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William N. Parham, III
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10912, OMB 0938-NEW

Re: Information Collection Request: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Director Parham:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS, the Agency) on the Information Collection Request (ICR) for the *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*, which CMS released on October 28, 2024. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

Below, PhRMA provides comments and requests for clarity across the Supporting Statement, Appendix A (the Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form), Appendix B (the Primary Manufacturer MFP Effectuation Plan Form), Appendix C (the Drug Price Negotiation Program Primary Manufacturer Payment Elements Form), and Appendix D (the Drug Price Negotiation Program Complaint and Dispute Intake Form). In addition to this feedback, we encourage CMS to provide additional information and clarity as soon as possible on timelines for how manufacturers of selected drugs can test the systems developed by the Medicare Transaction Facilitator Data Module (MTF DM) and Payment Module (MTF PM). Early opportunities for systems testing will be crucial as selected manufacturers develop MFP effectuation plans and for the smooth effectuation of Maximum Fair Prices under the IRA.

More broadly, and as we have previously communicated with the Agency, PhRMA continues to believe that the best, least burdensome, and most efficient way to effectuate the Maximum Fair

[1] PhRMA. (August 16, 2024). 2024 PhRMA Annual Membership Survey. Available at: https://phrma.org/resource-center/Topics/Research-and-Development/2024-PhRMA-Annual-Membership-Survey

Price (MFP) would be for CMS to utilize an approach similar to the Part D Coverage Gap Discount Program (CGDP), including pass-through of MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication. If CMS were to adopt this approach, the Agency likely would improve the efficiency of the program by eliminating the need for the development and review of MFP effectuation plans, as well as the need for dispensers to enter into agreements with the MTF DM and the need for manufacturers to develop cash flow mitigation plans. While PhRMA supports ensuring prompt payment to pharmacies, we have significant concerns on how stakeholders did not have opportunity to provide comment on the cashflow mitigation plan requirement.

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I. MTF ICR Supporting Statement

PhRMA believes that CMS is significantly underestimating the burden for Primary Manufacturers to complete the applicable ICR forms and strongly disagrees with the total annual burden estimates published in the Supporting Statement. The MFP Effectuation Plan Form will require input from many different divisions within each Primary Manufacturer, including *multiple* staff from groups identified by CMS in the ICR, not just sole employee representatives, along with outside legal counsel and outside consultants. Similarly, given the volume of claims data selected drug manufacturers will be receiving on a near daily basis,[2] the Agency's estimate of only two staff dedicated to sampling and analyzing data for the MTF DM payment elements form is woefully inadequate.[3]

Moreover, the ICR notes that "CMS also anticipates some Primary Manufacturers will need to develop novel internal processes to establish their approach to MFP effectuation and engage with the [Medicare Transaction Facilitator (MTF)] system." However, the total annual burden estimates do not adequately reflect the necessary staff resources and expertise to develop and implement the significant internal processes within the companies that are necessary to develop these novel approaches for MFP effectuation. CMS also does not include adequate burden estimates of the necessary time that Primary Manufacturers will need to fully integrate internal systems with the MTF system in order to gain an adequate understanding of MTF processes and to successfully complete the MFP Effectuation Plan Form.

We would highly recommend that CMS talk with Primary Manufacturers to develop more realistic estimates of time and burden costs.

II. Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form

PhRMA recommends that CMS make dispenser information reported on the enrollment form available to manufacturers of selected drugs through the MTF DM portal. This would be similar to how CMS plans to make manufacturer MFP effectuation plans available to dispensers through the MTF DM portal and would ensure critical information from both dispensers and manufacturers is available to all parties involved in MFP effectuation.

[2] Based on the 2022 Part D dashboard, daily claims for one of the 10 drugs selected for Initial Price Applicability Year (IPAY) 2026 averaged nearly 52,000. *See* https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

[3] In addition, on a technical basis, CMS will require manufacturers to authorize payment of MFP refunds seven days a week, but the burden estimate only contemplates staff working five days per week to sample and analyze data.

III. Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Q4: Details on Primary Manufacturers' processes for 340B nonduplication.

PhRMA remains highly concerned about the continued lack of a role for CMS in identifying and deduplicating 340B claims, with CMS stating in the Final Guidance for the Medicare Drug Price Negotiation Program[4] (Final Guidance) that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[5]

Manufacturers have in many cases very limited insight into which Part D units are subject to 340B pricing. While PhRMA appreciates the addition of the Prescriber ID data field to the data elements that will be shared with Primary Manufacturers through the MTF Data Module (DM), CMS noted in the Final Guidance that "…[National Provider Identifier (NPI)] alone (whether a prescriber NPI or a hospital/provider NPI) generally will not constitute sufficient evidence that a claim was 340B-eligible…." Without some requirement from CMS and/or the Health Resources and Services Administration (HRSA) for covered entities to identify 340B units and share appropriate information with manufacturers, manufacturers face virtually certain risk of paying duplicate MFP and 340B discounts in direct contradiction to the prohibition under the IRA.[6]

Furthermore, in the Final Guidance, CMS stated that it "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B [third party administrators], and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and 340B ceiling price…. CMS anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders…."[7] However, as CMS should be aware, one state has passed a law expressly prohibiting manufacturers from requiring 340B claim-level data from covered entities (or contract pharmacies acting on their behalf) in certain circumstances, with more states expected to consider similar legislation next year. And, to date, HRSA has rejected reasonable business solutions that could help manufacturers address 340B and MFP duplicate discount risks through 340B rebate models.[8] The Agency's expectation that manufacturers will be able to rely on claims data submission processes for 340B identification is infeasible given certain state laws and actions by HRSA.

We urge CMS and HRSA to implement a coordinated, comprehensive approach to achieve the IRA's statutory command of no duplicate 340B/MFP discounts. One component of such an approach would be to utilize the claims data repository CMS described in the CY 2025 Medicare Physician Fee Schedule Final Rule[9] for use in the Part D inflation rebate program. In all cases, implementation

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[4] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[5] Final Guidance, p. 55.

[6] Social Security Act (SSA) § 1193(d).

[7] Final Guidance, p. 232.

[8] *See, e.g.*, *Eli Lilly and Co. v. Becerra*, No. 1:24-cv-03220 (D.D.C. Nov. 14, 2024); *Johnson & Johnson Health Care Sys. Inc. v. Becerra*, No. 1:24-cv-03188 (D.D.C. Nov. 12, 2024); *Kalderos v. United States*, No. 1:21-cv-02608 (D.D.C. Oct. 6, 2021).

[9] *See* https://public-inspection.federalregister.gov/2024-25382.pdf

of a repository should be accompanied by clear requirements for covered entities to timely and accurately report claims data with HHS oversight and enforcement.

Q6 – Q7: Primary Manufacturers' plans for calculating the MFP Refund amount.

CMS should clarify that Questions 6 and 7 are only applicable for manufacturers choosing to provide access to the MFP retrospectively. Manufacturers choosing to provide access prospectively would not need to answer these questions.

More broadly, PhRMA has significant concerns with the Agency's statement in the Final Guidance that "SDRA may not be universally appropriate or sufficient to effectuate the MFP."[10] Based on conversations with supply chain experts, we believe the extra charges above WAC are not due to manufacturer prices, but instead additional charges by other supply chain entities (such as wholesalers). In other words, manufacturers have very limited control of pricing in the supply chain beyond WAC. We believe the Final Guidance as written could undermine the integrity of the Drug Price Negotiation Program (DPNP) by creating perverse incentives for dispensers and others in the pharmaceutical supply chain to improperly increase profits through arrangements that artificially increase MFP refund amounts.[11]

Concerns with potential manipulation of prices and profits are not hypothetical, as instances of stakeholders artificially increasing costs to others in the supply chain are abundant. For example, until CMS prohibited the practice beginning in January 2024, Part D plan sponsors could enter into arrangements with pharmacies (or, in some cases, unilaterally impose arrangements) that resulted in the Part D negotiated price being higher than the final payment from the Part D plan sponsor to the pharmacy.[12] The resulting inflated negotiated price increased costs to the federal government in the form of higher low-income subsidies, to manufacturers in the form of higher Part D coverage gap discounts, and to beneficiaries with coinsurance in the form of higher cost sharing, as all of these figures are calculated based on the Part D negotiated price.[13] Similarly, recent work by the Brookings Institution has observed that vertical integration "permits [Medicare Advantage (MA)] plans to circumvent regulations aimed at constraining the profits that can be earned from the MA program." Specifically, "a vertically integrated MA plan can move profits from the MA plan to the

[10] Final Guidance, p. 69.

[11] For example, consider an illustrative selected drug with a WAC of $100 and an MFP of $40. Wholesaler A typically purchases the selected drug from the Primary Manufacturer at a price of $96, and Dispenser B typically purchases the selected drug from Wholesaler A at a price of $98. Utilizing the SDRA, the Primary Manufacturer would owe an MFP refund of $60, giving Dispenser B a margin of $2 on the transaction (excluding dispensing fees) and Wholesaler A likewise a margin of $2. However, consider that Dispenser B could enter into an arrangement with Wholesaler A to acquire the selected drug at a cost of $120. The Primary Manufacturer would then owe an MFP refund of $80. If Wholesaler A agrees to retrospectively refund $10 of the acquisition price to Dispenser B, Wholesaler A would earn a margin of $14 and Dispenser B could earn a margin of $10 (excluding dispensing fees), substantially higher than before.

[12] CMS. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. Final Rule. May 9, 2022. Available at: https://public-inspection.federalregister.gov/2022-09375.pdf

[13] Ibid.

related business. This increases the MA plan's [medical loss ratio] without reducing the parent company's profits, weakening the MLR constraint."[14]

In addition, basing manufacturer refund obligations on acquisition costs that ostensibly exceed WAC would be a unique approach differing from other federal programs that require customer-specific pricing for drugs. For example, in the 340B program, wholesaler chargebacks for 340B-eligible units of covered outpatient drugs are typically calculated using the difference between WAC (regardless of the CE's acquisition cost for the drug) and the applicable 340B price.

Finally, CMS should not be assessing whether a Primary Manufacturer is providing access to the MFP by relying on prices set by an entity other than the Primary Manufacturer (e.g., the price a wholesaler charges a dispenser to acquire a drug). Manufacturers do not control the price at which dispensers purchase drugs from supply chain intermediaries such as wholesalers. PhRMA is highly skeptical that Congress could have intended to obligate Primary Manufacturers to pay an MFP refund based on an unbounded acquisition cost over which Primary Manufacturers have no control given the perverse supply chain incentives.

Thus, PhRMA continues to strongly urge CMS to specify in future guidance that MFP refunds can be no larger than the SDRA (i.e., WAC minus the MFP).

We also recommend that CMS monitor how SDRA MFP refund payments impact dispenser reimbursement in Part D. According to the National Average Drug Acquisition Cost (NADAC) survey, on average, pharmacies acquire single source brand drugs for prices that are about 4% below WAC.[15] Thus, on average, an SRDA MFP refund value results in small overpayment to dispensers. CMS should closely track pharmacy reimbursement by Part D plan sponsors and pharmacy benefit managers (PBMs) acting on their behalf to ensure that Part D plans are not clawing back pharmacy payment.

Q10 – Q11: Alternative Arrangements to Provide Access to the MFP Outside the MTF PM.

While PhRMA appreciates the need to provide CMS with information on alternative arrangements to provide access to the MFP, we urge the Agency to simplify Question 10. For example, if a manufacturer is adopting an alternative arrangement outside of the MTF PM that will apply to all dispensers or a large group of dispensers, CMS should make clear that manufacturers could indicate "all dispensers" or the types of dispensers covered by the alternative arrangement as opposed to uploading the NPIs of over 60,000 pharmacies. Requiring the uploading of individual NPIs is extremely burdensome and of questionable value to CMS in evaluating manufacturer plans.

PhRMA also encourages CMS to provide access to the credit/debit ledger system to manufacturers that choose to utilize alternative arrangements outside the MTF PM to provide access to the MFP. Because manufacturers using alternative arrangements will still be reporting claims-level payment information to the MTF DM, this information can be used to populate a simple, non-dynamic

[14] Frank RG, Milhaupt C. Related businesses and preservation of Medicare's Medical Loss Ratio Rules. *Brookings*, June 2023. https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicares-medical-loss-ratio-rules/
[15] Myers and Stauffer. NADAC Equivalency Metrics. Last Updated September 20, 2024. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf

credit/debit record system. While we understand the credit/debit ledger system could not be used to alter payments for manufacturers utilizing alternative arrangements, it will still be useful to manufacturers in having a central record of payments within the MTF system.

More broadly, PhRMA remains concerned with the Agency's interpretation of the IRA as placing "sole responsibility" to provide access to the MFP on manufacturers, yet at the same time, placing strict requirements on manufacturers if they choose to use an approach outside the MTF PM. For example, CMS is maintaining the requirement for manufacturers to transmit payment to dispensers within 14 days from receipt of MTF DM claim data even if a pharmacy and manufacturer have agreed to a different timeline under an alternative arrangement. And in Question 11, CMS notes that it may request copies of private pharmacy-manufacturer contracts without limitation. Given the Agency's repeated statements that it is "sole responsibility" of manufacturers to provide access, then for arrangements outside of the MTF PM, CMS should defer to terms governing pharmacy and manufacturer agreements.

Q14 – Q18: Information on MFP effectuation for selected drugs with Secondary Manufacturers.

PhRMA continues to maintain significant concerns regarding the Agency's establishment of separate categories of "Primary" and "Secondary" manufacturers and the Agency holding Primary Manufacturers responsible for other distinct corporate entities ("Secondary" manufacturers) to make discounts available on behalf of separate entities. This liability is unworkable and not supported by statute.

Nothing in the IRA authorizes CMS to impose requirements or liability on a legal actor who maintains a distinct corporate identity. The Agency's approach also exceeds its authority, as imposing such requirements is not "necessary for purposes of administering the program and monitoring compliance with the program."[16] In fact, CMS could more easily monitor a manufacturer's compliance if it required separate effectuation plans from Primary and Secondary Manufacturers and entered into separate agreements with such manufacturers. PhRMA has repeatedly explained why CMS' continued stance runs afoul of fundamental corporate law principles. We refer the agency to our comments on the IPAY 2026 guidance, particularly on section 40 of such guidance,[17] as well as Appendix B to our comments on the IPAY 2027 guidance.[18]

[16] SSA § 1193(a)(5)

[17] PhRMA comments are available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/PhRMA-Comments-on-CMS-Initial-Guidance-on-Medicare-Drug-Price-Negotiation-Program22948.pdf

[18] In those comments we noted that "PhRMA continues to object to CMS' unfounded 'Primary Manufacturer/Secondary Manufacturer' construct, including making Primary Manufacturers liable for Secondary Manufacturers' conduct (e.g., failure to make the MFP available) and imposing civil monetary penalties for violations by Secondary Manufacturers. Secondary Manufacturers are distinct corporate entities, and CMS' policy appears likely to result in unforeseen, unworkable scenarios, including situations where a Primary Manufacturer may need to provide or receive proprietary data from the Secondary Manufacturer in order to comply with CMS' policy, conflicting with fundamental corporate law principles, such as that independent corporations are distinct legal entities with limited liability. *See, e.g.*, Fletcher, *Fletcher Cyclopedia of the Law of Corporations*, §§ 28-29; Phillip I. Blumberg, *Limited Liability and Corporate Groups*, 11 J. Corp. L. 573, 591–592 (1986); Franklin A. Gevurtz, *The Globalization of Corporate Law: The End of History or A Never-Ending Story?*, 86 Wash. L. Rev. 475, 487 (2011); Douglas G. Smith, *A Federalism-Based Rationale for Limited Liability*, 60 Ala. L. Rev. 649, 667 (2009)"

We continue to urge CMS to abandon the Primary and Secondary Manufacturer construct in future guidance.

Q21: Primary Manufacturers' processes for effectuating the MFP outside of the MTF PM.

PhRMA urges CMS to clarify that Primary Manufacturers can respond to Question 21 by providing information that is aggregated across dispensers or types of dispensers. We believe reporting at the aggregate level will still provide CMS with the information required from manufacturers choosing not to participate in the MTF PM but will help to minimize the burden on Primary Manufacturers.

Q22: Interactions with dispensing entities with material cashflow concerns.

PhRMA is opposed to the requirement to develop mitigation plans for dispensers with material cashflow concerns. While we share the Agency's goal of ensuring dispensers are paid promptly, we continue to believe that the best, least burdensome, and most efficient way to effectuate the MFP would be for CMS to utilize an approach similar to the Part D CGDP, including pass-through of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication with manufacturers invoiced at a later date. This should be paired with a claims data repository to deduplicate 340B and MFP claims, as noted above, with required reporting by covered entities and HHS oversight and enforcement.

In addition, PhRMA has significant concerns with the fact that the mitigation plan requirement was not included in the draft guidance for MFP effectuation in 2026 and 2027.[19] By introducing this new concept solely in the Final Guidance, CMS deprived stakeholders, including manufacturers, of the opportunity to provide comment and input.

If the Agency continues to decline to adopt an MFP effectuation model similar to the CGDP with pre-funded MFP refunds, then we would strongly encourage CMS to provide more transparency about the types of mitigation plans the Agency is expecting. While we appreciate the ability of Primary Manufacturers to develop qualifying criteria for their mitigation plans under Question 22C, the lack of clarity from CMS on what types of qualifying criteria and types of mitigation plans the Agency would consider acceptable presents significant uncertainty and compliance burden on Primary Manufacturers.[20] CMS should also affirmatively acknowledge that Primary Manufacturers are permitted to require that any pharmacies claiming material cashflow concerns provide documentation to support such claims.

We also ask that CMS monitor Part D plan sponsor and dispenser actions surrounding the mitigation plans. PhRMA is concerned about unintended outcomes in response to different manufacturers developing different mitigation plans.

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[19] *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[20] *See* Final Guidance, p. 287: "CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP effectuation plan."

Other topics for comment in Appendix B.

Confidentiality of manufacturer effectuation plans.

PhRMA appreciates the change made by CMS in the Final Guidance to limit distribution of the MFP effectuation plans to dispensers through the MTF DM. However, we remain concerned about protecting the confidentiality of proprietary information that may be included in the MFP effectuation plans. We recommend that CMS add a field to the MFP effectuation plan form that would enable Primary Manufacturers to indicate which information is proprietary and would need to be redacted upon distribution to dispensers through the MTF DM.

In addition, prior to effectuation plans being distributed, CMS must ensure that Primary Manufacturers are provided an opportunity to object to the distribution of any confidential commercial information, as required by HHS' FOIA procedures in 45 C.F.R. Part 5, Subpart D.

Document uploads.

PhRMA recommends that CMS allow Primary Manufacturers to upload documents for a broader number of questions, including Questions 4, 10, 15, 16, 17, 21, and 22. This would give Primary Manufacturers the option to include a schematic or other visual that may help to clarify written explanations. Alternatively, CMS could also provide the option to upload documents at the end of the form, and Primary Manufacturers could reference those attachments in their answers to individual questions.

IV. Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

General comments.

PhRMA urges CMS to provide mathematical or numerical examples for the payment element fields as the Agency continues to work to implement the MTF PM. This would be similar to the mathematical examples CMS provided as part of the Medicare Prescription Payment Plan guidance and materials. Providing these examples in advance will allow CMS and the MTF PM contractor to pressure test the payment field formats and provide time for field adjustments if necessary.

In addition, PhRMA continues to urge CMS to add a de-identified beneficiary ID field to the MTF DM data elements. We agree with the Agency that this field would not be useful to manufacturers for verifying beneficiaries' Medicare eligibility.[21] Rather, this field is necessary to help avoid erroneous duplicate claims for the same Medicare beneficiary. PhRMA appreciates that both Part D plan sponsors and the DDPS will be verifying Medicare eligibility, but neither entity appears to be

[21] *See* Final Guidance, pp. 205 – 206: "The provision of additional patient information (such as an encrypted "Medicare Beneficiary Identifier") by the MTF DM will not help the Primary Manufacturer to verify the selected drug was dispensed to an MFP-eligible individual because the Primary Manufacturer would also need access to the individual's Medicare eligibility status to verify eligibility."

scrubbing claims data for duplicates or other types of claim errors. By providing manufacturers with a randomized, de-identified ID field that is unique to each Medicare beneficiary, CMS can protect patient privacy while making it easier and faster for manufacturers to verify that no claim records received from the MTF DM are duplicates, improving efficiency and lessening disputes.

Quantity of Selected Drug field.

We encourage CMS to clarify how manufacturers should report the "Quantity of Selected Drug" field. For example, should manufacturers use the same quantity included in the "Quantity Dispensed" data field included in the elements shared by the MTF DM?

V. Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

To lessen the burden on all stakeholders in the supply chain, PhRMA recommends that CMS aggregate or batch disputes for dispensers by parent organization or by Pharmacy Services Administrative Organization (PSAO) for dispensers participating in a PSAO. This would lessen the volume of separate disputes and improve efficiency.

VI. General Comments Across Appendices

In Appendices B, C, and D the ICR notes that both questions about the ICR and technical assistance questions should be sent to "XXX@xxx.xxx". This appears to be a placeholder email address, which one is not able to utilize to ask questions of the Agency. For example, in Appendix B the ICR notes, "For technical assistance related to the submission of information in the MTF DM, questions should be sent to XXX@xxx.xxx. Questions about MTF DM user access should be sent to XXX@xxx.xxx."

Moreover, the ICR directs users to several placeholder URLs noted as [SYSTEM URL]. For example, in Appendix B the ICR notes, "Primary Manufacturers will submit the information for Sections 1 through 6 via the MTF DM, which can be accessed here: [SYSTEM URL]."

Primary manufacturers need usable email addresses and URLs in order to direct their questions and gain the necessary information to complete required information as outlined in this ICR. We urge CMS to include working email and URL addresses in the next iteration of the ICR.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Should you have any questions, please feel free to reach out to us at the email addresses below.

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