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June 25, 2025

VIA ELECTRONIC SUBMISSION (IRARebateandNegotiation@cms.hhs.gov)

The Honorable Chris Klomp
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Deputy Administrator Klomp:

On behalf of the Senior Care Pharmacy Coalition (SCPC), we write to comment on the draft Guidance entitled: "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028." We appreciate the opportunity to comment on the draft Guidance, particularly to address several considerations for CMS as the agency implements the Manufacturer Transaction Facilitator (MTF) for Part B drugs dispensed by pharmacies in 2028, when several Part B drugs are expected to be subject to Medicare drug price negotiation.

SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 75% of all independent, closed-door LTC pharmacies. Our members serve one million residents daily in LTC facilities across the country. Given the distinct characteristics of the LTC patient population and the enhanced clinical and other responsibilities of LTC pharmacies, we offer unique perspectives on CMS' initiatives and proposals, particularly how Medicare Prescription Drug Benefit (Part D) policies and requirements impact Part D enrollees with institutional level of care needs and the LTC pharmacies that serve them.

SCPC notes with interest the references to the expansion of the MTF for Part B drugs in 2028. We appreciate that the agency is not yet ready to propose specific implementation information for the expansion of the MTF program pending initial implementation for Part D drugs starting January 1, 2026. However, we wish to provide CMS with several suggestions related to the 2028 Part B expansion, set out below.

• CMS must ensure that pharmacies are included in Ensure Pharmacies are Included in Part B Implementation. While most Part B providers are physicians and hospitals, many pharmacies, including LTC pharmacies, dispense Part B drugs and must be included

in the Part B MTF implementation. We urge CMS to consult pharmacies – particularly LTC pharmacies - as the agency adapts the MTF to Part B drugs to assure that Medicare beneficiaries maintain access to part B drugs dispensed by pharmacies. The implementation process CMS established should work for all Part D providers.

- CMS must ensure that Part B implementation includes "835 data". CMS certainly appreciates that "dispensing entities" must be able to track manufacturer payments to specific dispensing events through the MTF. Under Part D, CMS which relies on the X12 Health Care Claim Payment/Advice or the "835" transaction to allow pharmacies to connect manufacturer payments to specific claims/dispensing events. The agency relies on the "Prescription Dispensing Event" (PDE) to initiate the data exchange and payment processes. For Part B, however, CMS Medicare Administrative Contractors (MACs) do not use the X12 system or process 835 records, and there are no PDEs involved in Part B Claims. While CMS is likely considering using the "Form 1500" claim submission (paper or electronic) to be the record triggering the MTF payment process for manufacturers, the Form 1500 does not contain the requisite information that would allow pharmacies to connect a manufacturer payment back to the dispensing event. MACs have the capacity to provide 835 transaction reports to pharmacies, and we urge CMS to require that they do so for pharmacy-dispensed MFP Part B drugs, so that the manufacturers can use that file and return the same file with payment information to the pharmacies.
- Enrollment. As CMS develops the Part B protocols for the MTF process, we appreciate that enrolling providers will be a significant task. Many, if not all, pharmacies dispensing Part B drugs will have already been enrolled in the MTF DM (and likely the MTF PM) starting in 2026. We urge CMS to rely on existing pharmacy registrations rather than require that pharmacies re-enroll in the MTF for Part B drugs.

Thank you for your consideration. If you have questions or wish to discuss our comments, please feel free to contact me at arosenbloom@seniorcarepharmacies.org or (717) 503-0516.

Respectfully submitted,

Alan G. Rosenbloom President & CEO

Senior Care Pharmacy Coalition

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