

# Universe Preparation and Submission



*Jennifer Smith*

*Director, Division of Analysis, Policy,  
& Strategy (DAPS)*

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# Background

- CMS has created new record layouts for submitting universes and new requirements around universe submission.
- Record layout changes are mainly in ODAG and CDAG and include more information with respect to field definitions.
- There is now a limit on the number of resubmissions that will be allowed.

# Universe Preparation

- Why is it important?
- Review record layouts and forward any questions to the mailbox: [part\\_c\\_part\\_d\\_audit@cms.hhs.gov](mailto:part_c_part_d_audit@cms.hhs.gov)
- Program your systems and collect data from FDRs.
- Conduct “Mock” universe pulls.
  - Combine data across platforms.
  - Combine data from FDRs with plan data or other FDRs.

# Universe Preparation (cont.)

- Conduct your own QA before submitting to CMS.
- CMS conducts an engagement letter follow-up call—have the right people on the phone.
- CMS conducts a webinar to verify that the dates and times provided in the timeliness universes are accurate.

# Standard Coverage Determination Exception Requests Record Layout

| Field Name                    | Field Type           | Field Length | Description  |
|-------------------------------|----------------------|--------------|--|
| <b>Beneficiary HICN</b>       | CHAR Always Required | 11           | Health Insurance Claim Number assigned by the Social Security Administration to an individual for the purpose of identifying him/her as a Medicare beneficiary. The number is between seven and 11 digits long (e.g., 123456789A). Do not include any spaces, hyphens or other special characters. |
| <b>Beneficiary First Name</b> | CHAR Always Required | 30           | First name of the beneficiary.   |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name                       | Field Type           | Field Length | Description  |
|----------------------------------|----------------------|--------------|--|
| <b>Beneficiary Last Name</b>     | CHAR Always Required | 30           | Last name of the beneficiary.  |
| <b>Enrollment Effective Date</b> | CHAR Always Required | 10           | Effective date of enrollment for the beneficiary into their current PBP. Submit in CCYY/MM/DD format (e.g., 2015/01/01). |
| <b>Cardholder ID</b>             | CHAR Always Required | 20           | Cardholder identifier used to identify the beneficiary. This is assigned by the sponsor.                                 |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name  | Field Type           | Field Length | Description   |
|-------------|----------------------|--------------|---|
| Contract ID | CHAR Always Required | 5            | The contract number (e.g., H1234, S1234) of the organization. |
| Plan ID     | CHAR Always Required | 3            | The plan number (e.g., 001, 002) of the organization.         |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name        | Field Type           | Field Length | Description  |
|-------------------|----------------------|--------------|--|
| Patient Residence | CHAR Always Required | 2            | <p>Residence code for the beneficiary. Valid values are:</p> <p>00 – Not specified, other patient residence not identified below</p> <p>01 – Home</p> <p>03 – Nursing Facility</p> <p>04 – Assisted Living Facility</p> <p>06 – Group Home</p> <p>09 – Intermediate Care Facility/Mentally Retarded</p> <p>11 – Hospice</p> <p>Note: When the patient residence code is not directly populated on the incoming coverage determination (CD) the sponsor can obtain the information from the rejected claim prompting the CD, other paid claims occurring within 3 days of the CD, or any medical information the plan may have at the initiation of a coverage request. If the sponsor still cannot determine the patient residence code, then enter 00- not specified in the universe field.</p> |



# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name                    | Field Type           | Field Length | Description   |
|-------------------------------|----------------------|--------------|---|
| Date the request was received | CHAR Always Required | 10           | Date the request was received from the beneficiary, their authorized representative, or their prescriber. Submit in CCYY/MM/DD format (e.g., 2015/01/01).                   |
| Time the request was received | CHAR Always Required | 8            | Time of day the request was received from the beneficiary, their authorized representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name                       | Field Type           | Field Length | Description  |
|----------------------------------|----------------------|--------------|--|
| Was the case approved or denied? | CHAR Always Required | 16           | Enter the final disposition of the case. Valid values are: approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened. Enter NA if the request was never resolved/ processed. |
| Description of the issue         | CHAR Always Required | 2000         | Description of the issue. For denials, also include an explanation of why the case was denied.   |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name   | Field Type           | Field Length | Description  |
|--|----------------------|--------------|--|
| <b>NDC_11</b>  | CHAR Always Required | 11           | 11-Digit National Drug Code. When no NDC is available enter the applicable Uniform Product Code (UPC) or Health Related Item Code (HRI). Do not include any spaces, hyphens or other special characters. Enter NA if not applicable. |
| <b>Drug Name, Strength &amp; Dosage Form</b>   | CHAR Always Required | 150          | Drug name, strength & dosage form.   |
| <b>Was request made under the expedited timeframe but processed by the sponsor under the standard timeframe?</b> | CHAR Always Required | 1            | Yes/No indicator of whether request made under expedited timeframe was processed under the standard timeframe based on the sponsor deciding that expedited case was unnecessary. (Y/N)   |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name                                    | Field Type           | Field Length | Description  |
|---|----------------------|--------------|--|
| Clearly indicate exception type.              | CHAR Always Required | 19           | Type of exception request. Valid values are: tier, non-formulary, prior authorization, quantity limit, step therapy, or hospice.     |
| Please list expiration date of the approval.  | CHAR Always Required | 10           | Expiration date of the exception approval. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter NA if not applicable.               |
| Is this a protected class drug?               | CHAR Always Required | 1            | Protected class drug indicator. (Y/N)  |
| Date prescriber supporting statement received | CHAR Always Required | 10           | Date the prescriber's supporting statement was received. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter NA if not applicable. |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name   | Field Type           | Field Length | Description  |
|--|----------------------|--------------|--|
| <b>Time prescriber supporting statement received</b>     | CHAR Always Required | 8            | Time the prescriber's supporting statement was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if not applicable.                       |
| <b>Disposition of the request</b>                        | CHAR Always Required | 16           | Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened. Enter NA if the request was never resolved/ processed. |
| <b>Was request denied for lack of medical necessity?</b> | CHAR Always Required | 2            | Yes/No indicator of whether request denied for lack of medical necessity. (Y/N/NA)   |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name  | Field Type           | Field Length | Description  |
|---|----------------------|--------------|--|
| If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional? | CHAR Always Required | 2            | Yes/No indicator of review by physician or other appropriate health care professional if case was denied for lack of medical necessity. (Y/N/NA)                                   |
| Date of plan decision   | CHAR Always Required | 10           | Date of the plan decision (e.g., approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened). Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter NA if not applicable. |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name                                   | Field Type           | Field Length | Description  |
|--|----------------------|--------------|--|
| <b>Time of plan decision</b>                 | CHAR Always Required | 8            | Time of the plan decision (e.g., approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened). Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if not applicable. |
| <b>Date effectuated in the plan's system</b> | CHAR Always Required | 10           | Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2015/01/01). For denials and IRE auto-forwards indicate NA.  |
| <b>Time effectuated in the plans' system</b> | CHAR Always Required | 8            | Time effectuated in the plan's system. Submit in HH:MM:SS military time format (e.g., 23:59:59). For denials and IRE auto-forwards indicate NA.  |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name   | Field Type           | Field Length | Description  |
|--|----------------------|--------------|--|
| <b>Date oral notification provided to enrollee</b> | CHAR Always Required | 10           | Date oral notification (or documented good faith attempt) provided to enrollee (or their authorized representative). Submit in CCYY/MM/DD format (e.g., 2015/01/01). If no oral notification, indicate NA. |
| <b>Time oral notification provided to enrollee</b> | CHAR Always Required | 8            | Time oral notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). If no oral notification, indicate NA.   |



# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name  | Field Type           | Field Length | Description  |
|---|----------------------|--------------|--|
| <b>Date written notification provided to enrollee</b> | CHAR Always Required | 10           | Date written notification provided to enrollee. The term “provided” means when the letter left the sponsor’s establishment by either US Mail, fax, or electronic communication. This field is not for when a letter is generated or printed within the sponsor’s organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Enter NA if not applicable. |
| <b>Time written notification provided to enrollee</b> | CHAR Always Required | 8            | Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if not applicable.  |

# Standard Coverage Determination Exception Requests Record Layout (cont.)

| Field Name   | Field Type           | Field Length | Description   |
|--|----------------------|--------------|---|
| <b>If untimely, date forwarded to IRE</b>                                    | CHAR Always Required | 10           | For untimely decisions, date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2015/01/01). For timely decisions indicate NA.                      |
| <b>If untimely, time forwarded to IRE</b>                                    | CHAR Always Required | 8            | For untimely decisions, time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59). For timely decisions indicate NA.            |
| <b>If untimely, date enrollee notified request has been forwarded to IRE</b> | CHAR Always Required | 10           | For untimely decisions, date the enrollee was notified of request forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2015/01/01). For timely decisions indicate NA. |

# Universe Submission

## What is the new submission requirement?

*Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified. When multiple attempts are made, CMS will only use the last universe submitted.*

*If multiple attempts are made and the sponsor fails to provide accurate and timely universe submissions after the first 2 attempts, CMS will document this as an observation in the sponsor's program audit report. After the 3<sup>rd</sup> failed attempt or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited ICARs for the conditions related to the inaccurate universes as a result of being unable to fully audit that element.*

# Universe Submission (cont.)

Why the new submission requirement?

- Equity and consistency across audited sponsors.
- Efficiency and need to complete the audit.
- You are responsible for being able to collect and submit accurate data.

# Universe Submission (cont.)

When will the new submission requirement be applied?

- When the data is so incomplete or inaccurate that we cannot conduct our audit; or
- For timeliness (CDAG and ODAG), when we are unable to confirm the accuracy of the dates and times applicable to the timeframe we are testing.

# Universe Submission (cont.)

- Not having accurate universes can drastically affect your audit score.
- Poor audit results may lead to a referral for possible enforcement actions.
- Can adversely affect STAR ratings and past performance.

# Questions

