PRA 0938-0676: Response to Comment - 1k5-91fr-stnn

PRA Package 0938-0676, Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a) received two comments during the 60-day period. One comment (1k5-91fr-stnn) is from a Collaborative Workgroup composed of individuals from states, pharmaceutical manufacturers, and industry professionals, and one comment (1k5-91hy-chh8) is from a State (Nebraska).

Overview:

The Collaborative Workgroup is suggesting that CMS combine the Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a) into one form, add additional fields to include payment details and a unique identifier field, and mandate that it only be submitted electronically. The commenter further suggests that this new/expanded combined ROSI/PQAS electronic format be implemented on or before July 2023.

CMS Response:

The purpose of this PRA package is to address specific updates needed to accommodate changes made to the field lengths and file formats to accommodate the changes that will go into effect when CMS transitions to the Medicaid Drug Programs (MDP) system in July 2021. While CMS appreciates the suggestions made by the commenter, we are unable to commit to the suggested July, 2023, timeframe. Furthermore, CMS is not prepared, at this time to determine if it would mandate the use of the suggested new/expanded electronic ROSI/PQAS format.

Action(s) Taken:

CMS will take the commenter suggested edits to the Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a) under advisement, however we are unable to confirm a specified timeframe in doing so, nor is it a guarantee that all the suggested edits will be implemented. CMS would additionally like to note that a second comment received from a state, mentions several reasons that their system is unable to accept/accommodate electronic uploaded ROSI/PQAS. Therefore, prior to making any enhancements to the functionality of the current ROSI or PQAS, CMS would reach out to all stakeholders to solicit feedback on any potential issues/limitations that they might identify. All responses/feedback would be taken into consideration prior to moving forward with making any updates.

PRA 0938-0676: Response to Comment - 1k5-91hy-chh8

PRA Package 0938-0676, Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a) received two comments during the 60-day period. One comment (1k5-91fr-stnn) is from a Collaborative Workgroup composed of individuals from states, pharmaceutical manufacturers, and industry professionals, and one comment (1k5-91hy-chh8) is from a state (Nebraska).

Overview:

The state commenter mentions that their system is "home-grown" and is unable to accommodate electronic submission of the Reconciliation of State Invoice (ROSI) (CMS-304) and Prior

Quarter Adjustment Statement (PQAS) (CMS-304a). They mention that it would be a long process for all 51 states and the manufacturers (in which there are currently ~740 manufacturers participating in the Medicaid Drug Rebate Program (MDRP)) to create/buy new systems. Additionally, it could be a major cost to all. The commenter further mentions that they only have two assigned MDRP accountants to handle all of the manufacturers. The commenter also mentions that certain manufacturers only send the state invoice back as documentation, and asked if these manufacturers would also need to adapt their system even though they are sending back to the state exactly what was sent to them (the manufacturer). They additionally inquired if there would be a way that these "electronic format ROSIs/PQAS" could be made to be printed so that they could still be entered manually if a state is unable to upload them to their system.

CMS Response:

At this time, CMS is not mandating the use of the electronic Reconciliation of State Invoice (ROSI) (CMS-304) or Prior Quarter Adjustment Statement (PQAS) (CMS-304a). States may continue to utilize any manual processes currently in place. The purpose of this PRA package is to address specific updates needed in order to accommodate changes being made to the field lengths and file formats that will go into effect when CMS transitions to the Medicaid Drug Programs (MDP) system in July 2021. States and manufacturers may still utilize the manual process for sending invoices as well as ROSI and PQAS. CMS is unable to provide specific responses to the commenter's two inquires mentioned in the above overview, as we are not mandating the use of the ROSI and PQAS at this time.

Action(s) Taken:

CMS will take the suggested edits to the Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a) under advisement. However, prior to making any enhancements to the functionality of the current ROSI or PQAS, CMS would reach out to all stakeholders to solicit feedback on any potential issues/limitations or additional burden that might be identified. All responses/feedback would be taken into consideration prior to moving forward with making any updates.