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VIA ELECTRONIC DELIVERY

May 1, 2025

Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10912, OMB 0938-NEW)

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the second round of the Information Collection Request (ICR) regarding information collected from manufacturers to facilitate the effectuation of the MFP utilizing the Medicare Transaction Facilitator (MTF) for 2026 and 2027.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay the onset of such diseases, or prevent them in the first place. As a result, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO's members include biologic and vaccine manufacturers, which have worked closely with stakeholders across the spectrum, including the public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO appreciates CMS' continuous efforts to establish guidance around the MTF, including this revised ICR as well as the recent final rulemaking on CY 2026 Policy and Technical Changes to the Medicare Advantage Program. In particular, BIO greatly appreciates CMS' recent finalization of the provision that requires dispensing entities to enroll in the MTF-DM, which will greatly improve logistical coordination between the tens of thousands of dispensing entities and manufacturers so that MFP rebate claims can be processed accurately. BIO also appreciates the areas of clarification that have been added to this ICR to address some of our initial concerns, including clarification around reporting for Primary Manufacturers that do not intend to use retrospective reimbursements. BIO also welcomes the streamlined questions around alternative arrangements to effectuate the MFP, which addressed our initial concerns around reporting burden given the significant number of dispenser NPIs. As CMS continues to refine and develop new guidance on MFP effectuation, BIO welcomes the opportunity to partner with the Agency to prepare for the September effectuation plan deadline and January 2026 effectuation date.

In light of the looming effectuation deadlines, BIO remains concerned that there are still many operational questions that remain. We urge the Agency to promptly issue guidance or additional clarification around the technical operation of the credit/debit ledger system, including examples of how credits, debits, reversals, and adjustments would be processed through the system and how

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potential disputes would be resolved within the system. As it stands, many manufacturers have already begun system development and testing in order to meet the effectuation deadlines. Without clarity around the operation of the credit/debit ledger system, there is a risk of misalignment that could lead to costly rework, delays, or system incompatibility. Early and transparent guidance is necessary to reduce confusion and support successful implementation across all parties.

In addition, BIO remains deeply concerned that the 14-day prompt pay window for manufacturers to process MFP rebate claims is unreasonably short and does not provide sufficient time to complete the necessary internal reviews, validations, and processes to verify accurate rebate payments. As BIO has expressed in the past, imposing this tight timeline increases the risk of errors, delays, and administrative burden, potentially undermining the integrity of the effectuation process. BIO continues to recommend that CMS follow a similar timeline and process as the Coverage Gap Discount Program[1], which has a 38-day timeline and counts calendar days whereby if a deadline falls on a weekend or holiday, the payment is still considered timely if received on the next business day.

It is also critical that CMS ensure that the 340B and MFP programs operate in compliance with the statutory 340B non-duplication requirement. As BIO stated in the first round of comments, CMS must quickly move forward with the establishment of the Medicare Part D data repository, as well as guidance to require covered entities to furnish claims level data to manufacturers through the 340B and non-340B claims modifiers. It is imperative that the repository and the MTF cooperate in the identification of 340B claims to ensure appropriate effectuation of the MFP, as well as removal of 340B claims from the Inflation Rebate Program.

As BIO has expressed in our previous comments, we are also concerned that the forms contained in the revised ICR do not contain sufficient confidentiality protections. Although CMS states that the MFP Effectuation Plans will not be shared publicly by the agency, BIO remains concerned that redacted MFP Effectuation Plans may be shared outside the agency. To ensure proper redaction of the Effectuation Plan, BIO reiterates that manufacturers should be allowed to designate within the Plan which specific information is confidential, enabling the safeguarding of sensitive data as determined by the manufacturer.

Finally, BIO continues to object to instances where manufacturer responsibilities are unreasonably shifted beyond the appropriate scope as set out in the statute. As we have stated previously, manufacturers have no ability, as well as no statutory obligation, to address pharmacy cashflow concerns, and should not be held responsible for mitigating cashflow challenges for dispensing entities. In addition, Primary Manufacturers should not be held responsible for submitting applicable information concerning a Secondary Manufacturer, as a Primary Manufacturer has no authority to compel a Secondary Manufacturer to act or not act, including to share information on operational processes established for MFP effectuation.

[1] 5 42 C.F.R. § 423.2315

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We look forward to continuing to work with the Agency to ensure proper implementation of the effectuation program. Should you have any questions, please contact us at 202-962-9200.

/s/
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Director
Health Policy and Reimbursement