30-Day Comment Response Document

Overview of Comments

CMS received various comments from Part D sponsors, PBMs and other associations. We received 11 comments regarding the following reporting sections: Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations and Organization Determinations and Reconsiderations.

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR	Within the crosswalk outlining the proposed changes to Appendix B, CMS indicates that a specific reporting element (Part D DUR reporting elements CC-EE) requires entities to match Opioid Naïve Coverage Determination data to Opioid Naïve POS Reject data with specific parameters (i.e., same drug and date). 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.	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.	Addition of "same drug and date" language to the crosswalk for Appendix B was incorrect and will be revised. As Note #5 in DUR Technical Specifications addresses rejected claims and the specifications include aspects beyond drug and date, such as quantity, strength and dosage form, as such the "specific to same drug and date" language was removed from 2022 Appendix B and Appendix J. This is reflected in Appendix B and Appendix J.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Change in Frequency of MA Data Valudation Audits for High-scoring plans.	"...CMS requires that health plans hire an external independent auditing firm to conduct these audits, which is a costly annual administrative expense that diverts health plan resources away from the administration of benefits for our members." "XXXX is subject to a host of annual audits, and the volume of annual CMS oversight activities—audits, reviews, validations, and others—has dramatically increased over the past few years. While smaller plans with few contracts may not be subject to all these oversite activities every year, XXXX is subject to the majority. Further, the impact of these audits are intensified because samples for many of them are selected at the contract level, not at the parent organization level. During 2021, XXX-sponsored Medicare plans have been subject to over 25 different CMS audits. In addition, XXXX has supported 45 health plan clients in over 600 CMS audits during the same period. Again, as stated above, XXXX must divert critical resources to these audits that would otherwise be used to care for our members."	o For plans that consistently scored above 98% to 99% over the previous three years, require the DVA less frequently, e.g., every three years; and o For those plans that do not score as well, continue to audit, annually.	This comment is out of scope for this information collection request.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR - Appendix B	RSC 8-biii: Includes all coverage determination or appeal requests subject to the opioid naive edit specific to the same drug and date.	Appendix B and Appendix J criteria do not match for RSC8biii. Appendix B states “RSC 8-biii: Includes all coverage determination or appeal requests subject to the opioid naive edit specific to the same drug and date.” And Appendix J states “RSC 8biii: Includes all coverage determination or appeal requests subject to the opioid naive edit.“	Addition of "same drug and date" language to the crosswalk for Appendix B was incorrect and will be revised. As Note #5 in DUR Technical Specifications addresses rejected claims and the specifications include aspects beyond drug and date, such as quantity, strength and dosage form, as such the "specific to same drug and date" language was removed from 2022 Appendix B and Appendix J. This is reflected in Appendix B and Appendix J.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DUR - Appendix J	RSC 8biii: Includes all coverage determination or appeal requests subject to the opioid naive edit.	Appendix B and Appendix J criteria do not match for RSC8biii. Appendix B states “RSC 8-biii: Includes all coverage determination or appeal requests subject to the opioid naive edit specific to the same drug and date.” And Appendix J states “RSC 8biii: Includes all coverage determination or appeal requests subject to the opioid naive edit.“	Addition of "same drug and date" language to the crosswalk for Appendix B was incorrect and will be revised. As Note #5 in DUR Technical Specifications addresses rejected claims and the specifications include aspects beyond drug and date, such as quantity, strength and dosage form, as such the "specific to same drug and date" language was removed from 2022 Appendix B and Appendix J. This is reflected in Appendix B and Appendix J.	No	No
Change in Frequency of Valudation Audits for High-scoring plans.	Health plans are subject to a host of annual audits, and the volume of annual CMS oversight activities—audits, reviews, validations, and others—has dramatically increased over the past few years. While smaller plans with few contracts may not be subject to all these oversite activities every year, most plans are subject to the majority. Further, samples for many of these audits are selected at the contract level versus the parent organization level, which intensifies the impact. XXXX plans report having been subject to as many as 14 new audits annually, some of which span greater than nine months. This has resulted in as many as 20 audits occurring within the same time frame. Again, as stated above, health plans have to divert critical resources to these audits that would otherwise be used to care for our members.	XXXX plan members propose two options for plans that consistently scored above 98% to 99% over the previous three years: • Indefinitely suspend the DVA, or • Require the DVA less frequently, e.g., every three years. Those plans that do not score as well would continue to be audited on an annual basis.	This comment is out of scope for this information collection request.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Data Validation in General	We requests CMS develop a system where pharmacies are able to validate the data submitted by the plans/PBMs. Currently, CMS accords plans and PBMs to reconcile, validate, dispute, and review submitted data. Since pharmacies are being judged on similar criteria, they should have the same opportunity to audit the submitted data to correct for mistakes and inaccuracies. XXXX continues to have instances where community pharmacies are finding errors and discrepancies with published data in the Medicare Plan Finder – including data does not match the true cost associated with the contractual rates for pharmacies and incorrectly excluding network participation of certain community pharmacies.	By inviting pharmacies to participate earlier in the process, all such information can be checked, and any mistakes can be corrected prior to the open enrollment period.	This comment is out of scope for this information collection request.	No	No
Transparency in Coverage	We remain concerned about the ability of PBMs to attempt to mask incoming revenue associated with prescription drugs as service fees. Previously, the HHS Office of Inspector General found that PBMs were claiming certain fees as bona fide service fees1 and were therefore not reported to Medicare Part D plans or to CMS, provided they were paid at fair market value. However, the contracts between the Part D plans and the PBMs had only limited information about these bona fide service fees, and neither CMS nor the Part D plans were able to verify whether claimed bona fide service fees should actually have been considered rebates and therefore part of the net price for inclusion in the collection.	We urge CMS to consider the inclusion of pharmacy direct and indirect renumeration (DIR) fees in their calculations of renumeration. These fees are assessed post point of sale and collected by the PBMs after the prescription is dispensed – and the inclusion of DIR fees would increase the transparency of the financial operations of the PBMs and the costs associated with prescription drugs.	This comment is out of scope for this information collection request.	No	No
DV Training	We recommend CMS modify the language in the proposed 2022 Data Validation Manual Changes in Section 3.3 Complete the Web-Based Data Validation Training.	They propose to change it to: "During the DV preparation phase, all SO staff facilitating the DV must complete the CMS web-based DV Training to familiarize themselves with the DV process and requirements. Additionally, all DV staff facilitating the audit are required to take the CMS web-based DV Training prior to working on the DV project."	The current language sufficiently clarifies that SO staff involved in the DV process and all DV staff working on the DV project are required to take the CMS web-based DV Training.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Crosswalk of DV Manual, page 2, Section 3.2.2.2.	Crosskwalk of DV Manual, page 2, Section 3.2.2.2. - According to the change proposed all SO staff should complete the CMS web-based training.	The new text does not specify how CMS or the DVCs will monitor the certificates of completion. Will it be included as part of the documentation requested during the DV audit? Is the completion of the training required before a specific date? Also, the page included in the new text is unavailable (i.e. page not found)	As per Section 3.2.2.2 of the DV Training Manual, SOs will submit an official letter in either hardcopy or an emailed pdf format to DVC which includes acknowledgement that the SOs have completed the Web-based DV Training in order to gain access to the PRDVM. Model language for this letter can be found in the Model Language for Letter to Confirm Selection of Data Validation Contractor (Appendix C). Completion of the DV Training should occur between February and March of the DV calendar year as noted in Exhibit 2 on Page 6 of the DV Procedure Manual.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Crosswalk of Appendix J, page 1, Part D CDR	The new language states that the final decision is based in the date the party is notified in writing of the coverage determination decision.	Should MAPD plans also consider this for the Organizations, Determinations and Reconsiderations report (ODR)? The current ODR language is not specific and it would be helpful to align Part C and Part D reporting when using the same reporting systems.	The data validation language for Part C Organization Determinations and Reconsiderations in the most recent PRA Data Validation package cannot align Part C ODR data validation standards with Part D coverage determination standards for this particular provision since the regs do not align and therefore, the original language for Part C will remain the same.	No	No

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Change in Frequency of Valudation Audits	XXXX is a small- to medium-sized local plan in XXXX with two Medicare Advantage (MA) contracts. We would like to share our perspective, comments, and suggestions concerning the 2022 Medicare Part C and Part D Reporting Requirements Data Validation Audit (DVA). The DVA is designed to validate that the information health plans provide in their Part C and D reports is accurate. PHP understands the importance of accurate reporting, which is relied upon by CMS and congressional members. For a plan of XXX's size, the cost of the independent auditing firm ranges between $30K and $35K for each annual audit. In addition, the audit's data requirements are extensive and the assembly of this data for the external auditing firm consumes, on average, between 200 and 250 staff hours per year. These hours could better be spent on services to members or improvement in plan operations to reduce administrative costs rather than producing proof year over year data for this audit which has year over year been proven to be accurate. DATA The DVA was unquestionably necessary when it was initiated, but in recent years few plans have scored less than 100%. This is documented in the recent CMS HPMS memo titled Results of the 2021 Part C and D Reporting Requirements Data Validation. 96.4% of the plans scored 99% or higher in the data validation study with a mean score of 99.6%. 639 of the 715 audited plans scored 100%. These results are typical of previous years' results and demonstrate the reliability of the data currently submitted to CMS. Clearly the DVA has accomplished its mission, which was to ensure that data submitted by MA plans is valid and accurate.	XXXX respectfully proposes that CMS consider discontinuing or modifying the DVA requirement. The time and expense required to support the annual DVA represent a significant annual burden that – particularly for local plans - diverts our and other MA plans' critical resources away from the administration of benefits for MA beneficiaries, especially during the on-going National Health Emergency. If CMS is reluctant to discontinue the DVA, XXXX proposes possible alternatives: • Audit new MA plans where this audit would be of value. • Audit plans demonstrating poor performance. • Reduce the audit frequency to every 3 to 5 years for those plans scoring above 95% accuracy.	This comment is out of scope for this information collection request.	No	No