## 60- Day Comment Response Document

### Overview of Comments

CMS received various comments from Part D sponsors, PBMs and other associations. We received 53 comments regarding the following reporting sections: Enrollment/Disenrollment, Grievances, Coverage Determinations and Redeterminations and Improving Drug Utilization Review Controls. There were several major comments regarding the new section- Improving Drug Utilization Review Controls and Coverage Determinations and Redeterminations.

### Detailed Summary of Comments

| Section | Comment | Commenter's Recommendation |
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| Enrollment/Disenrollment | Enrollment: 1 P: The total number of individuals included in the advance notification for seamless conversion enrollment for effective dates occurring within the reporting period. | We recommend that CMS clarifies that the instructions contained in section 1P under enrollment actually applies to pre-enrollment rather than enrollment. What is CMS' intent? |

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| Enrollment/Disenrollment | Enrollment: 1 Q: Of the total reported in A, the number of individuals whose Medicare eligibility is based on age. | We recommend that CMS be more specific about what is meant by “eligibility based on age” since some individuals that enroll in an HMO plan who may not be 65. |
| Enrollment/Disenrollment | Enrollment: 1 R: Of the total reported in A, the number of individuals whose Medicare eligibility is based on disability. | We recommend that CMS indicate specifically which group/category of individuals these instructions relate to since the plan may not be aware of their disability or status at the advance notification period or at enrollment. |
| Enrollment/Disenrollment | Enrollment: 1 S: Of the total reported in A, the number of enrollments submitted to CMS. | We recommend that CMS provide additional information around these instructions so that it is clear which category/categories of individuals these instructions relate to. Do they relate to actual members enrolled in both HMO and D-SNP? |

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| Enrollment/Disenrollment | Clarification regarding whether the reference to 1.A was intended. It is also unclear how the information collected might be useful to CMS especially since the data reported would be reported only by a subset of organizations. | We recommend that CMS clarify these issues. |
| Enrollment/Disenrollment | The value of reporting the proposed data elements Q-S is unclear, particularly given that these data would be reported by only a subset of sponsors approved to offer seamless conversion. Further, it is unclear how these data would assist CMS in evaluating sponsors' processing of enrollment requests in accordance with CMS requirements, Including as it relates to seamless conversion enrollment. | We recommend that CMS reevaluate the utility of the proposed data collection, and also consider whether the agency already has access to some or all of these data before moving forward with the proposed change. |

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| Enrollment/Disenrollment | Please clarify: The new elements of 1.Q through 1.S are a subset of 1.A rather than 1.P. Element 1.A includes all enrollments while the specifications indicate 1.Q through 1.S apply only to MA organizations approved by CMS to offer seamless conversion enrollment. | N/A |

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| Grievances/CD | Grievances/Coverage Determinations TS question (Not able to identify changes in fields) | The following fields were listed on the crosswalk between the 2016 requirements to the 2017 requirements as revised, saying that technical clarification had been provided. Since the technical specs weren't released with the documents, we don't know what the revisions are, so are unable to provide<br>useful comments:<br>Total Number of Grievances<br>Number of Expedited Grievances<br>Other Grievances<br>Coverage Determinations and Exceptions: 1 KS<br>Redeterminations: 2 AG<br>Coverage Determinations and Redeterminations: Reopenings: 4: Date of original disposition<br>Coverage Determinations and Redeterminations: Reopenings: 7: Date case was reopened" |

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| Grievances | Report layout: Data to be reported at the Contract level:<br>Number of grievances<br>Number of grievances in which timely notification was given<br>Total Grievances<br>Expedited Grievances<br>Dismissed Grievances<br>N/A | We would like to confirm that the Dismissed Grievances column will include all cancelled grievances, regardless of the reason for the cancellation? For example, some grievances are cancelled because they are 60 days past the Grievance report date and some are cancelled as there is no Appointment of Representative or Power of Attorney on file. |

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| Grievances | The definition of grievance in the reporting requirements is not consistent with the definition in the regulation at 423.560 or that in Chapter 18 Section 10.1 of the Medicare Prescription Drug Benefit Manual (see below). In particular, the language “expressing dissatisfaction with” was removed but is present in both the regulation and Chapter 18. The text “or appeal” was added to the reporting requirements but doesn’t appear in the regulation or Chapter 18. Aligning this language with guidance and regulation would be helpful for plans. If CMS chooses not to align the language, please clarify for plans the purpose of the change to this wording. | N/A |

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| Grievances | Under the section Data to be reported at the Contract level, CMS added “Dismissed Grievances”. Please define this further and give examples of a dismissed grievance. | It would be helpful to plans if the draft Technical Specifications were released simultaneously with the draft Part D reporting requirements. |
| Grievances | Examples given refer to Dismissals based on no AOR | It would be helpful if additional examples to explain what CMS considers a Dismissed grievance to better distinguish from member withdrawn grievances. |

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| Grievances | Dismissed Grievances | We recommend that CMS explain what information should be included under this data element and provide examples to further ensure clarity. |
| Grievances | To our knowledge, the term “dismissed grievance” is a novel term for purposes of this information collection request; | We therefore respectfully request that CMS provide its definition along with the finalized document. |
| Improving Drug Utilization Review Controls | Will the "Improving Drug Utilization Review Controls" report be included in Data Validation audits? | N/A |

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| Improving Drug Utilization Review Controls | In the "Improving Drug Utilization Review Controls" report, the instructions for data element ""H"" state<br>"Of the total reported in element F, the number of soft edit claim rejections overridden at the pharmacy level by the pharmacist submitting appropriate NCPDP codes". Can CMS define "appropriate NCPDP codes"? | N/A |

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| Improving Drug Utilization Review Controls | Since CMS is considering the opioid MED edit as a coverage determination, should these coverage determination be included in the Coverage Determination reports? | N/A |
| Improving Drug Utilization Review Controls | Please provide examples of how CMS expects the table to be completed in the technical specifications. | N/A |

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| Improving Drug Utilization Review Controls | For Part V on P. 13: Element H<br>We expect situations where the pharmacist can not submit an override code (usually for technical reasons), or does not want to (e.g. pharmacist observes suspicious behavior,is missing info, etc.). In the first case, we expect the call center to enter the pharmacist's override code into the system, and these will be captured in Element H. If the pharmacist chooses not to override, and the member contacts us, this would (today) trigger a coverage determination process. Is that appropriate? And if so, would we be expected to report these in Element H, or Element S? | N/A |

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| Improving Drug Utilization Review Controls | Quarterly Reporting | "We are hoping CMS will consider eliminating the requirement to review and upload overutilization monitoring reports quarterly if the plan has implemented a hard edit at the point of service. With a hard edit at the point of service, plans end up reviewing opioid needs for every member that uses large amounts of opioids in ""real time"". Any beneficiary that shows up on the overutilization reports will have already been reviewed for appropriateness of opioid use and the overutilization report becomes duplicative." |
| Improving Drug Utilization Review Controls | Clarity regarding the cumulative opioid MED edit: Data elements D and M state "If yes to element A [J], the pharmacy count criterion used, if applicable." | United respectfully requests clarification on whether plans can report “N/A” if a pharmacy count was not part of the plan’s criteria. |

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| Improving Drug Utilization Review Controls | Clarity regarding the cumulative opioid MED edit: data element S states "Of the total reported in element O, the number of claims resolved and paid at the POS (either through a favorable decision through the coverage determination or appeals process, or other mechanism)." | We ask that CMS also provide clarification on what may be considered an “other mechanism” under these reporting requirements. |
| Improving Drug Utilization Review Controls | In order to determine if we have any questions or if we can capture all data elements in regards to this new measure can you please provide the proposed technical specifications? | N/A |
| Improving Drug Utilization Review Controls | There are twenty data elements under this proposed new reporting section. It is our understanding that sponsors may need to implement systems and process enhancements to comply with this new reporting requirement and will need sufficient time to do so. | We recommend that CMS issue the related technical specifications as close in time as possible to the issuance of the final Part D reporting requirements. |

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| Improving Drug Utilization Review Controls | In the 2017 Part C and D Call Letter, CMS indicated that it was relying on the Pharmacy Quality Alliance (PQA) to develop measures to monitor opioid utilization. PerformRx is an active member of the PQA and has representatives on several PQA workgroups and standard advisory panels (SAPs) that are currently developing these measures. Thus far, the PQA is still in the measure development process. The PQA is grappling with how to create valid methodology to truly capture opioid drug utilization while excluding beneficiaries with known exceptions. | We ask CMS to consider suspending this proposed reporting requirement until the PQA has developed and endorsed the measure. |

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| | The proposed reporting requirement does not provide instructions for removing beneficiaries who have been excluded based on the known edit exceptions. Was this CMS' intent? Would CMS provide additional guidance on this point? If the agency does not expect sponsors to exclude these beneficiaries from reporting, would CMS clarify how the collected data will be used to monitor the plan sponsors? | N/A |

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| Improving Drug Utilization Review Controls | Would CMS consider removing elements A through E and J through N from the quarterly reporting requirement for CY 2017? According to the 2017 Part C and D Call Letter (pages 213-214), CMS is requiring all Part D sponsors to submit this detailed operational information for review by September 1, 2016. As a result, CMS would have already collected this information at the contract or plan benefit package (PBP) level. CMS committed to providing Part D sponsors with a specific template to report the hard and soft edit methodology but has not yet released it. The guidance in the Call Letter does not indicate that sponsors will be permitted to modify the hard and soft morphine equivalent dose (MED) point of sale (POS) edits during the course of the year.<br>Conversely, if CMS still wishes for Part D sponsors to re-report this information, would it be possible not to include these elements in the quarterly report templates? Again, unless CMS clarifies that mid-year changes are permissible, collecting this information quarterly may not provide value for CMS because edits would not be expected to change on a quarterly basis. One possible alternative is for CMS to create a second report template for these elements and require reporting at | N/A |

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| Improving Drug Utilization Review Controls | Would CMS please clarify its definition of “unique beneficiaries”? Specifically, is this to be based on health insurance claim number (HICN) or member ID number? In the case of a member ID number, CMS would receive an inflated number of beneficiaries because many dual eligible members experience breaks in coverage throughout a plan year. They are generally assigned a different member ID number each time that they re-enroll in a plan. Clarifying the definition of “unique member” will help to ensure accurate and consistent reporting across all plan sponsors. | N/A |

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| Improving Drug Utilization Review Controls | Would CMS confirm whether or not this new reporting requirement would be included in the Part D Data Validation process? | We request that CMS consider not including this report in the data validation standards in the first report year. This would allow CMS and the industry an opportunity to work through any potential clarifications in instructions from CMS that tend to surface when new reporting requirements are introduced. |
| Improving Drug Utilization Review Controls | Would CMS consider removing element Q from the reporting requirements? Would CMS consider revising element R to state, “Of the total reported in element P, the number of unique beneficiaries with at least one hard edit claim rejection that also had a coverage determination request for an opioid drug subject to a hard opioid MED edit”? These modifications would allow for accurate reporting." | N/A |

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| Improving Drug Utilization Review Controls | Claims resolved and paid at the POS because of coverage determination, appeals or “other mechanism”. The proposed language creates unintended operational challenges for reporting because it assumes that coverage determinations, appeals and “other mechanism[s]” are all administered in the same system and/or by the same company, or that aggregating this data would not pose a significant challenge for sponsors. | We encourage modification of element S to strike reference to element O and to read, “The number of coverage determinations approved or claim authorizations granted for opioid drugs subject to hard MED edits.” While a coverage determination approval should result in a subsequent paid claim, any combination of activities by the beneficiary, the pharmacy and the prescriber could result in that claim not being submitted by the pharmacy. |
| Improving Drug Utilization Review Controls | Unique beneficiaries’ claims with at least one rejected claim resolved and paid at the POS because of coverage determination, appeals or “other mechanism”. | As stated above, “other mechanism” is too vague a term to result in consistent application across the industry. Thus, PerformRx would recommend the following change to the element T description to read, “Of the total reported in element S, the number of unique beneficiaries who received coverage determination approvals or claim authorizations for opioid drugs subject to hard MED edits.” |

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| Improving Drug Utilization Review Controls | Is the report to include cumulative Year-to-Date (YTD) data for each quarter? | N/A |
| Improving Drug Utilization Review Controls | Is it CMS' expectation that sponsors enter data at the plan level, or will there be a file upload capability? | N/A |
| Improving Drug Utilization Review Controls | For Elements Q and S: We respectfully requests clarification as to what timeframe (i.e. number of days) plans should account for when determining the number of coverage reviews resulting from a claim rejection. Similarly, we also recommend that CMS provide the timeframe (i.e. number of days) plans should take into consideration when determining the number of resolved and paid claims resulting from coverage review/appeals. | For example: a claim rejects in January 2016; and a coverage review for that claim is requested in April, 2016; are the 60 days between January and April the timeframe CMS is seeking for reporting? |

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| Improving Drug Utilization Review Controls | For Elements R and T: As with the previous question, we respectfully requests that CMS specify what timeframe should be used to correlate a rejected claim to a coverage review once the rejection takes place; i.e. look-forward for an associated coverage review. | For example: if a claim reject occurred in Q1 without a corresponding coverage review occurring within that timeframe for purposes of inclusion in the first quarter report, Element Q would have a reject “counted” and element R would not. In the following Q2 report, element Q would continue to treat the reject as counted while in this case element R would have the associated coverage review counted. |
| Coverage Determinations/Redeterminatic | Reopenings | Due to the common practice of assigning a new number to a new determination, the data reported may not display the original case ID. To promote standardization in reporting, we recommend the following text change: Data element 3. Case ID, Field Description:<br>Current specification: This is the unique internal tracking number the contract assigned to the case that is being reopened.<br>Recommended specification: Original Case ID, prior to reopening. |

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| Coverage Determinations/Redeterminations | Coverage Determination (CD) and Redetermination (RD) Reporting layout: Please clarify how this information is to be reported. Will it be data entry, data upload or combination? | N/A |
| Coverage Determinations/Redeterminations | CD - Exceptions - Requests for Benefits: How will PA requests be reported? Currently the reporting appears to only include exception requests. | N/A |
| Coverage Determinations/Redeterminations | CD - Exceptions - Requests for Reimbursements: Is it CMS expectations that reimbursement requests be broken down by exception types? | N/A |
| Coverage Determinations/Redeterminations | CD - Exceptions - Requests for Reimbursements: How are reimbursement requests for drugs that require a PA to be reported? | N/A |
| Coverage Determinations/Redeterminations | Reopenings: CMS has added “Other Error” and “Other” as potential data elements to be reported at the Contract level. | We respectfully request that CMS provide further explanation as to the difference between “Other Error” and “Other” as well as examples of each. |

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| Coverage Determinations/Redeterminations | Is a revised decision (for reporting purposes) only when the disposition of the case is changed or does it include those case some part of the case needed to be modified due to a clerical error or new and material evidence, or other reason, but the actual disposition of the case was not changed? For example an adverse decision case is reopened because the denial reason was not correct or the presentation of the drug was inaccurate however the decision will remain adverse. The enrollee is sent a new denial letter with the updated denial reason or drug name. The disposition for this case did not change, but some detail regarding the case or enrollee communication changed. | N/A |
| Coverage Determinations/Redeterminations | Will the report layout change as shown on page 15 of the draft document? Reporting is at the contract level, can you please confirm we will report each contract separately. | N/A |

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| Coverage Determinations/Redeterminations | Can you please elaborate more as to what data is to be reported under the UM heading (is the value expected only PA and ST)? | N/A |
| Coverage Determinations/Redeterminations | Should Formulary column include all exceptions including excluding Tier? | N/A |
| Coverage Determinations/Redeterminations | Should Step Therapy (ST) be included under UM or Formulary? | N/A |
| Coverage Determinations/Redeterminations | Deletion of “(QL) requirements based on CMS approved formulary.” | We recommend that CMS keep the clarifying statement, from the 2016 Medicare Part D Reporting Requirements, “(QL) requirements based on CMS approved formulary.” |

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| Coverage Determinations/Redeterminations | We are concerned that CMS' use of certain well-understood terms may appear to be somewhat ambiguous within the context of this proposed information collection document. For example, under "CD – Exceptions – Requests for Benefits," does CMS contemplate applying different expectations as to what information it seeks to collect regarding Utilization Management, Formulary Tiers, and Non-Exceptions? | If so, we respectfully request that the Centers provide additional details on any such changes along with the final document. |

| CMS Response | Revised Requirements/Documents | Revised Burden Estimates |
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| CMS disagrees. This element covers activity taking place prior to an individual's enrollment effective date and, as such, is no different than other enrollment elements that cover similar "pre-enrollment" activity. The intent is the same, in that it represents CMS' collection of data which are otherwise not available to CMS, in order to evaluate the organizations' processing of seamless conversion enrollments in accordance with CMS requirements. | No | No |

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| CMS believes it is generally understood that "eligibility based on age" refers to individuals who will qualify for Medicare at the age of 65, as opposed to those under 65 who will qualify for Medicare because they have ESRD or have received Social Security Disability Income (SSDI) payments for 24 months (first month of disability for ALS ("Lou Gehrig's Disease")). | No | No |
| The requirements for being approved to offer the seamless conversion enrollment option are outlined in Section 40.1.4 of Chapter 2 of the Medicare Managed Care Manual. An organization approved for this optional enrollment mechanism must be able to identify all potential MA eligible individuals no fewer than 90 days prior to the date of their initial Medicare eligibility. This must include individuals whose eligibility is based on disability as well as age. An organization that is unable to comply with this requirement cannot offer this enrollment option. | No | No |
| CMS agrees. Elements 1.Q. through 1.S. should reference "1P" instead of "1A." We will make this correction so that it is clear which category of individuals the organization is to include in the reporting for this element. | Yes | No |

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| CMS agrees. "Elements 1.Q. through 1.S. should reference ""1P"" instead of ""1A.""  We will make this correction.<br><br>The data collected via these reporting requirements are an important resource for CMS oversight, monitoring and auditing activities necessary to ensure compliance with the seamless conversion enrollment requirements. The data to be reported represents the most basic aspects of seamless conversion enrollment processing and is otherwise not available to CMS. This information is needed by CMS in order to evaluate the organizations' processing of seamless conversion enrollments in accordance with CMS requirements. | Yes | No |
| The data to be reported represents the most basic aspects of seamless conversion enrollment processing and is otherwise not available to CMS. This information is needed by CMS in order to evaluate the organizations' processing of seamless conversion enrollments in accordance with CMS requirements. | No | No |

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| Elements 1.Q. through 1.S. should reference "1P" instead of "1A." We will make this correction so that it is clear which category of individuals the organization is to include in the reporting for this element. | Yes | No |

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| CMS expanded the CD/RD collection data process and changed the language in the reopenings section. Please review the previously released Reporting Requirements and Technical Specifications documents for reference. | No | No |

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| Yes, this is correct. Dismissed Grievances column will include all dismissed grievances. | No | No |

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| Slight changes were made in the grievance definition to help clarify that a request for an appeal is not a grievance, or to simplify terminology (e.g. the term complaint implies dissatisfaction has been expressed). Sponsors should continue to refer to Chapter 18 and the regulation for full references. | No | No |

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| Technical specifications will be released via HPMS, and do not alter the data collection proposed. We note a dismissal (1) is a plan action, and (2) only occurs when the plan has not received a valid complaint. CMS expects limited use by plans of the dismissed category of grievances; it should be for invalid grievances, e.g., no AOR/POA; or grievance received more than 60 days from incident. Dismissed grievances should represent a very small percentage of total Part D grievances a plan receives. However, this element has been added to provide plans with a means to report grievances that are received but not processed by the plan because they do not meet the requirements for a valid grievance. Generally, a dismissal would occur when the procedure requirements for a valid grievance are not met and the plan is unable to cure the defect. For example, a grievance is received from a purported representative of the enrollee, but a properly executed appointment of representative form has not been filed and there is no other documentation to show that the individual is legally authorized to act on the enrollee's behalf and the plan is unable to obtain the required documentation in a reasonable amount of time and therefore, dismisses the grievance. See guidance set forth in section 10.4.1 of Chapter 13. | No | No |
| See response above | No | No |

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| See response above | No | No |
| See response above | No | No |
| Yes, CMS plans to develop standards and data validation criteria for the proposed Improving Drug Utilization Review Controls section of the Part D Reporting Requirements. In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. Without data validation, we risk receiving invalid data. New data validation criteria would be proposed through a separate and future Paperwork Reduction Act submission (OMB 0938-1115; CMS-10305). | No | No |

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| CMS edited the elements G and H (revised lettering) to state, “overridden by the pharmacist at the pharmacy.” | Yes | No |

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| CMS appreciates this question and opportunity to clarify. Pursuant to 42 CFR 423.566(b) and Chapter 18, section 40.3.1, a point of sale claim transaction, rejected or paid, is not a coverage determination in Part D unless the plan chooses to treat it as such. Therefore, when this edit is returned (hard edit, or soft edit that is not overridden by the pharmacy), the plan must return the 569 reject code with messaging to the pharmacy to deliver the CMS pharmacy notice. The rejected claim is generally not a coverage determination, and should NOT be reported as a coverage determination. However, if the enrollee, the enrollee's representative, or the enrollee's prescriber then contacts the plan to request coverage, that request must be processed as a coverage determination. The coverage determination should be reported, as appropriate, in elements O and P (revised lettering) of this section, as well as in section VI - Coverage Determinations and Redeterminations. | No | No |
| CMS will clarify in the forthcoming technical specifications document. | No | No |

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| Thank you for the question. Soft opioid MED edit claims overridden by the pharmacist at the pharmacy with assistance from the plan for technical reasons “should” be included in element G and H (revised lettering). If the pharmacist chooses not to override a soft edit and the drug is not dispensed, the network pharmacy must provide the enrollee with a copy of the CMS pharmacy notice. The claim (and unique beneficiaries with at least one claim) rejected due to the soft edit would be reported in elements E and F. If the enrollee, the enrollee’s representative, or the enrollee’s prescriber then contacts the plan to request the drug, the plan must process that request as a coverage determination. We are currently not collecting information on soft opioid MED edit claim rejections that resulted in requests for coverage determinations. However, coverage determinations must be reported in Section VI - Coverage Determinations and Redeterminations. | No | No |

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| CMS disagrees with this suggestion. It is premature to discontinue reporting through the Overutilization Monitoring System (OMS). We will monitor if the prospective formulary-level cumulative opioid MED POS edits reduce the number of beneficiaries identified via retrospective review and reevaluate OMS reporting at a later time. | No | No |
| CMS will clarify in the forthcoming technical specifications document how to report if a pharmacy count criterion was not part of the sponsor's edit specifications. | No | No |

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| CMS will consider providing additional clarification in the forthcoming technical specifications document regarding "other mechanisms". CMS edited elements O and P (revised lettering). | No | No |
| As usual, the technical specifications will be released with the final Reporting Requirements. | No | No |
| As usual, the technical specifications will be released with the final Reporting Requirements. | No | No |

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| CMS disagrees. As described in the Call Letter, we expect sponsors to implement either a soft and/or hard formulary-level cumulative opioid morphine equivalent dose MED POS edit beginning January 1, 2017 and need to monitor the impact of such edits beginning in 2017. This is not contingent on industry developing quality measures which may be adopted by CMS in the future. | No | No |

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| Based on this question, CMS edited the section introduction to clarify that Part D sponsors will report data based on the beneficiaries subject to the soft and/or hard formulary-level cumulative opioid MED POS edit as implemented by the sponsor. Sponsors are expected to develop specifications to exclude beneficiaries with known exceptions from the edit. Therefore, any beneficiaries that the sponsor excludes up front would not trigger the edit and would not be reported in the data. Any data for beneficiaries that trigger the edit would be reported. | Yes | No |

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| CMS disagrees with the suggestion to remove the suggested elements from the reporting requirements. The elements allow this information to be collected in an automated way for monitoring and analysis. CMS has not issued guidance regarding midyear changes for this edit. | No | No |

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| The number of unique beneficiaries is a count of unique health insurance claim numbers (HICNs). This section's introduction has been updated to reflect this clarification. | No | No |

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| CMS disagrees. CMS plans to develop standards and data validation criteria for the proposed Improving Drug Utilization Review Controls section of the Part D Reporting Requirements. In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. Without data validation, we risk receiving invalid data. New data validation criteria would be proposed through a separate and future Paperwork Reduction Act submission (OMB 0938-1115; CMS-10305). | No | No |
| This feedback was useful. CMS removed element Q. CMS revised element R (now element O). | Yes | No |

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| CMS appreciates this recommendation, deleted element Q and S, and revised element O and P (revised lettering). | Yes | No |
| CMS appreciates this recommendation, deleted element Q and S, and revised element O and P (revised lettering). | Yes | No |

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| Yes. Based on this question, CMS edited the section introduction to clarify cumulative YTD. And Quarter 4 includes data for the entire 12 months reporting period. | Yes | No |
| There will be file upload capability. | No | No |
| CMS deleted elements Q and S. CMS will issue additional technical specifications as appropriate. | Yes | No |

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| CMS deleted elements Q and S. CMS will issue additional technical specifications as appropriate. | Yes | No |
| CMS agrees and will update. We will also add the following to the technical specifications: “If the plan assigns a new case ID when it reopens a case, the plan should populate the case ID for the original CD/RD in this field.” | No | No |

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| Please submit comments re: the preferred format, e.g. HPMS data upload to assist CMS in finalizing this proposal. Please see the revised layout. | Yes | No |
| PA requests should be reported in the total number of CDs. Please see revised layout. | Yes | No |
| Yes, this is CMS' expectation. | No | No |
| PA requests should be reported in the total number of CDs. Please see revised layout. | Yes | No |
| CMS will provide clarifying info in the technical specifications on these categories. | No | No |

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| CMS will provide clarifying info in the technical specifications. | No | No |
| Please submit comments re: the format, e.g. HPMS data entry or upload to assist CMS in finalizing this proposal. We confirm that each contract would submit these data separately. | No | No |

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| CMS will clarify in the technical specifications that "UM exceptions" refers to PA, ST and QL exceptions; "formulary exceptions" refers to requests for non-formulary drugs. | No | No |
| The formulary column should include exception requests for drugs not included in a plan's formulary. Tier exceptions should not be included in the formulary exceptions column. | No | No |
| An exception request to a plan's Step therapy requirement should be reported under the UM column | No | No |
| CMS agrees and will add this language for the draft posted for the 30-day comment period. | Yes | No |

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| CMS will clarify in the technical specifications that "UM exceptions" refers to PA, ST and QL exceptions; "formulary exceptions" refers to requests for non-formulary drugs. Also, please see the new layout that revises the layout. | No | No |