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June 18, 2010

Michelle Shortt

Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Center for Medicare and Medicaid Services (CMS)

7500 Security Boulevard,

Baltimore, Maryland 21244-1850.

RE: Information Collection: Medicare Part C and Part D Data Validation (42 C.F.R. §422.516(g) and §423.514(g))

Dear Ms. Shortt:

Express Scripts appreciates the opportunity to provide comments on CMS’ April 6thth, 2010 Regulation on Medicare Part C and Part D Data Validation (42 C.F.R. §422.516(g) and §423.514(g)), as required under 1857(e) and 1860D-12 of the Social Security Act. We recognize that developing data standards that would determine reliability, validity, completeness, and comparability of measures reported by plan sponsors is an important undertaking for CMS. We also realize that preparation for detailed external data audits will be a significant challenge for Part D sponsors and their subcontracted pharmacy benefit managers (PBMs).

Express Scripts is one of the largest pharmacy benefit management companies in North America. Headquartered in St. Louis, Express Scripts provides integrated PBM services including network-pharmacy claims management, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management and medical and drug data analysis services to more than 50 million Americans.

First and foremost, we appreciate CMS’ desire to utilize the experience and intimate knowledge that Part D sponsors and their subcontracted pharmacy benefit managers have in collecting and processing data for CMS reported measures. We agree with CMS’ conclusion that validating reported data is a necessary precursor to fulfilling its responsibilities in responding to questions from Congress, oversight agencies, and the public. Hence, we are supportive of CMS’ decision to standardize data validation across reported measures and data elements and across plans.

While we are overall supportive of CMS’ guidance, we do offer the following recommendations:

1. Audit Timeframe:

In the *Supporting Statement for Paperwork Reduction Act Submissions* – *B. Justification -16.Publication/Tabulation Dates*, CMS states that the collection of the Part C and Part D validation data will commence around March 1, 2011 and that the audits are expected to occur each year over a three-month period.

**Express Scripts Recommendation:** *First, we would request CMS to confirm if we are right to assume that the audits are expected to be completed before May 31, 2011. If so, we believe that the three months given as the audit timeframe will not be sufficient for PBMs. Many plans outsource their reporting to PBMs, and to schedule and accommodate large numbers of simultaneous on-site audits is a significant administrative burden. Based on past experience, we estimate at least five business days of on-site visits, with probable follow-up later. Hence, we strongly recommend CMS to extend the audit period to at least nine months, and preferably to twelve months. This will help not only in scheduling of the audits, but also will increase audit quality and acceptance of results. In addition, it will also alleviate resource and bottleneck issues on the external auditor side, since we believe there are, at present, a limited number of audit firms that have the qualifications that CMS is looking for.*

1. Pass/Fail Explanation

In the *Supporting Statement for Paperwork Reduction Act Submissions* – *B. Justification- 1. Need and Legal Basis*, CMS states that reviewer will share their findings with the organization and then submit the completed Findings Data Collection Form to CMS, who will process the measure-level or data element-level findings for each measure’s standards to derive an overall “Pass” or “Not Pass” determination. In addition, in the answer to Question 15 of the Q&A section of the November 23, 2009 memorandum titled *Medicare Part C and Part D Reporting Requirements and Data Validation*, CMS has stated that “a scoring system will be developed and a “pass” or “not pass” will be assigned based on information reported to us by the independent data validation contractor hired by the MAO or Part D sponsor.”

***Express Scripts Recommendation:*** *Part C and D Data Validation Audit is the first of its kind and presents a learning opportunity for both the plans and CMS. Hence, instead of deciding upon an evaluation system in advance, we would recommend that CMS use the findings as a guide toward the selection of an evaluation system that would ultimately best focus and direct plans toward CMS’ goals of data validity, reliability and comparabilit****y****.* *We would also suggest that, before finalizing it, CMS open the evaluation system it proposes to public comment, which could provide helpful insight about its advantages and disadvantages. However, if CMS has made a firm decision toward a Pass/Fail system, then we would request CMS explain the evaluation criteria and methodology on how the Pass/Fail grade will be given. Transparency of the methodology would help plans prevent incorrect or unnecessary weightings, would reduce objections to the outcome of the audit and give more credibility to the final evaluation.*

1. Appeals Process

In Question 22 of the Q&A section of the November 23, 2009 memorandum titled Medicare Part C and Part D Reporting Requirements and Data Validation, CMS has stated that the plan will not have the right of appeal. CMS also states that the plan may disagree with the results of the audit, but that process solely involves the plan and the external auditor. CMS states in Question 20 of the same memorandum that sponsors “that are found to be deficient will be requested to develop corrective action plans or could be subject to other enforcement actions”. It adds that a Fail grade will be considered non-compliant and may be used to adjust plan performance measurement.

***Express Scripts Recommendation:*** *We would like to understand the implications of failure to pass the audit more clearly, especially the scope of “other enforcement actions” mentioned in the CMS memo. If a failure on any part or whole of the audit can lead into contractual sanctions including prohibition from bidding or contract termination, then we believe that the plans should be provided with an appeals process. Such a process, by itself and by its sheer availability, would reduce issues that may originate from auditor errors or bias, facilitate acceptance of the results and also help CMS maintain accuracy and impartiality in evaluating plans and informing beneficiaries. Otherwise, the plans have no recourse for significant disagreements. As an example and possible precedent, we would like to point out to the three-stage appeals process for RADV payment error calculations mentioned in the MA Part D Final Rule (CMS-4085-F). While the aforementioned interaction is entirely between CMS and the plan, we believe that CMS can institute in this case an appeals process that would allow reexamination of the audit results by a third party, as well as allow plans to appeal to CMS’ cumulative evaluation itself.*

1. Long-term Care Utilization Reports

CMS has stated in *Medicare Part C and Part D Measure Instructions for Findings Data Collection Form for Data Validation Contractors* that Long-term Care Utilization will be included in the 2011 audit.

***Express Scripts Recommendation:*** *Long-term Care Utilization report for PY 2010 is due on June 30, 2011. Data Validation Audits, which start in March 1, 2011, may end before this report is submitted. In addition, operational build-out, technical development and QA testing of the report process may continue beyond March 1, 2011, before the report is submitted in June. Hence, while we support the evaluation of Long-term Care Utilization reporting, we would recommend that this portion of the audit be carried out in 2012 for PY 2010 data, when the full year of data and the reports will be available.*

1. Data Sharing Risk

CMS has stated in *the Supporting Statement for Paperwork Reduction Act Submissions* that the *Findings Data Form* “allows the reviewer to record notes, data sources referenced and findings for different standards and criteria specified for a given measure” to be submitted to CMS. In Question 1 of the Q&A section of the November 23, 2009 memorandum, CMS has also mentioned that “audited data will ensure that health and drug plans are on equal footing for public reporting” and, in the 2010 Call Letter and elsewhere, has confirmed that it “may adjust performance measurements to reflect the plan’s non-compliance with CMS audit specifications.”

***Express Scripts Recommendation:***

*We are concerned with possible release of sensitive, detailed information that can be traced to plans or PBMs when CMS makes public the results of the audit. We understand CMS’ desire to provide as transparent a Part D program as possible, however, we also believe that the data collected by the auditors may reveal to the auditing team and CMS sensitive information, proprietary business processes and financial detail that have been developed through years of investment and effort, and whose release to the public domain would seriously jeopardize competition between plans and the ensuing beneficiary and Federal Government savings. Hence, we recommend that, if it chooses to do so, CMS disclose information in a form which does not allow connections to be made between specific plans or PBMs and validation processes, data elements or financial information.*

In closing, we appreciate your attention to our comments. We look forward to continuing to work with you in meeting the needs of beneficiaries in the Medicare Part D program.

Sincerely,

Britton Pim

Vice President, Medicare & Medicaid

COO, Express Scripts Insurance Company