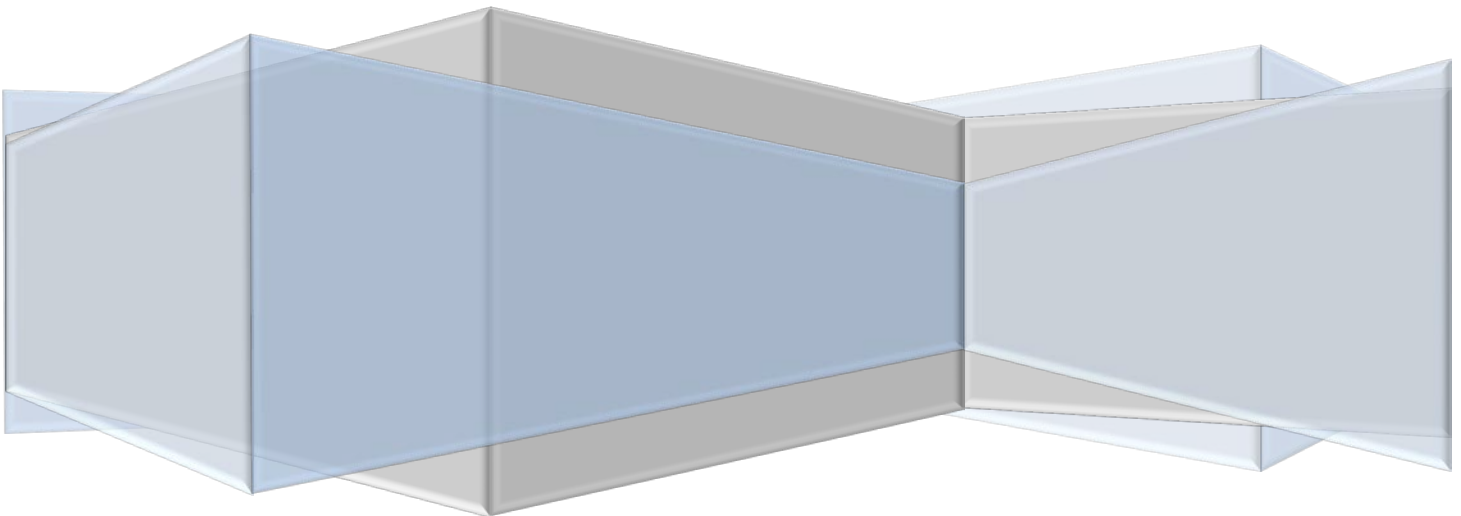# Part D Coverage Determinations, Appeals, and Grievances (CDAG)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST

Program Audit Protocol and Data Request
Part D Coverage Determinations, Appeals, and Grievances (CDAG)

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Program Audit Protocol

Purpose
To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Coverage Determinations, Appeals and Grievances (CDAG). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the CDAG Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related CDAG requirements not being met.

Audit Elements Tested
1. Timeliness
2. Processing of Coverage Requests
3. Classification of Requests
4. Administration of Drug Management Program

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Not Applicable	Universe Integrity Testing	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determination and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD) Universe Table 5: Part D Effectuations of Overturned Decisions by the IRE, ALJ, or MAC (EFF_D) Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)	Select 10 cases from each universe, Tables 1 through 7 for a total of 70 cases. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within the universe submissions, and to confirm effectuation of approved requests for each of the sampled cases. For Universe Table 2, verify during the webinar that the sampled cases are exception requests. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.505(e) 42 CFR § 423.505(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Timeliness	1.1	Universe Table 1: Standard and Expedited Coverage Determination (CD)	Conduct timeliness test at the universe level on standard coverage determinations to determine whether the Sponsoring organization provided notification of its determination no later than 72 hours after receipt of the request.	42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f)
Timeliness	1.2	Universe Table 1: Standard and Expedited Coverage Determination (CD)	Conduct timeliness test at the universe level on expedited coverage determinations to determine whether the Sponsoring organization provided notification of its determination no later than 24 hours after receipt of the request.	42 CFR § 423.572(a) 42 CFR § 423.572(b)
Timeliness	1.3	Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	Conduct timeliness test at the universe level on standard coverage determination exception requests to determine whether the Sponsoring organization provided notification of its determination no later than 72 hours after the Sponsoring organization received the physician's or other prescriber's supporting statement. If a supporting statement was not received by the end of 14 calendar days from receipt of the exceptions request, determine whether the Sponsoring organization provided notification of its determination no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.	42 CFR § 423.568(b) 42 CFR § 423.568(d) 42 CFR § 423.568(f)
Timeliness	1.4	Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	Conduct timeliness test at the universe level on expedited coverage determination exception requests to determine whether the Sponsoring organization provided notification of its determination no later than 24 hours after the Sponsoring organization received the physician's or other prescriber's supporting statement. If a supporting statement was not received by the end of 14 calendar days from receipt of the exceptions request, determine whether the Sponsoring organization provided notification of its determination no later than 24 hours from the end of 14 calendar days from receipt of the exceptions request.	42 CFR § 423.572(a) 42 CFR § 423.572(b)
Timeliness	1.5	Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	Conduct timeliness test at the universe level on payment coverage determinations to determine whether the Sponsoring organization provided notification of its determination and made payment (when applicable) no later than 14 calendar days after receipt of the request.	42 CFR § 423.568(c)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Timeliness	1.6	Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)	Conduct timeliness test at the universe level on at-risk determinations to determine whether the Sponsoring organization provided the second notice or the alternate second notice not less than 30 days and not more than the earlier of the date the Sponsoring organization made the relevant determination or 60 days after the date of the Sponsoring organization's initial notice.	42 CFR § 423.153(f)
Timeliness	1.7	Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	Conduct timeliness test at the universe level on payment coverage redeterminations to determine whether the Sponsoring organization issued its redetermination no later than 14 calendar days after the Sponsoring organization received the redetermination request and made payment (when applicable) no later than 30 calendar days after receipt of the request.	42 CFR § 423.590(b) 42 CFR § 423.636(a)
Timeliness	1.8	Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct timeliness test at the universe level on standard redeterminations to determine whether the Sponsoring organization provided notification no later than 7 calendar days after receipt of the request.	42 CFR § 423.590(a)
Timeliness	1.9	Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct timeliness test at the universe level on expedited redeterminations to determine whether the Sponsoring organization provided notification no later than 72 hours after receipt of the request.	42 CFR § 423.590(d)
Timeliness	1.10	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on pre-benefit standard decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized or provided the benefit under dispute no later than 72 hours after receipt of the notice reversing the determination.	42 CFR § 423.636(b)
Timeliness	1.11	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on standard at-risk determination decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization implemented the change to the at-risk determination no later than 72 hours after receipt of the notice reversing the determination.	42 CFR § 423.636(b)
Timeliness	1.12	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on post-service (payment) decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized the payment no later than 72 hours after receipt of the notice reversing the determination and whether the Sponsoring organization made payment no later than 30 calendar days after receipt of the notice reversing the determination.	42 CFR § 423.636(b)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Timeliness	1.13	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on pre-benefit expedited decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization authorized or provided the benefit under dispute no later than 24 hours after receipt of the notice reversing the determination.	42 CFR § 423.638(b)
Timeliness	1.14	Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D)	Conduct timeliness test at the universe level on expedited at-risk determination decisions overturned by the IRE, ALJ or MAC to determine whether the Sponsoring organization implemented the change to the at-risk determination no later than 24 hours after receipt of the notice reversing the determination.	42 CFR § 423.638(b)
Timeliness	1.15	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Conduct timeliness test at the universe level on standard grievances to determine whether the Sponsoring organization notified the enrollee of its decision no later than 30 calendar days after receipt of the grievance, or, if an extension was taken, no later than 44 calendar days after receipt of the grievance.	42 CFR § 423.564(e)
Timeliness	1.16	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Conduct timeliness test at the universe level on expedited grievances to determine whether the Sponsoring organization responded to the enrollee's grievance no later than 24 hours after receipt of the grievance.	42 CFR § 423.564(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Timeliness	1.17	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Conduct review at the universe level. If notification was untimely and auto-forwarding to the Independent Review Entity (IRE) is required, determine if the Sponsoring organization auto-forwarded the case to the IRE. Determine the total number of cases in Tables 1-4, the number of cases in Tables 1-4 that required auto-forwarding to the IRE, and the total number of cases in Tables 1-4 that were not auto-forwarded to the IRE as required.	42 CFR § 423.568(h) 42 CFR § 423.572(d) 42 CFR § 423.568(h) 42 CFR § 423.578(c) 42 CFR § 423.572(d) 42 CFR § 423.578(c) 42 CFR § 423.568(h) 42 CFR § 423.590(c) 42 CFR § 423.590(e)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Processing of Coverage Requests	2.1	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select 10 approval cases. Ensure sample set represents various types of CDs (e.g. prior authorization, step therapy authorization, tiering exception, formulary exception (including both non-formulary drugs and formulary drugs with a UM requirement, reimbursement request etc.). For each approval case, review case file documentation for proper notification of the approval decision. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. If a prescriber requested the coverage, review case file to determine if notification of the decision was also sent to the prescriber. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.568(d) 42 CFR § 423.568(e) 42 CFR § 423.572(c) 42 CFR § 423.590(h) 42 CFR § 423.560 42 CFR §423.568(b) 42 CFR §423.572(a) 42 CFR §423.590(d)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Processing of Coverage Requests	2.2	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	For each sampled approval case, review case file documentation for proper effectuation duration.	42 CFR § 423.578(c)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Processing of Coverage Requests	2.3	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select 30 denial cases. Target cases that are protected class drug denials. Ensure sample set represents various types of CDs (e.g. prior authorization, step therapy authorization, tiering exception, formulary exception, including both non-formulary drugs and formulary drugs with a UM requirement, reimbursement request etc.). For each denial case, review case file documentation for proper notification and appropriate consideration of clinical information. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. If a prescriber requested the coverage, review case file to determine if notification of the decision was also sent to the prescriber. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.568(f) 42 CFR § 423.568(g) 42 CFR § 423.572(c) 42 CFR § 423.590(g) 42 CFR § 423.560 42 CFR § 423.578(c) 42 CFR § 423.568(b) 42 CFR § 423.572(a) 42 CFR § 423.590(d)
Processing of Coverage Requests	2.4	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D)	For each denial case sampled, review case file documentation for evidence that the Sponsoring organization's Medical Director (physician) or other appropriate health care professional with sufficient medical and other expertise reviewed the request for clinical accuracy.	42 CFR § 423.562(a) 42 CFR § 423.566(d)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Processing of Coverage Requests	2.5	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER)	For each case sampled, review case file documentation for proper downgrade from an expedited determination request to a standard determination and for proper notification to the enrollee and prescribing physician or other prescriber that explains that the Sponsoring organization must process the request using the 72 hour timeframe for standard determinations, informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Sponsoring organization not to expedite, informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support, and provides instructions about the Sponsoring organization's grievance process and its timeframes. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 423.570(c) 42 CFR § 423.570(d) 42 CFR § 423.560
Processing of Coverage Requests	2.6	Universe Table 3: Payment Coverage Determination and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	For the sampled redetermination cases sampled review case file documentation for proper for evidence that the person(s) who were involved in making the coverage determination or at-risk determination under a drug management program did not conduct the redetermination, and if the denial of coverage was based on a lack of medical necessity, that the redetermination was made by a physician with expertise in the field of medicine that was appropriate for the services at issue.	42 CFR § 423.562(a) 42 CFR § 423.590(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Classification of Requests	3.1	Universe Table 1: Standard and Expedited Coverage Determination (CD) Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Universe Table 4: Standard and Expedited Redeterminations (RD)	Select up to 10 dismissed cases from Tables 1-4. Review case file documentation to determine if the request was appropriately dismissed or whether it should have been treated as a coverage request or grievance. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.566 42 CFR § 423.580 42 CFR § 423.582 42 CFR § 423.584 42 CFR § 423.590 42 CFR § 423.564
Classification of Requests	3.2	Universe Table 6: Part D Standard and Expedited Grievances (GRV_D)	Select 20 grievance sample cases from Table 6. Sample both verbal and written grievances. Target samples that appear to relate to quality of care; involve multiple issues and do not appear in the coverage determination and redetermination universes; and appear to be misclassified requests. Review sample case file documentation to determine if proper notification (i.e., written or verbal) was provided. If the Sponsoring organization extended the deadline, review case file for documentation stating how the delay is in the interest of the enrollee. Also review case file for written notification to the enrollee of the reason(s) for the delay. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.564(a) 42 CFR § 423.564(b) 42 CFR § 423.564(e) 42 CFR § 423.564(g) 42 CFR § 423.560

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Administration of Drug Management Program	4.1	Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)	Select up to 15 drug management program administration cases. For each case sampled, review case file documentation for proper initial written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.153(f)
Administration of Drug Management Program	4.2	Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)	For each case sampled, review case file documentation to determine whether the enrollee submitted preferences for prescribers or pharmacies and review for proper second written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 423.153(f)
Administration of Drug Management Program	4.3	Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR)	For each case sampled, review case file documentation for proper alternate second written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice. If the enrollee identified a representative, review case file to determine if notification was sent to the enrollee's representative.	42 CFR § 423.153(f)

Program Audit Data Request

Audit Engagement and Universe Submission Phase

Universe Submissions

Sponsoring organizations must submit each universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Universe Requests

1. Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout
2. Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout
3. Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout
4. Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout
5. Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout
6. Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout
7. Universe Table 7: Comprehensive Addition and Recovery Act (CARA) At-Risk Determination (AR) Record Layout

Universe Record Layout	Scope of Universe Request*
Table 1 Table 2 Table 3 Table 4 Table 5 Table 6 Table 7	Sponsoring organizations with PDP/MAPD enrollment of – • <50,000 enrollees: submit the 12-week period preceding, and including, the date of the audit engagement letter. • ≥50,000 but <250,000 enrollees: submit the 8-week period preceding, and including, the date of the audit engagement letter. • ≥250,000 but <500,000 enrollees: submit the 4-week period preceding, and including, the date of the audit engagement letter. • ≥500,000 enrollees: submit the 2-week period preceding, and including, the date of the audit engagement letter.

* CMS reserves the right to expand the review period to ensure sufficient universe size.

Please use the guidance below for the following record layout:

Universe Table 1: Standard and Expedited Coverage Determination (CD) Record Layout

- Include all coverage determinations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID U) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each coverage determination request must be listed as its own line item in the submitted universe.
  - o If a request for multiple drugs is made at the same time, enter each drug in a separate row.
  - o Requests for a single drug involving multiple UM criteria (e.g. step therapy and a prior authorization) must be entered as a single line item.
  - o Enter any request denied in whole or in part as denied.
- Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in the same time zone.
- Exclude all requests processed as payment coverage determinations, direct member reimbursement requests, withdraws and exception requests.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.

Column ID	Field Name	Field Type	Field Length	Description
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested.
G	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.

Column ID	Field Name	Field Type	Field Length	Description
H	Is this a protected class drug?	CHAR Always Required	1	Enter whether it is a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	CHAR Always Required	40	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	CHAR Always Required	10	Enter the date the request was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
K	Time the request was received	CHAR Always Required	8	Enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59).
L	AOR/Equivalent notice Receipt Date	CHAR Always Required	10	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.
M	AOR/Equivalent notice Receipt Time	CHAR Always Required	8	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Field Type	Field Length	Description
N	Request Determination	CHAR Always Required	18	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
O	Was the request processed as Standard or Expedited?	CHAR Always Required	1	Enter the manner by which the request was processed: • S for Standard • E for Expedited
P	Was the original request made under the standard timeframe and later requested to be expedited?	CHAR Always Required	4	Enter: • Y for Yes • N for No • None if the request was made under the expedited timeframe.
Q	Date request was upgraded to expedited	CHAR Always Required	10	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.

Column ID	Field Name	Field Type	Field Length	Description
R	Time the request was upgraded to expedited	CHAR Always Required	8	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
S	Issue Description	CHAR Always Required	2,000	Enter a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
T	Formulary UM Type	CHAR Always Required	2	Enter the formulary UM criteria the enrollee satisfied or was attempting to satisfy. Enter: • PA for Prior Authorization • ST for Step Therapy If multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason.
U	Date of Determination	CHAR Always Required	10	Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed cases, enter the date the sponsoring organization dismissed the request.

Column ID	Field Name	Field Type	Field Length	Description
V	Time of Determination	CHAR Always Required	8	Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases.
W	Date effectuated in the system	CHAR Always Required	10	Enter the date the approved decision was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for requests that were not approved.
X	Time effectuated in the system	CHAR Always Required	8	Enter the time the approved decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for requests that were not approved.
Y	Date oral notification provided to enrollee	CHAR Always Required	10	Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no oral notification was provided.
Z	Time oral notification provided to enrollee	CHAR Always Required	8	Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases or if no oral notification was provided.

Column ID	Field Name	Field Type	Field Length	Description
AA	Date written notification provided to enrollee	CHAR Always Required	10	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
AB	Time written notification provided to enrollee	CHAR Always Required	8	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases or if no written notification was provided.
AC	Who made the request?	CHAR Always Required	2	Enter who made the request: • E for enrollee • ER for enrollee's representative • P for prescribing physician or other prescriber
AD	Date forwarded to IRE	CHAR Always Required	10	Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the request was not forwarded to the IRE.
AE	Time forwarded to IRE	CHAR Always Required	8	Enter the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 2: Standard and Expedited Coverage Determination Exception Requests (CDER) Record Layout

- Include all coverage determination exception requests (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID X) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each exception request must be listed as its own line item in the submitted universe.
    - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
    - Requests for a single drug involving multiple exception types (e.g., tiering exception, prior authorization exception, quantity limit exception, and step therapy exception) must be entered as a single line item.
    - Enter any request denied in whole or in part as denied.
- Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone.
- Exclude all requests processed as payment coverage determinations, direct member reimbursement requests, withdraws, and non-exception request coverage determinations.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.

Column ID	Field Name	Field Type	Field Length	Description
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested.
G	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.

Column ID	Field Name	Field Type	Field Length	Description
H	Is this a protected class drug?	CHAR Always Required	1	Enter whether it was a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	CHAR Always Required	40	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	CHAR Always Required	10	Enter the date the request was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
K	Time the request was received	CHAR Always Required	8	Enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59).
L	AOR/Equivalent notice Receipt Date	CHAR Always Required	10	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.
M	AOR/Equivalent notice Receipt Time	CHAR Always Required	8	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Field Type	Field Length	Description
N	Request Determination	CHAR Always Required	18	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
O	Was the request processed as Standard or Expedited?	CHAR Always Required	1	Enter the manner by which the request was processed: • S for Standard • E for Expedited
P	Was the original request made under the standard timeframe and later requested to be expedited?	CHAR Always Required	4	Enter: • Y for Yes • N for No • None if the original request was made under the expedited timeframe.
Q	Date request was upgraded to expedited	CHAR Always Required	10	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.

Column ID	Field Name	Field Type	Field Length	Description
R	Time request was upgraded to expedited	CHAR Always Required	8	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
S	Issue Description	CHAR Always Required	2,000	Provide a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
T	Exception Type	CHAR Always Required	25	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception

Column ID	Field Name	Field Type	Field Length	Description
U	Formulary UM Exception Type	CHAR Always Required	4	If the case was a formulary UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception enter: • SE for Safety Edit Enter None if the request was not a formulary UM exception or safety edit exception. If multiple formulary UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.
V	Date prescriber supporting statement received	CHAR Always Required	10	Enter the date the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the date the exception request was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no prescriber supporting statement was received.
W	Time prescriber supporting statement received	CHAR Always Required	8	Enter the time the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the time the exception request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if no prescriber supporting statement was received.

Column ID	Field Name	Field Type	Field Length	Description
X	Date of Determination	CHAR Always Required	10	Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed cases, enter the date the sponsoring organization dismissed the request.
Y	Time of Determination	CHAR Always Required	8	Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases.
Z	Date effectuated in the system	CHAR Always Required	10	Enter the date the approved decision was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the exception was not approved.
AA	Time effectuated in the system	CHAR Always Required	8	Enter the time the approved decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the exception was not approved.
AB	Expiration date of the approval	CHAR Always Required	10	Enter the expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the exception was not approved.
AC	Date oral notification provided to enrollee	CHAR Always Required	10	Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no oral notification was provided.

Column ID	Field Name	Field Type	Field Length	Description
AD	Time oral notification provided to enrollee	CHAR Always Required	8	Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases or if no oral notification was provided.
AE	Date written notification provided to enrollee	CHAR Always Required	10	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
AF	Time written notification provided to enrollee	CHAR Always Required	8	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed cases or if no written notification was provided.
AG	Who made the request?	CHAR Always Required	2	Enter who made the request: • E for enrollee • ER for enrollee's representative • P for prescribing physician or other prescriber
AH	Date forwarded to IRE	CHAR Always Required	10	Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the request was not forwarded to the IRE.

Column ID	Field Name	Field Type	Field Length	Description
AI	Time forwarded to IRE	CHAR Always Required	8	Enter the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

<u>**Universe Table 3: Payment Coverage Determinations and Redeterminations (PYMT_D) Record Layout**</u>

- Include all payment coverage determinations and redeterminations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID T) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each payment request must be listed as its own line item in the submitted universe.
  - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
  - Requests for a single drug must be entered as a single line item.
  - Enter any request denied in whole or in part as denied.
- Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone.
- Exclude requests for coverage that were withdrawn.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.

Column ID	Field Name	Field Type	Field Length	Description
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested.
G	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size.

When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted.

If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field.

For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE. |

Column ID	Field Name	Field Type	Field Length	Description
H	Is this a protected class drug?	CHAR Always Required	1	Enter whether it was a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	CHAR Always Required	40	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the request was received	CHAR Always Required	10	Enter the date the request was received. If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
K	AOR/Equivalent notice Receipt Date	CHAR Always Required	10	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.
L	Type of Request	CHAR Always Required	30	Enter: • payment coverage determination • payment redetermination

Column ID	Field Name	Field Type	Field Length	Description
M	Request Determination	CHAR Always Required	18	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
N	Was the request processed as an exception request?	CHAR Always Required	1	Enter: • Y for Yes • N for No
O	Issue Description	CHAR Always Required	2,000	Enter a description of the issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
P	Exception Type	CHAR Always Required	25	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception Enter None if the request was not an exception request.

Column ID	Field Name	Field Type	Field Length	Description
Q	Formulary UM Exception Type	CHAR Always Required	4	If the case was a formulary UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception enter: • SE for Safety Edit Enter None if the request was not a formulary UM exception or safety edit exception. If multiple formulary UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.
R	Date prescriber supporting statement received	CHAR Always Required	10	Enter the date the prescriber's supporting statement was received. If the prescriber statement was received with the initial request, enter the date the exception request was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no prescriber supporting statement was received.
S	Was the coverage determination request denied for lack of medical necessity?	CHAR Always Required	4	Enter: • Y for Yes • N for No • None if the request was not denied (i.e., approved, auto-forwarded, dismissed).

Column ID	Field Name	Field Type	Field Length	Description
T	Date of Determination	CHAR Always Required	10	Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed cases, enter the date the sponsoring organization dismissed the request.
U	Date effectuated in the system	CHAR Always Required	10	Enter the date the approved decision was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the payment request was not approved.
V	Expiration date of the approval	CHAR Always Required	10	Enter the expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the exception was not approved or if the request was not an exception request.
W	Date written notification provided to enrollee	CHAR Always Required	10	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
X	Who made the request?	CHAR Always Required	2	Enter who made the request: • E for enrollee • ER for enrollee's representative • P for prescribing physician or other prescriber

Column ID	Field Name	Field Type	Field Length	Description
Y	Date reimbursement provided	CHAR Always Required	10	Enter the date the check or reimbursement was provided to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NRD if the request was approved but no reimbursement was due to the enrollee. Enter NP if the payment has not been issued at the time of the universe submission. Enter None if the request was not approved.
Z	Date forwarded to IRE	CHAR Always Required	10	Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 4: Standard and Expedited Redeterminations (RD) Record Layout
- Include all redeterminations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization's determination (Column ID W) must fall within the universe request period.
- For cases with a Request Determination of re-opened approved or re-opened denied, the date and time the request was received must be the date and time the case was re-opened (i.e., the determination was made to re-open the case). The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the original determination date falls within the audit review period.
- Each redetermination request must be listed as its own line item in the submitted universe.
  - If a request for multiple drugs is made at the same time, enter each drug in a separate row.
  - Requests for a single drug involving multiple UM criteria (e.g. step therapy and a prior authorization) must be entered as a single line item.
  - Enter any request denied in whole or in part as denied.

- Enter all fields for a single request in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone.
- Exclude all requests processed as payment redeterminations and withdrawn cases.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested. Enter None if not applicable.

Column ID	Field Name	Field Type	Field Length	Description
G	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.
H	Is this a protected class drug?	CHAR Always Required	1	Enter whether it is a protected class drug: • Y for Yes • N for No
I	Authorization or Claim Number	CHAR Always Required	40	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.

Column ID	Field Name	Field Type	Field Length	Description
J	Date the request was received	CHAR Always Required	10	Enter the date the request was received. If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the date the Sponsoring organization received the information establishing good cause. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
K	Time the request was received	CHAR Always Required	8	Enter the time the request was received. If the Sponsoring organization obtained information establishing good cause after the 60-day filing timeframe, enter the time the Sponsoring organization received the information establishing good cause. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases.
L	AOR/Equivalent notice Receipt Date	CHAR Always Required	10	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Field Type	Field Length	Description
M	AOR/Equivalent notice Receipt Time	CHAR Always Required	8	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard cases, dismissed cases or if no AOR or equivalent written notice was received or required.
N	Request Determination	CHAR Always Required	18	Enter: • Approved • Denied • IRE auto-forward • Re-opened Approved • Re-opened Denied • Dismissed
O	Was the request processed as Standard or Expedited?	CHAR Always Required	1	Enter the manner by which the request was processed: • S for Standard • E for Expedited
P	Was the original request made under the standard timeframe and later requested to be expedited?	CHAR Always Required	4	Enter: • Y for Yes • N for No • None if the request was made under the expedited timeframe

Column ID	Field Name	Field Type	Field Length	Description
Q	Date request was upgraded to expedited	CHAR Always Required	10	Enter the date the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.
R	Time request was upgraded to expedited	CHAR Always Required	8	Enter the time the request was received to upgrade the initial standard request to expedited from the enrollee, their authorized representative, or their prescriber, or the Sponsoring organization determined the request should be expedited. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the initial request was made under the expedited timeframe, if the Sponsoring organization chose not to expedite the request, or if the request was received and processed under the standard timeframe.

Column ID	Field Name	Field Type	Field Length	Description
S	Issue Description	CHAR Always Required	2,000	Enter a description of the redetermination issue and, if applicable, why the request was denied. For dismissed cases, provide the reason for dismissal.
T	Exception Type	CHAR Always Required	25	Enter the type of exception request: • Tiering exception • Non-formulary exception • Formulary UM exception • Hospice • Safety edit exception Enter None if the request was not an exception request.
U	Formulary UM Exception Type	CHAR Always Required	4	If the case was a formulary UM exception, indicate what criteria the enrollee was attempting to waive. Enter: • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit If the case was a safety edit exception enter: • SE for Safety Edit Enter None if the request was not a formulary UM exception or safety edit exception. If multiple formulary UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.
V	Was the coverage determination request denied for lack of medical necessity?	CHAR Always Required	4	Enter: • Y for Yes • N for No • None if the request was auto-forwarded

Column ID	Field Name	Field Type	Field Length	Description
W	Date of Determination	CHAR Always Required	10	Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed cases, enter the date the sponsoring organization dismissed the request.
X	Time of Determination	CHAR Always Required	8	Enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases and dismissed cases.
Y	Date effectuated in the system	CHAR Always Required	10	Enter the date the approved decision was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for requests that were not approved.
Z	Time effectuated in the system	CHAR Always Required	8	Enter the time the approved decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases and requests that were not approved
AA	Expiration date of the approval	CHAR Always Required	10	Enter the expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the exception was not approved or if it is not an exception request.

Column ID	Field Name	Field Type	Field Length	Description
AB	Date oral notification provided to enrollee	CHAR Always Required	10	Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for standard cases, dismissed cases or if no oral notification was provided.
AC	Time oral notification provided to enrollee	CHAR Always Required	8	Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases, dismissed cases or if no oral notification was provided.
AD	Date written notification provided to enrollee	CHAR Always Required	10	Enter the date written notification of determination was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
AE	Time written notification provided to enrollee	CHAR Always Required	8	Enter the time written notification of determination was provided to the enrollee. Do not enter the time a letter is generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases, dismissed cases or if no written notification was provided.
AF	Who made the request?	CHAR Always Required	2	Enter who made the request: • E for enrollee • ER for enrollee's representative • P for prescribing physician or other prescriber

Column ID	Field Name	Field Type	Field Length	Description
AG	Date forwarded to IRE	CHAR Always Required	10	Enter the date the redetermination request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the request was not forwarded to the IRE.
AH	Time forwarded to IRE	CHAR Always Required	8	Enter the time the redetermination request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the request was not forwarded to the IRE.

Please use the guidance below for the following record layout:

Universe Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D) Record Layout

- Include all coverage determinations, redeterminations, or at-risk determinations fully or partially overturned by the IRE, ALJ, or MAC requiring an effectuation as pre-benefit, post-service (payment), or an at-risk determination received from the IRE, ALJ, or MAC during the universe request period. The date of the Sponsoring organization's receipt of the overturn decision (Column ID J) must fall within the universe request period.
- If a case contains multiple drugs, enter each drug in a separate row.
- Exclude any cases that were re-opened by the Sponsoring organization or that were dismissed or upheld by the IRE, ALJ, or MAC.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.

Column ID	Field Name	Field Type	Field Length	Description
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested.
G	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, or NDC is not applicable (e.g., for at-risk redeterminations), populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.

Column ID	Field Name	Field Type	Field Length	Description
H	Is this a protected class drug?	CHAR Always Required	4	Enter whether it is a protected class drug: • Y for Yes • N for No • None if not applicable
I	Authorization or Claim Number	CHAR Always Required	40	Enter the associated authorization or claim number for this request. If an authorization or claim number is not available, provide the internal tracking or case number. Enter None if there is no authorization, claim or other tracking number available.
J	Date the overturn decision was received	CHAR Always Required	10	Enter the date the overturn decision was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
K	Time the overturn decision was received	CHAR Always Required	8	Enter the time the overturn decision was received. Submit in HH:MM:SS military time format (e.g., 23:59:59).
L	Type of Request reversed by review entity	CHAR Always Required	43	Enter the type of request: • Standard request for benefits • Standard request for payment • Standard request for at-risk determination • Expedited request for benefits • Expedited request for at-risk determination
M	Date the overturn decision was effectuated in the system	CHAR Always Required	10	Enter the date the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if the overturn decision was not effectuated or if no effectuation was required.

Column ID	Field Name	Field Type	Field Length	Description
N	Time the overturn decision was effectuated in the system	CHAR Always Required	8	Enter the time the benefit was provided, payment was authorized or the change to the at-risk determination was implemented. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None if the overturn decision was not effectuated or if no effectuation was required.
O	Date reimbursement provided	CHAR Always Required	10	Enter the date the check or reimbursement was provided to the enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NRD if the request was approved but no reimbursement was due to the enrollee. Enter NP if the payment has not been issued at the time of the universe submission.
P	Expiration date of the approval	CHAR Always Required	10	Enter the expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if it was not an exception request.

Please use the guidance below for the following record layout:

Universe Table 6: Part D Standard and Expedited Grievances (GRV_D) Record Layout
- Include all grievances the Sponsoring organization responded to during the universe request period. The date of the Sponsoring organization's notification (Column ID P or R) must fall within the universe request period.
- Exclude all grievances that were withdrawn and dismissed during the universe request period.
- Exclude complaints filed only within the Complaints Tracking Module (CTM) in HPMS. If a complaint was processed both within the CTM and was also received as a grievance, exclude the CTM complaint but include the grievance as processed by the Sponsoring organization.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Date the grievance was received	CHAR Always Required	10	Enter the date the grievance was received. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
G	Time the grievance was received	CHAR Always Required	8	Enter the time the grievance was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases.
H	AOR/Equivalent notice Receipt Date	CHAR Always Required	10	Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received or required.

Column ID	Field Name	Field Type	Field Length	Description
I	AOR/Equivalent notice Receipt Time	CHAR Always Required	8	Enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard cases or if no AOR or equivalent written notice was received or required.
J	How was the grievance received?	CHAR Always Required	7	Enter: • Oral • Written
K	Was the grievance processed as Standard, or Expedited?	CHAR Always Required	1	Enter: • S for Standard • E for Expedited
L	Category of the issue	CHAR Always Required	50	Enter the category of the grievance as assigned by the Sponsoring organization. Enter based on the Sponsoring organization's internal labeling system.
M	Grievance Description	CHAR Always Required	1,800	Enter the description of the grievance.
N	Was this processed as a quality of care grievance?	CHAR Always Required	1	Enter: • Y for Yes • N for No
O	Was a timeframe extension taken?	CHAR Always Required	1	Enter: • Y for Yes • N for No
P	Date oral notification provided to enrollee	CHAR Always Required	10	Enter the date oral notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no oral notification was provided.
Q	Time oral notification provided to enrollee	CHAR Always Required	8	Enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases or if no oral notification was provided.

Column ID	Field Name	Field Type	Field Length	Description
R	Date written notification provided to enrollee	CHAR Always Required	10	Enter the date written notification was provided to enrollee. Do not enter the date a letter is generated or printed. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
S	Time written notification provided to enrollee	CHAR Always Required	8	Enter the time written notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard cases or if no written notification was provided.

Please use the guidance below for the following record layout:

Universe Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determination (AR) Record Layout

- Include all at-risk determinations made by the Sponsoring organization pursuant to 42 CFR §423.153(f) during the universe request period. The date of the Sponsoring organization's determination (Column ID I), must fall within the universe request period.
- Enter all fields for a single at-risk determination in the same time zone. For example, if the Sponsoring organization has systems in EST and CST, all data in a single line item must be in a single time zone.
- Exclude appeals of at-risk determinations.

Column ID	Field Name	Field Type	Field Lengt	Description
A	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
B	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.

Column ID	Field Name	Field Type	Field Length	Description
C	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
D	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234).
E	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
F	Drug Name, Strength, and Dosage Form	CHAR Always Required	150	Enter the drug name, strength, and dosage form requested. Enter None if not related to a specific drug (e.g. pharmacy lock-in, prescriber lock-in) or if the at-risk determination is drug related, but is not specific to a single drug (e.g. beneficiary level edit blocking all opioid access, beneficiary level edit allowing a defined cumulative MME dosage).
G	Date the Initial Written Notification of potential at-risk status was provided to enrollee	CHAR Always Required	10	Enter the date the initial notification was provided to the enrollee that identified them as potentially at-risk. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.

Column ID	Field Name	Field Type	Field Length	Description
H	Date Second Written Notification of At-Risk Determination Provided to Enrollee	CHAR Always Required	10	Enter the date the second written notification or alternate second written notification was provided to enrollee. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no written notification was provided.
I	Date the At-Risk Determination was made	CHAR Always Required	10	Enter the date the at-risk determination was made. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
J	Request Determination	CHAR Always Required	11	Enter the determination: • At-Risk • Not At-Risk
K	Type of At-Risk Limitation	CHAR Always Required	54	Enter the type of at-risk limitation imposed upon the enrollee: • Point of Sale Edit • Pharmacy Lock-In • Provider Lock-In If there are multiple limitations, enter all limitations that apply (e.g., POS edit, pharmacy lock-in and prescriber lock-in). Enter None if an at-risk determination was not imposed on the enrollee.
L	Confirmation of Agreement to Place Limitation upon Enrollee	CHAR Always Required	4	Identify if agreement to place limitation was confirmed by either the pharmacy, provider or both. Enter: • YPR for Yes from Provider • YPH for Yes from Pharmacy • YBO for Yes from Both Enter None if no confirmation of agreement was received.

Column ID	Field Name	Field Type	Field Length	Description
M	If an enrollee edit was used, date the edit was effectuated in the system	CHAR Always Required	10	Enter the date the enrollee edit/limitation was effectuated in the system. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no limitations were entered into the system.
N	Expiration date of the at-risk restriction/lock-in	CHAR Always Required	10	Enter the expiration date of the at-risk restriction/lock-in. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if there was not a restriction/lock-in placed on enrollee.

Audit Field Work Phase

Supporting Documentation Submissions

Each case will be evaluated to determine whether the Sponsoring organization is compliant with its Part D contract requirements. To facilitate this review, the Sponsoring organization must have access to, and the ability to save and upload screenshots of, supporting documentation and data relevant for a particular case, including, but not limited to:

- The initial coverage request.
  - If request was received via fax/mail/email, copy of original request including date/time stamp of receipt.
  - If request was received via phone, copy of CSR notes and/or documentation of call including date/time stamp of call and call details.
- Copy of appointment of representative (AOR) or equivalent written notice, if patient's representative placed request and/or received response.
- Copy of all notices, letters, call logs, or other documentation showing when the sponsoring organization requested additional information from the prescriber. If the request was made via phone call, copy of call log detailing what was communicated to the prescriber.
- Copy of all supplemental information submitted by the prescriber.
  - If information was received via fax/mail/email, copy of documentation provided including date/time stamp and call details.
  - If information was received via phone, copy of CSR notes and/or documentation of call including date/time stamp.
- Documentation of the decision (approved or denied), including:
  - Documentation showing denial, partial denial, or approval notification to the enrollee and/or their representative and prescriber, if applicable.
  - Name and title of final reviewer and rationale for the decision. Additional documentation will include, but is not limited to: Sponsoring organization formulary/EOC, Sponsoring organization clinical criteria, Federal Regulations, CMS Guidance, compendia, peer

reviewed literature (where allowed), or any other documentation used when considering the request.

- o Copy of the written decision letter and documentation of date/time letter was mailed.
- o If oral notification was given, copy of CSR notes and/or documentation of call including date/time stamp.
- For approvals: documentation of effectuation of request, including:
  - o Approval in coverage determinations/redeterminations system(s) and evidence of effectuation in Sponsoring organization claims system clearly showing date and time override was entered.
  - o Documentation of paid or rejected claims following the approved coverage determination or redetermination.
  - o For approved exception requests, proof that the approval is effective for the remainder of the plan year.
- If case was untimely:
  - o Documentation showing when the Sponsoring organization auto-forwarded the request to the IRE.
- For reopenings:
  - o Copy of any case notes as to why the decision was reopened,
  - o Copy of any notice sent to the enrollee regarding the reason for the reopening,
  - o Copy of all documentation relating to the decision of the reopening and any subsequent notification regarding the decision.
- If applicable, all documentation to support the Sponsoring organization's decision to process an expedited request under the standard timeframe, including any pertinent medical documentation, and any associated notices provided to the enrollee and the requesting provider/physician.
- If applicable, notice to the enrollee that their request is not being expedited and the right to file a grievance.
- All previous case history/ documentation of initial coverage determinations and/or redeterminations related to the overturn.
- Copy of overturn notice from IRE/ALJ/MAC including date/time stamp of receipt by Sponsoring organization.
- Documentation of effectuation including approval in coverage determinations/ redeterminations system(s) and evidence of effectuation in Sponsoring organization claims system clearly showing date/time the override was entered. For approved exception requests, proof that the approval is effective for the remainder of the plan year.
- Claims history for drug subsequent to the effectuation showing either paid or rejected claims.
- Copies of any case notes as to why the case was dismissed.
- Any notification regarding the dismissal.
- Initial complaint:
  - o If complaint was received via fax/mail/email, copy of original complaint.
  - o If request was received via phone, copy of CSR notes and/or documentation of call including the call details.
- Copy of appointment of representative (AOR) or equivalent written notice, if patient's representative filed grievance or received notification.
- Copy of all supplemental information submitted by enrollee and/or their representative.
  - o If information was received via fax/mail/email, copy of documentation provided.

- o If information was received via phone, copy of CSR notes and/or documentation of call.
- Documentation showing the steps the Sponsoring organization took to resolve the issue, including appropriate correspondence with other departments within the organization, referral to Sponsoring organization's fraud, waste, and abuse department, outreach to network pharmacies, and description of the final response.
- Documentation showing response to the enrollee and/or their representative.
  - o Copy of the written decision letter sent and documentation of date letter was mailed.
  - o If oral notification was given, copy of CSR notes and/or documentation of call.
- Documentation that supports a Sponsoring organizations record layout population (e.g. mailroom policies).

Sponsoring organizations are expected to submit supporting documentation within two business days of the request.

Root Cause Analysis Submissions
Sponsoring organizations may be required to provide a root cause analysis using the Root Cause Template provided by CMS. Sponsoring organizations have two business days from the date of request to respond.

Impact Analysis Submissions
When non-compliance with contract requirements is identified on audit, Sponsoring organizations must submit each requested impact analysis, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row using one of the universe record layouts above, as specified by CMS. The Sponsoring organization must include all requests impacted by the issue of non-compliance during the impact analysis request period. Sponsoring organizations must provide accurate and timely impact analysis submissions within 10 business days of the request. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Verification of Information Collected: CMS may conduct integrity tests to validate the accuracy of all universes, impact analyses, and other related documentation submitted in furtherance of the audit. If data integrity issues are noted, Sponsoring organizations may be required to resubmit their data.