HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Re: Medicare Drug Price Negotiation Program **Draft Guidance**

Deputy Administrator Seshamani,

Thank you for the opportunity to respond to the Draft Guidance on the Medicare Drug Price Negotiation Program issued on May 3, 2024. Our comments address the sections of the guidance pertaining to the Manufacturer Effectuation of the Maximum Fair Price (MFP).

As you know, the Healthcare Distribution Alliance (HDA) is the national trade organization representing primary pharmaceutical distributors. HDA's members ensure the safe and efficient distribution of prescription medications to healthcare providers and the patients they serve. Our members are the vital link between the nation's pharmaceutical manufacturers and more than 300,000 pharmacies, hospitals, physicians, clinics, long-term care facilities, durable medical equipment providers, and other licensed sites of care nationwide.

1. Cash Flow Impact on Pharmacies

By its nature, a retrospective discount model strains the operating cash requirements of pharmacies because they must purchase inventory at the wholesale acquisition cost (WAC) and then endure a waiting period following dispensing to receive the retrospective discount.

We believe the projected length of the waiting period, as outlined in the guidance, will exacerbate the financial stress pharmacies are currently facing. Assuming it takes seven days for the claim to arrive at CMS' Drug Data Processing System (DDPS), one to two additional days for the claim to be delivered to the Medicare Transaction Facilitator (MTF), and another one to two days for the MTF to process and deliver the claim to the manufacturer, this results in a total of 9 to 11 days before the 14-day prompt pay clock begins, culminating in a potential waiting period of up to 25 days. Importantly, this best-case scenario assumes that the DDPS, the MTF, and the manufacturer efficiently process claims and that the current 30-day deadline for plans to submit data to DDPS is reduced to 7 days.

Most pharmacies pay their distributors on 15-day terms, so a 25-day waiting period will put extra pressure on even the best-operating pharmacies. It could worsen if the 30-day lag in submission of prescription drug event (PDE) data to DDPS is not reduced and the MTF reporting cadence is biweekly, potentially resulting in a 45-day waiting period before the 14-day prompt pay clock begins, even if the MTF is able to perform process claims and deliver them to manufacturers in a single day. Any measures that CMS can implement to shorten the duration of the best-case scenario would be beneficial to all dispensers. For example, if Part D plans could submit claims the day following adjudication, and if the DDPS and MTF processes could be optimized to ensure a one-day turnaround, the claims could reach manufacturers in three to four days, reducing the pressure on pharmacies.

2. Standard Default Refund Amount

We agree that requiring the standard default refund amount to be the difference between WAC and the negotiated MFP for Part D claims is both practical and equitable. We believe that if alternative refund methodologies are negotiated between manufacturers and pharmacies, there could be both operational and financial risks to pharmacies.

3. Electronic Remittance Advices

CMS is soliciting comments on electronic remittance advices. Many of our member companies operate Pharmacy Services Administrative Organizations (PSAOs) that provide central payment and central reconciliation services to independent pharmacies, routinely processing electronic data interchange (EDI) 835 remittance advices in their normal course of business.

In our collective experience, it is a best practice for the entity making the payment to produce the EDI 835, and it is essential that the grand total of the detail lines in the EDI 835 match the amount of the ACH deposit. While the EDI 835 is a healthcare remittance advice standard, it supports various implementation options. We recommend that CMS continue to engage with interested parties at the National Council for Prescription Drug Programs (NCPDP) to specify a formal implementation of the EDI 835 standard to support MFP payments. From a feature standpoint, a standardized implementation should allow for reporting one or more fields that can link details of a prospective payment to the retrospective process.

Since participation in any MTF payment facilitation will be voluntary for dispensing entities and manufacturers, we anticipate that manufacturers will require their contracted vendors to develop payment and remittance advice capabilities emphasizing the need for consistency. A standardized implementation with a single payment facilitator across all manufacturers would enable our members' central payment and reconciliation services to operate accurately and reliably for our pharmacy customers.

4. 340B Duplicate Discounts

CMS has encouraged wholesalers, along with other drug supply chain stakeholders, to collaborate with manufacturers and covered entities to address the 340B duplicate discount issue with potential industry solutions. We are concerned, however, that the lack of CMS guidance at this time may cause confusion and delay or limit industry from advancing the necessary solutions. We urge CMS to reconsider the MTF as a single entity handling data, payments, and 340B deduplication to ensure a seamless experience for the supply chain and patients on day one of the program.

It's important to note that duplicate discounts will occur at contract pharmacies if the covered entity (or its contracted administrator) follows the current practice of shipping replacement products to the contract pharmacy after retrospectively designating a Medicare claim as 340B eligible. We believe all affected parties are motivated to prevent duplicate discounts up front to eliminate the need for retrospective de-duplication and complex audits. This might be accomplished by patterning the processes in place today to ensure Medicaid claims are not dispensed using products purchased at the 340B price.

In addition, implementing a process that claws back MFP refunds as part of the 340B deduplication process would be confusing for dispensers and pose challenges for PSAOs and other entities managing reconciliation systems on behalf of pharmacies to align with 340B records, given the disparate and unconnected systems managing each function. Any 340B de-duplication process or system designed should take into account all stakeholders' operational and financial reporting requirements in the 340B process (manufacturers, distributors, dispensers, and covered entities).

5. Claim Adjustments and Reversals

With regard to whether CMS should recognize a specific timeframe for addressing claim adjustments, we believe that imposing such timeframes on the backend is unnecessary to ensure all parties are made whole. The Part D plans control the business rules governing these transactions, and they are best positioned to manage the timing of claim adjustments, which typically take the form of a reversal followed by a new claim. The backend process should mirror that of third-party payors when paying claims, where it is common for a claim to be paid in one payment cycle only to be reversed in the next payment cycle. It is critical that individual transactions flow through the entire backend system to ensure integrity, accountability, and accuracy at each step without the need for back-end imposed timeframes. In the case where a pharmacy submits and later reverses a claim within the same manufacturer payment batch, both transactions should be included as separate line items in the 835, reflecting a positive amount as payment for the claim and a corresponding negative amount for the reversal. This allows the reconciliation service receiving the remittance advice, such as the PSAOs operated by our member companies, to efficiently reconcile all transactions and address any discrepancies.

6. Function of CMS' DDPS System

In the revised guidance, CMS specifies that the MTF will furnish manufacturers with data verified independently by both the Part D plan sponsor and CMS' DDPS. This ensures dual verification for each claim, confirming both an individual's eligibility for Part D and coverage of the selected drug. However, this process introduces the risk of a claim being initially paid as an MFP claim by the plan but subsequently failing verification at the DDPS. Addressing this scenario requires thorough examination, as the dispenser will have already created a receivable record expecting payment for the claim. We would respectfully request that CMS provide guidance on what would be the remedy if this were to occur.

7. Collection of Pharmacy Payment Information.

CMS is soliciting comments on what information would be required by interested parties for either of its two options to efficiently facilitate payments. One critical element missing in the revised guidance is for CMS to also collect the delivery address for the EDI 835 remittance advice.

PSAOs that operate central pay and reconciliation services can play a valuable role by populating the pharmacy's financial information on behalf of the pharmacy, including the PSAOs central bank account information and the PSAOs delivery address for remittance advices.

Maintaining the financial information of dispensing entities will require more robust capabilities than might be apparent at first glance and warrants planning sessions with industry experts. Given that payors have been forced to implement over time, there must be protocols in place to control changes. Examples include pharmacy ownership changes and pharmacies switching from one PSAO to another. These changes typically require dual controls with future effective dates.

8. CMS Payment Facilitation Options

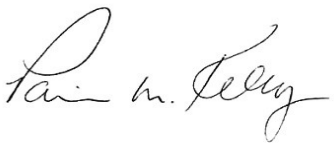
CMS is soliciting comments on the two MTF payment facilitation functionality options it is considering. Additionally, CMS is seeking input on any other functionalities interested parties believe would help facilitate timely refunds between manufacturers and dispensing entities to effectuate the MFP. As wholesalers, we are not directly affected and do not express a preference. However, we understand that our pharmacy customers favor "Option 2" as described in the draft guidance, with the MTF facilitating payments and remittance advices. Conversely, we have heard manufacturers express reluctance to comingle funds in the payment process. If this reluctance continues to be expressed in the comments CMS receives on this draft guidance, there is a middle ground that CMS might consider.

A hybrid option, akin to Option 2, would involve the MTF facilitating all payments. Instead of sending a single payment from a single MTF bank account, the MTF would issue a single payment and remittance advice for each manufacturer. To fund the payments, the ACH payment file would be compiled by the MTF and drawn directly from the manufacturers' designated bank accounts. For pharmacies, similar to Option 2, the MTF could play a central role and drive standardized processes and predictability. For manufacturers, it would eliminate the commingling of funds. In today's digital environment, the systems that ingest and process bank deposits and remittance advices would easily handle segregated payments, and the industry would still gain many of the same benefits from the efficiency, standardization, and predictability envisioned in Option 2.

Conclusion

Thank you for the opportunity to provide feedback on the MFP effectuation process. We appreciate serving as a resource for the MDPNP implementation team and stand ready to work with CMS to consider additional processes and solutions as needed. If you have any questions or require additional information, please contact Patrick Kelly (pkelly@hda.org).

Sincerely,



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