August 29, 2016

Centers for Medicare & Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number 0938-1115
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10305, Medicare Part C and Part D Data Validation

Dear Centers for Medicare & Medicaid Services (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 Contract Year (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 and VI - Coverage Determinations and Redeterminations.

PerformRx submits the following comments regarding the proposed Medicare Part D Data Validation of Reporting Requirements data for the 2017 and 2018 collection periods. When PerformRx reviewed the proposed data validation standards and criteria, we had very few comments on specific sections. Therefore, rather than commenting on specific sections, PerformRx is recommending ways to improve the Part D Data Validation process overall through:

- Auditor Training
- Consistent Auditor Interpretation
- Using Existing MTM Data Validation to Support the Program Audit Process
- Earlier and Consistent Release of Reporting Requirements
- Sharing Data Validation Results
- Post-Validation Guidance and Best Practices

- **Auditor Training:** Data Validation audits are performed by external contractors who are compensated by plan sponsors. CMS's current data validation auditor training is not at all rigorous. This training is at an individual level and in its current form does not represent excellence or competence on the part of the audit firm. To date, we understand that CMS does not have a process to certify specific audit contractors. While most firms are reputable, there is nothing to prevent less-than-qualified audit firms from conducting such audits. We believe that CMS should strengthen the data validation audit process by requiring higher auditor training standards.

- **Consistent Auditor Interpretation:** In order for the data to be reliable and valid, consistent audit interpretation is required amongst auditors. PerformRx has experienced inconsistency across data validation auditors first hand.

    - For example, for the Medication Therapy Management (MTM) data validation, we experienced one auditor who interpreted that we are *not* permitted to count the same recommendation twice to a different provider, regardless of quarter. Conversely, another data validation auditor

interpreted that a recommendation *could* count twice if the recommendation was made in a separate quarter.

As illustrated by this example, the same type of event may or may not be reported, depending on the particular interpretation of the auditor. Reporting by Part D sponsors therefore may not be a true measure of their services (i.e., underreporting or overreporting). Further, comparisons among sponsors may not be valid if data is reported differently due to data validation auditors' varying interpretations.

- Similarly, PerformRx has experienced a data validation auditor questioning our reporting a cognitive impairment for an enrollee in element H of the MTM Record Layout because we had spoken to the person the year before but had not done a CMR for the current year. There was no citation provided by the data validation auditor for his/her interpretation. The guidance is:
  - 2016 Reporting Requirements: Data Element H. Beneficiary identified as cognitively impaired at time of comprehensive medication review (CMR) offer or delivery of CMR. (Y (yes), N (no), or U (unknown)).
  - Data Validation Standards for Data Validation Occurring in 2016 and proposed for 2017: Organization accurately identifies MTM eligible members who are cognitively impaired at the time of CMR offer or delivery of CMR and uploads it into Gentran, including the following criteria:
    a. Properly identifies and includes whether each member was cognitively impaired and reports this status as of the date of the CMR offer or delivery of CMR.
    [Data Element H]

Further, we continue to recommend against using the data validation audit result to validate the CMR completion rate Star Ratings measure until the process is more consistent and more transparent.

- **Using Existing MTM Data Validation to Support the Program Audit Process:** In recent comments on CMS' 2017 Draft Part D Program Audit Protocols, PerformRx asked CMS to consider removing Table 1 2015 Universe Column IDs A-T from the Part D MTM Program Area PILOT Audit Process and Data Request in Appendix A. This is because CMS collects a similarly detailed MTM report from Part D sponsors annually as part of the Part D Reporting Requirements. The contents of this report are almost identical to the contents of the universe and could be used by the auditors to draw samples. Producing a second report with the same information in a second layout is duplicative.

  One option for CMS is to amend its data validation protocols to include a universe validation requirement on the part of the data validation auditors (for the MTM detail report specifically). CMS may find this approach more operationally efficient as well.

- **Earlier and Consistent Release of Reporting Requirements:** Would CMS be willing to release final reporting requirements earlier in the year and on a consistent basis? An earlier and consistent release would be especially helpful when there are significant changes. This would enable Part D sponsors and PBMs sufficient time to adjust and finalize logic and make other needed systems changes. This could lead to higher validation scores across the industry and reduce administrative burdens on CMS.

- **Sharing Data Validation Results:** We commend CMS for sharing the results of the data validation audits via its August 10, 2016 memo, "Results of the 2016 Part C and D Reporting Requirements Data Validation." This is a valuable resource for Part D sponsors and PBMs to understand how the industry is

performing in its annual data reporting. In our comments on CMS' draft 2017 Call Letter, PerformRx had suggested sharing the results. We appreciate CMS' partnership with the industry and would welcome additional results information year to year.

- **Post-Validation Guidance and Best Practices:** Relatedly, post-validation guidance and best practices from CMS would be beneficial for Part D sponsors and PBMs to know how to adjust reporting to better meet CMS' reporting requirements. PerformRx recommends, for example, that CMS issue a Best Practices and Common Findings memorandum, and CMS job aids, for the data validation audits similar to the memoranda that CMS issues for CDAG and ODAG audits. Additional training and communication from CMS would also be welcome to strengthen the process.

We appreciate the opportunity to participate in the public comment process and value CMS' commitment to seeking industry comments. Please contact me if there are questions or if more information is needed. Thank you for your consideration.

Sincerely,

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