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**Received Date :** 07/02/2025 10:24 AM

**Comments Received :**

**Key Questions and Clarification Requests**

**Field J – Intent of the Field**

Request clarification on the purpose of this field.

Is it intended to capture claims-level information?

**Field P – Definition Distinction**

Request clarification between the following categories:

“05 – Lack of Medical Necessity”

“11 – Step Therapy or UM Requirement Not Met”

Is the distinction based on clinical judgment vs. procedural requirements?

**Field R – Reviewer Qualifications and Applicability**

Does this field apply only to secondary review or also to the initial primary case?

If applicable to the primary review:

Request expanded definition for “O – Other Appropriate Healthcare Professional”.

Does this include pharmacists only, or also nurses, pharmacy techs, etc.?

Expanded definition may have system implications (e.g., configuration changes or manual workflows), particularly if medical director review becomes required for Part B drugs.

**Field S – CMS Coverage Guidance Criteria**

Request clarification on the definition of “criteria where CMS has not issued a CMS Coverage Guidance.”

Does this include:

Internally developed criteria?

Step therapy protocols?

Clarification will determine if a system change request (CR) is necessary.

**Field T – Delegated Entity Input**

Request guidance on how delegated entities should populate this field.

Would prefer input or confirmation from MAO as the reporting authority.

**Operational Feasibility Concerns**

**Burden of Data Collection**

The required level of detail (e.g., vendor attribution, reviewer credentials) spans multiple systems and sources.

Implementation at scale would require:

Manual extraction, increasing risk of inaccuracies, or

Extensive IT buildouts that may exceed the proposed timeline.

**Frequency and Accuracy Trade-Off**

Quarterly submission cadence may undermine data quality due to compressed validation timelines.

Recommend:

Biannual reporting during Year 1, with the option to ramp up.

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A phased implementation, starting with coverage determinations.

#### Audit and Delegation Concerns

Fields appear to assume uniform data availability across MAOs, including delegated vendors.

Request CMS to consider:

Allowing aggregate or categorical responses (e.g., Yes/No) instead of per-case level detail.

Clarifying whether these fields are mandatory for all determinations, including those handled under delegation.

#### Suggested Adjustments

Stagger reporting implementation: start with coverage decisions, then payment and appeals.

Allow a pilot phase to refine data definitions and reporting logic.

Permit sampling or summary-level reporting for fields like reviewer qualifications and vendor involvement.

Clarify accepted formats and submission processes to ensure MAO systems can comply.

#### System Update Feasibility

New fields (e.g., internal coverage criteria usage) will require system programming and reportable flag creation.

Recommend extending the implementation timeline to ensure accurate, comprehensive data capture and submission.