment, in valid MR documentation submitted by an MA organization. A risk adjustment discrepancy is identified when an original HCC(s) used for payment for a sampled enrollee, based on diagnosis code data self-reported by an MA organization, is not validated after RADV MR diagnosis code abstraction is completed by CMS through the RADV audit process. Risk adjustment discrepancies are aggregated for sampled enrollees to determine the: (1) sum of the RADV enrollee payment error amounts for all sampled enrollees, and (2) average change in sampled enrollees' risk scores as a result of the RADV audit, which may then be used to estimate an overpayment amount for the sampling frame using a statistically valid extrapolation technique.

Detailed information about MA risk adjustment and enrollee risk score calculation methods are published each year by CMS.²³ Risk adjustment models and supporting data and documentation are available for PY 2006 through the present. All enrollee risk score calculations during a RADV audit use the published model for the relevant PY, including the relevant normalization factor, MA coding pattern adjustment factor, and frailty score (if applicable). For this PY 2021 RADV audit, CMS will use updated data from CMS systems of records and post-RADV results of audited HCCs to calculate payment errors for sampled enrollees and the sampling frame.²⁴

9.1 Payment Error Calculation for Sampled Enrollees

CMS calculates the "RADV enrollee total payment error" for each enrollee selected in the RADV audit sample by completing the following steps:

1. Running the sampled enrollee's diagnosis codes that are abstracted by CMS from valid MRs submitted by the MA organization for RADV²⁵, and other necessary data for the enrollee sourced

²³ <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents>. These documents comprise the Medicare Advantage (MA), and Medicare+Choice (M+C) advance notices of methodological changes; announcements issued with MA or M+C rates; and special reports.

²⁴ Data from CMS systems of records that contributes to MA payment error calculations may include items such as the following: Medicare Beneficiary Identifier (MBI), Health Insurance Claim Number (HICN), Date of Birth, Sex, Original Reason for Entitlement Code (OREC), and Medicaid Dual Status. Given the timing of when PY 2021 RADV audits were initiated, CMS will refresh sampling frame data prior to calculating PY 2021 RADV audit results to ensure the accuracy of overpayment calculations.

²⁵ Hardship exceptions granted by CMS, for either a specific sampled enrollee or HCC, will not negatively impact payment error calculations.

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from CMS systems of records, through the relevant PY's MA payment model to determine the "RADV enrollee risk score"²⁶

2. Calculating "RADV monthly enrollee risk payment amounts" by multiplying the "RADV monthly enrollee risk score" after normalization, adjustment, and blending (if applicable) by the appropriate county rate²⁷ for months in which the sampled enrollee was covered by the plan and not in an End Stage Renal Disease (ESRD) or hospice status.
3. Summing the "RADV monthly enrollee risk payment amounts" and applying all other relevant payment components²⁸ and adjustments to determine the "RADV Enrollee Risk Payment Amount".
4. Calculating "RADV enrollee monthly payment error" by subtracting each month's "RADV monthly enrollee risk payment amount" from the "original monthly payment amount" that was previously received by the MA organization.
5. Summing the "RADV enrollee monthly payment error" amounts for the PY to determine the "RADV enrollee total payment error".

²⁶ If CMS abstracts a diagnosis code during a RADV audit that maps to an HCC, and that HCC was not previously supported by diagnoses submitted by the MA organization for risk adjusted payment prior to the final CMS MA data submission deadline, it is referred to as an "additional HCC". CMS updated its policy regarding additional HCCs for PY 2020 (in fiscal year 2022 financial reporting) when it categorized additional HCCs into two types: (1) additional HCCs within the same hierarchy as RADV audited HCCs, and (2) "spontaneous" additional HCCs (defined by HHS' Improper Payment Measurement Program (IPM) as those HCCs found as a result of MR coding reviews that were not originally submitted by the MA organization for payment purposes and that are not in the same hierarchy as another HCC that was the basis for risk adjusted payment). Spontaneous additional HCCs do not meet the definition of improper payment and are excluded under HHS's FY 2022 IPM methodology (<https://www.cms.gov/files/document/fy-2022-medicare-part-c-error-rate-findings-and-results.pdf-0>). HHS/CMS continued the same policy for PY 2021 (<https://www.cms.gov/files/document/fy-2023-medicare-part-c-error-rate-findings-and-results.pdf-0>). Additional HCCs within the same hierarchy as the audited HCCs are included under HHS's FY 2023 IPM methodology. Accordingly, for CMS RADV purposes only additional HCCs other than spontaneous additional HCCs will be permitted to offset any identified overpayment amounts. Further, identified additional HCCs can never result in additional risk adjustment payments to an MA organization since this would circumvent the final risk adjustment data submission deadlines described at 42 C.F.R. § 422.310(g)(2)(ii). An MA organization is not permitted to appeal determinations made by CMS during a RADV audit regarding whether to give credit for additional HCCs. See 79 Fed. Reg. 29,932 (May 23, 2014).

²⁷ The county rate refers to the Intra-Service Area Rate (ISAR)-adjusted county-level plan specific standardized bid. Additional information about the ISAR-adjusted county-level bids can be found at [https://www.csscooperations.com/internet/csscw3_files.nsf/F/CSSCparticipant-guide-publish_052909.pdf/\\$FILE/participant-guide-publish_052909.pdf](https://www.csscooperations.com/internet/csscw3_files.nsf/F/CSSCparticipant-guide-publish_052909.pdf/$FILE/participant-guide-publish_052909.pdf)

²⁸ Other relevant payment components include rebates, premiums, and other factors.

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Note that the “RADV enrollee total payment error” amount can be positive, \$0, or negative.²⁹ When positive, an overpayment condition exists related to the sampled enrollee.

9.2 Use of Extrapolation to Estimate Overpayment Amount for the Sampling Frame

For this MA contract-specific audit, unless certain conditions apply,³⁰ CMS may use extrapolation to estimate an overpayment amount by:

1. Calculating the average change in risk score ($\overline{\Delta R}$) for the sampled enrollees³¹, where n represents the number of sampled enrollees and ΔR_i ³² represents the change in risk score for a sampled enrollee (i.e., the amount determined by subtracting the enrollee’s RADV risk score from the original risk score that was used to calculate the payment previously received by the MA organization):

$$\overline{\Delta R} = \frac{1}{n} \sum_{i=1}^n \Delta R_i$$

2. Deriving the variance ($s_{\Delta R}^2$) of the change in risk score for each sampled enrollee³³:

²⁹ In rare instances when CMS decides not to extrapolate to estimate total payment error for the sampling frame, if a net underpayment condition exists when the “RADV enrollee total payment error” amounts for all sampled enrollees are summed, then the net underpayment amount will be capped at \$0.26

³⁰ When the original number of enrollees in the sampling frame is less than 30 and CMS is auditing all HCCs (for those original enrollees) for which the MA contract received risk adjusted payments, CMS will audit the entire sampling frame without the use of extrapolation. In instances where administrative exceptions (e.g. hardship exceptions) are granted by CMS and the total number of enrollees remaining in the sample falls below 30, CMS will not use extrapolation.

³¹ If any sampled enrollees were enrolled for fewer than 12 months, the average will be weighted by the number of enrollee months:

$$\overline{\Delta R} = \frac{1}{m} \sum_{i=1}^n \sum_{j=1}^{m_i} \Delta R_{ij}$$

Where: ΔR_{ij} is the change in risk score for the i^{th} enrollee in month j , m_i is the number of months for the i^{th} enrollee and m is the total number of months in the sample.

³² ΔR_i for a given enrollee represents the average change in risk score over enrolled months for that enrollee.

³³ If any sampled enrollees were enrolled for fewer than 12 months, the calculation of the variance estimate in Step 2 is performed using the Taylor Expansion Methodology:

https://documentation.sas.com/doc/en/statug/latest/statug_surveyfreq_details19.htm.

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$$s_{\Delta R}^2 = \sum_{i=1}^n \frac{(\Delta R_i - \overline{\Delta R})^2}{n-1}$$

3. Calculating the estimate of the variance of the average change in risk score ($VAR(\overline{\Delta R})$) for the sampling frame, where N represents the number of enrollees in the sampling frame:

$$VAR(\overline{\Delta R}) = \left(\frac{N-n}{N}\right) \frac{s_{\Delta R}^2}{n}$$

4. Computing the lower bound of the 90 percent confidence interval (δ)³⁴ of the change in risk score:

$$\delta = \overline{\Delta R} - t_{df} \sqrt{VAR(\overline{\Delta R})}$$

5. Multiplying the average change in risk score (from step 1 above) by the sum of county rates for all enrollees in the sampling frame to obtain an estimated payment error for the sampling frame³⁵, where c_i represents the county rate for an enrollee in the sampling frame of the audited MA contract:

$$PE = \sum_{i=1}^N \overline{\Delta R} c_i = \overline{\Delta R} \sum_{i=1}^N c_i$$

$$VAR(\overline{\Delta R}) = \left(\frac{n}{n-1}\right) \left(\frac{N-n}{N}\right) \sum_{i=1}^n (e_i - \bar{e})^2, \text{ where } e_i = \frac{1}{M} \sum_{j=1}^{m_i} \left(\frac{M}{m}\right) (\Delta R_{ij} - \overline{\Delta R}) \text{ and } \bar{e} = \frac{1}{n} \sum_{i=1}^n e_i$$

Where: ΔR_{ij} is the change in risk score for the i^{th} enrollee in month j , M is the total number of months in the sampling frame, m_i is the number of months for the i^{th} enrollee and m is the total number of months in the sample.

³⁴ t_{df} is the t-statistic with df degrees of freedom equal to $n-1$ where n is the number of enrollees in the sample.

³⁵ The county rate for an enrollee (c_i) is equal to the sum of the monthly county rates (c_{ij}) for that enrollee. $c_i = \sum_{j=1}^{m_i} c_{ij}$

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The extrapolated overpayment amount for the sampling frame is equal to the estimated payment error (from step 5 above) if the lower bound of the 90 percent confidence interval for the change in risk score (from step 4 above) is greater than zero.³⁶

9.3 Total Overpayment Amount to be Collected

For this PY 2021 CMS RADV audit, the total overpayment amount to be collected is the sum of the RADV enrollee payment error amounts for all sampled enrollees; however, CMS reserves the right to collect extrapolated overpayments at a later date using the methodology described in Section 9.2, if legally permissible. If the sum of the RADV enrollee payment error amounts for all sampled enrollees is greater than \$0, an overpayment condition exists and CMS will initiate collection activities. If the sum is equal to or less than \$0, then no overpayment exists. In this scenario, because the purpose of a RADV audit is to identify overpayments after the final risk adjustment data submission deadline (and not to reopen the submission deadline for CMS to make additional payments), a RADV audit will not result in additional payments being made to an MA organization.

10 Audit Report Package

When CMS completes the MA contract-specific RADV audit, it posts an Audit Report Package in the audited MA contract's secure portal within CDAT and notifies the MA organization's POCs via email. An Audit Report Package includes an Audit Results Notice and Excel workbook that will provide detailed feedback about each sampled enrollee and audited HCC. The possible outcomes for each audited HCC are:

- **Confirmed:** Audited HCC was confirmed (i.e., supported by valid MR documentation).
- **Confirmed Higher:** A higher-level HCC within the same hierarchy as the audited HCC was confirmed.
- **Discrepant:** Audited HCC was not confirmed (i.e., not supported by valid MR documentation).
- **Discrepant Lower:** Audited HCC was not confirmed, but a lower-level HCC within the same hierarchy was confirmed.
- **Administrative Exception:** Audited HCC is granted an exception by CMS and will not negatively impact payment error calculation.

CMS will also provide a data dictionary to assist with understanding audit results.

³⁶ If the lower bound of the 90 percent confidence interval for the change in risk score (from step 4) is either less than the sum of the RADV enrollee payment error amounts for all sampled enrollees or equal to or less than zero, then extrapolation will not be applied.

11 RADV and the Requirement to Report and Return Plan-Identified Overpayments

In accordance with 42 C.F.R. § 422.326, an MA organization is required to report and return any plan-identified overpayments within 60 days of being identified. However, as a contract selected for a CMS PY 2021 RADV audit and in accordance with 42 C.F.R. § 422.326(d), please suspend the reporting of overpayments to the Risk Adjustment Overpayment Reporting (RAOR) module in the Health Plan Management System (HPMS) and the submission of data corrections in RAPS and/or EDPS for PY 2021 for enrollees included in this audit's sampling frame (which includes the sampled enrollees) until further notice. For plan-identified overpayments related to enrollees in an audited MA contract that are not included in the sampling frame for this RADV audit, your organization is required to report any plan-identified overpayment to CMS in accordance with 42 C.F.R. § 422.326.

12 CMS Email Support Resources

The POCs associated with an audited MA contract may request technical support regarding use of the CDAT system by sending an email to the CDAT Technical Support Email Box at RADVCONTechsupport@radvcdat.com.

Individuals with general questions about CMS' MA contract-specific RADV audits may send an email to radv@cms.hhs.gov.

13 Document History

Version Number	Date Published	Summary of Changes
1	05/29/2026	Original document.

Appendix A: Invalid MR Reason Codes³⁷

INV1 – Wrong Record/No name. The MR name and identifying information is completely different from the name on the MR coversheet (sampled beneficiary CMS- HCC). Validity Check Question: *Does the MR correctly identify the sampled beneficiary?*

INV2 – Missing signature. The MR submitted is not signed. Note that an attestation is not a consideration for this invalid reason code, the only consideration is if the MR has a signature. Validity Check Question: *Is the MR signed?*

INV3 – Name variation. The name on the MR is similar but does not match the MR coversheet. Validity Check Question: *Is the name on the MR an acceptable variance of the name of the sampled beneficiary?*

INV4 – Date missing. The date of service is missing entirely or partially complete (e.g. month/day only). Validity Check Question: *Is there a complete date of service on the MR?*

INV5 – Invalid medical record source. The medical record source is not on the acceptable sources of data list.³⁸ Data from hospital inpatient facilities, outpatient facilities, and physician office visits are the only valid data sources for RADV. Invalid sources include hospice, home health, lab only, super-bill, and non-face to face encounters. Validity Check Question: *Is the MR from a valid source?*

INV7 – Credentials missing. The MR is signed but there is no credential in the signature and no credential (MD, DO, NP) or specialty reference (Renal, Cardiology, PCP, Hospitalist, Attending, etc.) for the one specific physician/practitioner named on the document (heading, defined provider type in signature line).³⁹ Validity Check Question: *Are you able to confirm an acceptable credential or specialty (e.g., MD, PA, DPM, Cardiology, Internal Medicine)?*

INV14 – Date outside data collection period. The MR date of service is not within the data collection period.⁴⁰ Validity Check Question: *Is the date on the MR within the data collection period?*

INV17 – Something other than a MR is attached. The submission includes a coversheet, but the attached document is not a MR. Validity Check Question: *Is acceptable MR documentation included?*

³⁷ Some invalid reason codes used in CMS RADV audits in the past have been discontinued, which is why there may be gaps between enumerated reason codes.

³⁸ Acceptable Sources of Data for PY2021 are located in Chapter 7 of the CMS Medicare Managed Care Manual, Table 22: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c07.pdf>.

³⁹ Acceptable Physician Specialty Types Effective for PY2021 are located on the Consumer Service and Support Center (CSSC) Operations website: [https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCAcc%20Phy%20Specialty%20Types%20PY2021.pdf/\\$FILE/Acc%20Phy%20Specialty%20Types%20PY2021.pdf](https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCAcc%20Phy%20Specialty%20Types%20PY2021.pdf/$FILE/Acc%20Phy%20Specialty%20Types%20PY2021.pdf)

⁴⁰ Valid Inpatient MRs must have a discharge date within the data collection period.

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INV20 – Miscellaneous INV. There is an MR issue that has not already been identified in any of the INV questions. Validity Check Question: *Is the record free from invalid issues not otherwise addressed through existing INV checks?*

Appendix B: Hardship Exception Request Process

Record Retention Requirements

The record retention requirements incorporated in MA contracts have been in place since the beginning of the MA program. Under 42 C.F.R. § 422.504(d), MA organizations are required to maintain records and other documentation for 10 years to accommodate the periodic auditing of financial records for such purposes as determining Medicare utilization, costs, and amounts payable under the contract. Further, 42 C.F.R. § 422.504(i) extends these record retention requirements to providers of health care services under contract with the MA organization. This regulation further specifies that the Federal Government has the right to audit an MA organization through 10 years from the end of the final contract period.

Obligation to Pursue All Potential Medical Record Sources

MA organizations should actively pursue and submit an alternative MR that supports an audited HCC(s) when the initial MR sought is unavailable or insufficient to support the audited HCC(s). MA organizations are encouraged to maintain documentation demonstrating their efforts to obtain alternative MRs. CMS expects the MA organization to request MRs from every health care provider for which the enrollee had an encounter (related to an audited HCC), if necessary, to submit at least one valid MR for each audited HCC.

MA organizations should be aware of state requirements for MRs to be placed in the care of a custodian for a period of time when a health care provider's office closes. When a health care provider has closed, retired, passed away, changed ownership, or otherwise undergone a change that, according to state law, should have led their MRs to be placed in the care of a custodian, MA organizations should contact the custodian to request the relevant MRs.

Failure to pursue all possible MR sources constitutes non-compliance with audit requirements.

Hardship Exception Request Submission Requirements

An MA organization must submit hardship exception requests with supporting documentation via email to radv@cms.hhs.gov.⁴¹ The email:

- Must include "PY 2021 Hardship Exception Request" in the subject line.
- May be submitted by an approved Point of Contact (POC); however, the CEO, CFO, COO, and/or MCO must be copied.
- Must not include any PHI or PII in the body of the email or in attachments; any submission containing PHI or PII will be rejected by CMS and treated as a PHI/PII data breach.
- Must use the relevant Hardship Exception Request Form. *(Note that the Hardship Exception Request Form template is available for download in the CDAT Plan Library)*

⁴¹ Note: The hardship exception request submission process may be updated later in the audit cycle to require submissions through CDAT. Until such time when CMS notifies MA organization POCs of the change in process, MA organizations should follow the submission requirements outlined in Appendix B. Please ensure POC information is kept current to ensure timely receipt of information and updates.

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MA organizations may submit the following types of hardship exception requests:

1. A hardship exception for the entire MA contract:
 - a. Must include the RADV Audit Number (RAN) communicated in the audit notice
 - b. Requires justification and supporting documentation for the entire contract
2. A hardship exception for a sampled enrollee and all their audited HCCs:
 - a. Must include a completed hardship exception request form specifying that the MA organization is seeking an exception for all audited HCCs for the sampled enrollee(s)
 - b. Requires justification and supporting documentation for each audited enrollee if multiple enrollees are included in the request
3. A hardship exception for specific audited HCCs:
 - a. Must include a completed hardship exception request form
 - b. Requires justification and supporting documentation for each audited HCC included in the request

An MA organization may submit multiple hardship exception requests, if necessary, but all emails and supporting documentation must be received before the hardship exception request submission deadline. An MA organization must withdraw a specific hardship exception request before resubmitting it with modifications. For example, if an MA organization submitted a hardship exception request for one or more audited HCCs for a specific enrollee, the MA organization is required to withdraw that existing hardship exception request submission prior to adding another HCC to the hardship exception request and resubmitting.

Please note that if an MA organization submits a valid MR for an audited HCC(s) for which it has submitted a hardship exception request, then the hardship exception request and any decision made by CMS (for the related audited HCC(s)) for the request shall be rendered moot. In other words, the valid MR submission will supersede any hardship exception request.

Supporting Documentation

The MA organization must submit supporting documentation with a hardship exception request that contains all relevant details required for CMS to comprehensively assess the incident or issue. Failure to submit supporting documentation will result in the hardship request being denied. **An MA organization should show evidence that it sought documentation from ALL providers that submitted an encounter for a particular HCC.** Supporting documentation includes, but is not limited to, any communications associated with the incident and all available evidence substantiating that the incident occurred.

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Table 1 provides examples of circumstances that may impede the timely acquisition of MRs and the types of supporting documentation that should be submitted to substantiate the circumstances. The examples provided are not exhaustive, and the submission of such documentation does not guarantee approval of a request.

Table 1: Examples of Circumstances and Supporting Documentation

Circumstance	Description	Examples of Supporting Documentation
Natural Disaster or Declared Emergency	Events such as hurricanes, wildfires, floods, or other declared emergencies that disrupt provider operations or access to records	FEMA or state emergency declarations; provider attestations; news releases; facility closure notices due to a national disaster
Public Health Emergency	Public health events that significantly impact staffing, operations, or access to MRs	Government-issued emergency declarations; internal contingency plans; provider attestations
Legal or Regulatory Restrictions	Court orders, subpoenas, or legal constraints preventing access to records within required timeframes	Court orders, legal correspondence, correspondence from custodian(s) of records and/or other official documents proving seizure and/or unavailability of MRs
Major system or Technology Failure	Significant IT outages or cyber incidents	Incident reports; vendor outage notices; other documentation such as system logs, error reports, security audit reports, data recovery attempts, incident documentation, and/or breach or loss of data reports
Provider's Office Closed and Custodial Requirements Lapsed	A provider sold, or closed their practice and the state law custodial requirements have lapsed	Announcement, news report, or signed attestation indicating closure; copies of relevant guidance, regulations, or statute demonstrating a lapse of custodial requirements
Other Extraordinary Circumstances	Circumstances beyond the organization's control that materially impact record retrieval	Detailed written explanation; third-party attestations or corroborating documentation

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Circumstances that Generally Do Not Qualify for An Exception

CMS does not consider the following scenarios to be justification for granting hardship exception:

- Record retention issues including State law retention periods that lapsed prior to CMS 10-year retention requirement
- Health care providers not responding to a request
- Issues related to lost records
- Retired or deceased health care providers where state law custodial requirements have not lapsed
- Practice transfers
- Facility closures where state law custodial requirements have not lapsed
- Human resource issues
- Ordinary IT issues (e.g., system upgrade issues, routine data migration issues, incomplete vendor handovers) that result in missing or inaccessible records

MA organizations are reminded of their obligation to pursue alternative medical records in these situations.

CMS Review and Decision

CMS provides feedback and decisions regarding hardship exception requests on an ongoing basis.

CMS reviews each hardship exception request individually, and submission does not guarantee approval by CMS. The hardship exception decision is valid only for the PY 2021 CMS RADV audit and only for the contract, enrollee, or HCCs specified. CMS communicates hardship exception decisions via email to an MA organization's registered POCs.

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Attachment 1: Lead Point of Contact Form

This attachment is incorporated by reference. Please see the document, *Lead Point of Contact Form*, which accompanied the Audit Notice in HPMS. Note the form is also available in the Plan Library in CDAT.