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Submitted via https://www.reginfo.gov/public/do/PRAMain

William N. Parham
Division of Regulations Development
Office of Strategic Operations and Regulatory Affairs
The Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: Document Identifier [Document Identifier: CMS–372(S), CMS–10305, CMS–10148, CMS–10784, CMS–10715, CMS–10768, CMS–R–43 and CMS–10417]
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Comments Regarding CMS' "Agency Information Collection Activities: Submission for OMB Review; Comment Request" Notice [Document Identifier: CMS–372(S), CMS–10305, CMS–10148, CMS–10784, CMS–10715, CMS–10768, CMS–R–43 and CMS–10417]

Dear Mr. Parham:

Navitus Health Solutions, LLC ("Navitus") is providing these comments regarding the U.S. Centers for Medicare and Medicaid Services' (CMS') October 14, 2021 Notice titled "Agency Information Collection Activities: Submission for OMB Review; Comment Request" [Document Identifier: CMS–372(S), CMS–10305, CMS–10148, CMS–10784, CMS–10715, CMS–10768, CMS–R–43 and CMS–10417].[1] In particular, Navitus would like to comment on Information Collection Request Item 2. "Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g)) (CMS-10305)," including CMS Form Number CMS-10305.[2]

As background, Navitus is a 100% pass-through, fully transparent pharmacy benefit manager (PBM). Since our founding in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for government programs, including Medicare, Managed Medicaid, and ACA/Exchange clients throughout the country.

We would specifically like to provide feedback and questions regarding proposed changes to Appendix B of the Data Validation Provider Manual.

Data Validation Provider Manual Appendix B: Data Validation Standards. Within the crosswalk outlining the proposed changes to Appendix B, CMS indicates that a specific reporting element (Part D DUR

[1] 86 Fed. Reg. 57151 (Oct. 14, 2021), *available at* https://www.govinfo.gov/content/pkg/FR-2021-10-14/pdf/2021-22444.pdf.

[2] https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10305.

reporting elements CC-EE)[3] requires entities to match Opioid Naïve Coverage Determination data to Opioid Naïve POS Reject data with specific parameters (*i.e.*, same drug and date).[4] Previous to this change, the match criteria used to line up Opioid Naïve Coverage Determination data to Opioid Naïve POS Reject data was not defined to include specific parameters. This crosswalk is not, however, supported by relevant changes within Appendix B itself.[5]

CMS should clarify whether these additions to the crosswalk were in error or whether the appropriate additions were mistakenly omitted from the proposed additions to Appendix B. If these proposed revisions were omitted from Appendix B, CMS should clarify the following match criteria:

1. Please confirm that a coverage determination should only be matched to an opioid naïve rejection if the date is the same. For example, please clarify whether coverage determinations occurring in the time following the rejection beyond the matched date should be included in reporting elements CC-EE? The absence of parameters has allowed plans the flexibility to report in the way they thought best. While we believe the addition of a standard could be beneficial, the proposed one is the incorrect one. Rather; if CMS were to create a standard, it should be coverage determinations finalized on or after the date of rejection.
2. Which date should be used to match the opioid naïve reject date of service in reporting: the date the coverage determination was initiated or the decision date? We believe it is appropriate to include any coverage determination for the same drug with a decision date on or after the date of the reject date because the coverage determination process can take time after the initiation of the process, including contacting providers for additional information as well as notifying the member.
3. Please confirm that a GPI 12 match is sufficient to define "same drug". We believe it ought to be sufficient.

Thank you for the opportunity to provide feedback on the proposed revisions. If we can provide any additional information or answer additional questions, please feel free to contact Navitus' Director of Government Relations, Collan Rosier, at collan.rosier@navitus.com.

Sincerely,

Carmen R. Backman
Vice President of Government Programs

Julie A. Olson, DNP, MS, RN, CQIA
Vice President of Clinical Innovation

[3] Medicare Part D Reporting Requirements (Effective as of January 1, 2021) at 13, *available at* https://www.cms.gov/files/document/cy2021-part-d-reporting-requirements-120920.pdf.

[4] *See* Appendix B Crosswalk of Changes from CY2020 to CY2022 from 60-Day Comment Period_508.

[5] Medicare Part C and Part D Reporting Requirements Data Validation Procedure Manual, Appendix B: Data Validation Standards For Data Validation Occurring in 2022 (Last Updated September 2021) at pp. 27 *et seq*.