July 5, 2016

Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number 10185
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Draft Contract Year (CY) 2017 Medicare Part D Reporting Requirements

Dear CMS:

PerformRx is a pharmacy benefit manager for Medicare Part D plans nationwide. Our mission is to help customers, doctors and patients use effective medication therapy to improve health and wellness. PerformRx produces data for the following proposed CY 2017 Medicare Part D Reporting Requirements sections:

- II - Retail, Home Infusion and Long-Term Care Pharmacy Access
- III - Medication Therapy Management Programs
- V - Improving Drug Utilization Review Controls
- VI - Coverage Determinations and Redeterminations

PerformRx submits the following comments regarding the draft CY 2017 Medicare Part D Reporting Requirements dated April 28, 2016 and released in May 2016. We value CMS' commitment to seeking industry comments.

Compliance is our first concern. We appreciate the opportunity to participate in the public comment process. Please contact me if there are questions or if more information is needed. Thank you for your consideration.

Sincerely,

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Section	Report Title	Page	Element	Draft Element Description	PerformRx Comment
V	Improving Drug Utilization Review Controls	13-14	n/a	n/a	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. PerformRx appreciates the rigor and quality of the PQA measure development process. We ask CMS to consider suspending this proposed reporting requirement until the PQA has developed and endorsed the measure.
V	Improving Drug Utilization Review Controls	13	N/A	"…while excluding beneficiaries with known exceptions from the edit." "…..minimize false positives by accounting for known exceptions..."	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? The introductory language places a great deal of emphasis on the application of exceptions for certain medical conditions, but there are no instructions to exclude those beneficiaries and their claims from the reporting requirements. At the same time, there is no good claim-based mechanism for excluding those beneficiaries. Failure to apply these exclusions in the reporting process will result in over reporting and false positives. 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?
V	Improving Drug Utilization Review Controls	13-14	A-E, J-N	Reporting timeline, quarterly reporting period	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

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					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. 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 the annual level for 2017, if CMS will allow sponsors to add and remove hard and soft edits outside of the September 1, 2016 submission window.
V	Improving Drug Utilization Review Controls	14	G, R	"number of unique beneficiaries"	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.
V	Improving Drug Utilization Review Controls	13-14	n/a	n/a	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.

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V	Improving Drug Utilization Review Controls	14	Q-R	Claim rejections resulting in coverage determinations and unique beneficiaries	In our organization, the process for adjudicating claims is managed through our claims processor in one system, and the coverage determination process is managed in our prior authorization department in a completely different system. In other words, the claims processing engine is separate from the system in which we process coverage determinations. Our organization does not consider a POS rejection to be a coverage determination, which is permissible according to Chapter 18 of the Medicare Prescription Drug Benefit Manual. Also, there is often more than one POS rejection for a drug, as pharmacies routinely submit claims over and over (with modifications to specific fields and codes) until they receive an authorization. Finally, beneficiaries and prescribers do submit coverage determination requests independent of what happens at the pharmacy. For all of these reasons, it is not possible with any level of empirical certainty to link a specific coverage determination request with a specific POS rejection. It would also be very difficult operationally to attempt to develop a process to even make an assumption. It would also likely fail data validation review. PerformRx had the opportunity to participate in the CMS POS pilot in 2015. We shared these challenges and concerns with CMS during the pilot process. 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.
V	Improving Drug Utilization Review Controls	14	S	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.

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					Our experience has been that Part D sponsors generally expect for the entity that is delegated a specific activity to produce the data for the CMS report. PerformRx may be delegated coverage determinations but not appeals, for example. In this case, we would only be able to provide the number of coverage determination approvals for opioid drugs subject to hard MED edits. We would not have a record of the appeals decisions in our systems. Additionally, "other mechanism" is too vague a term to result in consistent application across the industry. What other mechanisms did CMS envision should be included in this element? As with our comments above, attempting to make the data reported in element S a subtotal of what was reported in element O would result in inaccurate reporting. This is because the coverage determination is not tied to a specific rejection in our process. Also, a claim is the result of the pharmacy submission. A coverage determination approval occurs agnostic of that process. PerformRx can place an authorization in the claims processing system as a result of an approved coverage determination. However, only the pharmacy can submit the claim. PerformRx encourages 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. If CMS also wishes to capture the number of approved redeterminations, it could create a consecutive element to state, "The number of redeterminations approved or claim authorizations granted for opioid drugs subject to hard MED edits." While these changes may not create the same picture as proposed by CMS, they would make it possible for our organization and potentially others to provide

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					accurate data from which CMS may be able to make valuable inferences.
V	Improving Drug Utilization Review Controls	14	T	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. If CMS agrees to PerformRx's proposed modifications above, thus untethering the coverage determination reporting from the initial claim rejection, then element T would actually be a subset of element S as opposed to element P. This is because S seeks to collect the total paid claims/approvals because of the coverage determination process, and T appears to be designed to isolate the unique number of beneficiaries included in that count. 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." If CMS also wishes to capture the number of approved redeterminations, it could create a consecutive element to state, "Of the total reported in element **S**, the number of *unique beneficiaries* who received redetermination approvals or claim authorizations granted for opioid drugs subject to hard MED edits." While these changes may not create the same picture as proposed by CMS, they would make it possible for our organization and potentially others to provide accurate data from which CMS may be able to make valuable inferences.
VI	Coverage Determinations and Redeterminations	15	E	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."
II – *Tech. Specs. Doc.*	Retail, Home Infusion and Long-Term Care Pharmacy Access				In the Technical Specifications Document, while not issued for public comment, PerformRx recommends that CMS make layouts and templates publicly accessible and post them online. The final 2016 reporting requirements were revised to refer to HPMS. Vendors may not have immediate access to HPMS.