



VIA ELECTRONIC SUBMISSION

December 11, 2017

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development,
Room C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

Attention: CMS-10305

Re: **Agency Information Collection Activities: Proposed Collection; Comment Request; CMS-10305 [Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g))]**

Dear Mr. Parham:

Express Scripts appreciates the opportunity to submit comments on the proposed information collection document #CMS-10305 as published in the Federal Register on October 13, 2017 (82 FR 47747). 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 over 80 million Americans.

As a PBM whose mission is to make prescription drugs safer and more affordable, Express Scripts submits the following requests for clarification on the proposed collection:

1. Document ID: Appendix B Data Validation Standards-09282017.pdf; Page: 28—

For 2017 plan year DVA note number 15b under Coverage Determinations, we respectfully request CMS clarify that it intended to remove the words "as adverse" in the following sentence—as compared to the 2016 DVA note: [Emphasis added]

- 2017 DVA—"Includes untimely coverage determinations decisions auto-forwarded to the IRE."
- 2017 Tech Specs—"15. Untimely cases forwarded to the Independent Review Entity (IRE) are included in this reporting, and should be included as untimely coverage determinations as well as adverse decisions." [Emphasis added]

VS.

- 2016 DVA: "Includes untimely coverage determinations decisions auto-forwarded to the IRE as adverse." [Emphasis added]
- 2016 Tech Specs: "12. Untimely cases forwarded to the Independent Review Entity (IRE) are included in this reporting, and should be included as untimely coverage determinations as well as adverse decisions."

2. Document ID: Appendix B Data Validation Standards-09282017.pdf; Pgs: 26, 27—

ESI respectfully requests CMS provide an example/scenario along with its definition/description of the term “Input” as noted in the following sections, as it is newly-introduced term in this collection:

- COVERAGE DETERMINATIONS AND REDETERMINATIONS, Section 16, part c, Includes withdrawals and dismissals *input* by the IRE. [Emphasis added]
- COVERAGE DETERMINATIONS AND REDETERMINATIONS, Section 20, part c Includes withdrawals and dismissals *input* by the IRE. [Emphasis added]

3. Document ID: Appendix B Data Validation Standards-09282017.pdf; Pgs: 24, 25 and 29—

Lastly, we again respectfully request CMS reaffirm its intent to include withdrawn and dismissed Redeterminations as a subset of data Element A in this document. ESI is concerned that—absent additional clarification from CMS—the interpretation of Item #1 conflicts with the interpretation of item #2. Specifically:

- COVERAGE DETERMINATIONS AND REDETERMINATIONS, Section 5, part g:
 - Number of redeterminations by outcome (Data Element 3.E + Data Element 3.F + Data Element 3.G) is equal to total number of redeterminations (Data Element 3.A).
 - *Interpretation*: $3.A = 3.E + 3.F + 3.G$ [Emphasis added]
- COVERAGE DETERMINATIONS AND REDETERMINATIONS, Section 20, part d:
 - Each number calculated for requests for redeterminations that were withdrawn (Data Element 3.H) and requests for redeterminations that were dismissed (Data Element 3.I) is a *subset of the number of redeterminations decisions made (Data Element 3.A)*. [Emphasis added]
 - *Interpretation*: $3.A = 3.E + 3.F + 3.G + 3.H + 3.I$ [Emphasis added]

Again, Express Scripts thanks CMS for the opportunity to provide feedback on the proposed information collection. As always, we appreciate your consideration of our comments and look forward to continuing to work with you to ensure that Medicare enrollees receive the best coverage available. If you have any questions about these comments, please contact me at 202-383-7987 or sasantiviago@express-scripts.com.

Sincerely,



Sergio Santiviago
Director, Government Affairs
Express Scripts