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SUBMITTED ELECTRONICALLY

July 11, 2016

Mr. William N. Parham, III
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development,
Centers for Medicare and Medicaid Services
Room C4–26–05,
7500 Security Boulevard,
Baltimore, MD 21244–1850

Attention: Document Identifier/OMB Control Number(s): CMS–10185

Re: Agency Information Collection Activities; Proposed Collection; Comment Request

Dear Mr. Parham:

Express Scripts appreciates the opportunity to comment on the proposed revision of Document CMS–10185. Express Scripts (ESI) is a pharmacy benefit manager (PBM) that provides integrated PBM services including network-pharmacy claims processing, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management, and medical and drug-data analysis services for more than 90 million Americans.

ESI currently supports many plan sponsors that have a direct contract with CMS via a prescription drug plan (PDP) or Medicare Advantage (MA-PD) benefit, and sponsor our own prescription drug plans (PDP) as well. We take an active and consultative role with these plan sponsors to ensure their Medicare solutions are comprehensive, compliant with regulatory requirements, and aligned with their beneficiaries' needs. ESI strives to provide the best possible support and service to our plan sponsors and patients to ensure optimal performance. In that spirit, we respectfully submit for your review and consideration the following comments and requests for clarification:

Section V. Improving Drug Utilization Review Controls
ESI respectfully requests that CMS provide additional context upon releasing the finalized document to clarify further what the Centers' intent regarding the following questions under this particular section, namely:

1. Is the report to include cumulative Year-to-Date (YTD) data for each quarter?

2. Is it CMS' expectation that sponsors enter data at the plan level, or will there be a file upload capability?

3. **For Elements Q and S:** ESI 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?

4. **For Elements R and T:** As with the previous question, ESI 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.

Section IV. Grievances

To ESI's 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.

Section VI. Coverage Determinations and Redeterminations

- **Section 2 - Coverage Determinations (including exceptions) (CD) and Redeterminations (RD)**
  ESI is 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.

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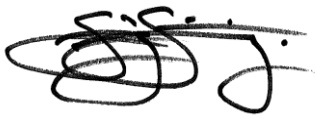
Express Scripts remains eager to work with CMS in efforts to improve and refine information collection documents for the Medicare program, and we reiterate our appreciation for this opportunity to share our comments on this proposed rule. If we can be of additional assistance, or if you have any questions, please contact me, Sergio Santiviago, via email at sasantiviago@express-scripts.com or by phone at 202.383.7987.

Sincerely,



Sergio A. Santiviago
Director, Government Affairs
Express Scripts, Inc.