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May 1, 2025

William Parham
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Information Collections and Regulatory Impacts
Attention: CMS-10912

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912)

Dear Director Parham,

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) Information Collection Request (ICR): Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912, OMB 0938-NEW).

At Johnson & Johnson (J&J), we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver tomorrow's breakthroughs to our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries. Our strength in both biology and medical technology means we are accelerating advances in care – from cell therapy to AI-assisted robotic surgery. We are using our wide range of expertise to address healthcare challenges that can be tackled by medical technology and innovative medicine, such as cancer, cardiovascular disease, and eye health. Our reach and depth across a continuum of healthcare and technology solutions give J&J the ability to impact health for humanity profoundly.

J&J appreciates the opportunity to comment on the revised Medicare Transaction Facilitator (MTF) forms. J&J recognizes the changes made by CMS including to increase the

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burden estimates and to clarify which questions from manufacturer Maximum Fair Price (MFP) Effectuation Plans will not be made public. However, with the January 1, 2026 start for initial payment year (IPAY) 2026, and the complexity of the technology build leading up to "go live", we underscore that manufacturers require immediate clarification on the MTF technical requirements and functionality to enable compliance with statutory obligations. Additionally, as manufacturers are developing systems with limited visibility of the end-to-end technical requirements, we strongly urge CMS to implement safeguards against civil monetary penalties (CMPs) for manufacturers acting in good faith for circumstances outside of their control.

Manufacturers Require Immediate Clarification on MTF Technical Requirements and Functionality

In J&J's December 23, 2024 response to CMS' initial ICR (see Appendix A), we outlined our position that CMS must implement a solution to enable 340B data transparency to improve program integrity and prevent duplicate discounts on eligible claims, and to address pharmacy cashflow concerns. J&J also underscored that manufacturers' ability to design and build systems to support MFP effectuation and integration with the Medicare Transaction Facilitator (MTF) relies upon having a clear understanding of CMS / MTF technical requirements. We recommended that CMS expedite the MTF build and enhance collaboration with manufacturers by implementing a co-development process, including sharing comprehensive end-to-end technical requirements with impacted manufacturers by March 1, 2025. Following the submission of those comments, J&J has continued to advocate for greater transparency regarding the technical requirements and specified our limited capacity to implement any new technical requirements communicated to manufacturers after April 15, 2025, by the go-live deadline of January 1, 2026.

Manufacturers Acting in Good Faith Should Receive Protection from Civil Monetary Penalties for Circumstances Outside of their Control

J&J appreciates the ongoing engagement with CMS, including the monthly manufacturer calls and the assignment of dedicated personnel to facilitate quicker responses to manufacturer inquiries. However, given that CMS is leveraging an agile process, the lack of visibility to end-to-end technical specifications, including critical components such as transaction codes and detailed information on the credit ledger process, has forced us to make our own assumptions in finalizing the development of our system build strategy. J&J is documenting these assumptions and will communicate them to CMS including in the submission of our MFP effectuation plan on September 1, 2025. J&J strongly urges CMS to provide adequate protection from civil monetary penalties (CMPs) for manufacturers

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acting in good faith, particularly in circumstances beyond their legal and operational control. This includes delays in CMS' release of technical MTF specifications that extend beyond the communicated, requisite manufacturer build timelines, as well as issues related to MTF operations.

Recommendations on the MFP Effectuation Plan Form

Section 4, Q22B on the MFP Effectuation Plan Form requires the Primary Manufacturer to describe its process for mitigating material cashflow concerns for dispensing entities. J&J acknowledges the financial challenges faced by pharmacies; however, it is important to emphasize that manufacturers have limited capacity and no statutory obligation to address these cash flow concerns. Financial reporting obligations under the Sarbanes-Oxley Act require manufacturers to ensure that payments provided to customers or third parties are substantiated and directly linked to specific purchases.[1] Compliance with these legal requirements limits a manufacturer's ability to resolve pharmacy cash flow issues. As previously recommended (see Recommendation III in Appendix A), J&J continues to urge CMS to leverage its statutory authority to establish a CMS pre-funded MFP discount pool to effectively mitigate these pharmacy cashflow concerns and reduce financial and operational burden for pharmacies and all stakeholders.

Recommendations on the Complaints and Dispute Form

J&J continues to ask CMS to clarify the details of the complaint and dispute process and how the dispute system will function, including clarification that the centralized complaint and dispute intake system will provide manufacturers with the ability to create, upload, download, and respond to disputes, including the ability to respond to thousands of lines at a time if needed. We refer CMS to J&J's December 23, 2024 comments on the Drug Price "Negotiation" Program Complaint and Dispute Intake Form (see Appendix A), where we outline our open questions related to timeframes required for responses, details on disputing errors, incomplete data and manufacturer complaints related to claims data provided by the MTF-DM, and handling of disputes with the MTF-DM and PM, including those related to reversals, payment, and check remittance. We underscore that to respond to disputes related to payment information, manufacturers will require visibility of claims level details and supporting documentation (redacted) to verify and resolve.

J&J continues to urge CMS to clarify its process for managing patient level information in the disputes and compliant process and ensuring compliance with all requirements under HIPAA. For example, for document upload functionality, J&J asks CMS to confirm it will

[1] Sarbanes-Oxley Act of 2002 can be cited as Public Law 107-204

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ensure evidence is protected and redacted. In addition, under Section 3: Privacy Statement, we ask CMS to provide a proper venue for managing proprietary information.

The General Instructions for the Complaints and Disputes Form states that "complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute." As outlined in J&J's December 23, 2024 ICR response, 340B data is not typically available to manufacturers within 120 calendar days from a claim. Without a CMS-driven solution for 340B transparency, manufacturer efforts to meet statutory requirements and maintain fiduciary responsibility for compliance with financial reporting requirements under the Sarbanes Oxley Act will require the use of unregulated, incomplete, and non-standardized third-party data. Most 340B data made available to manufacturers from third-party agreements is typically received up to 6 months after a claim (if at all), and not all manufacturers have access to this third-party 340B data. Therefore, 340B reconciliation will typically take place outside of the 120-day window, and therefore, 340B reconciliation should not be considered a dispute. Instead, manufacturers require the ability to seamlessly reopen a claim and process a 340B offset using the credit ledger at any point when a 340B claim is identified. We ask CMS to confirm this assumption and related documentation requirements for manufacturer MFP effectuation plans.

Dispensing Entity Enrollment Form

Under Section 2: Dispensing Entity, Questions 1 and 2, the form allows dispensing entities to verify the accuracy of the identifying information prepopulated from the NCPDP dataQ Pharmacy Database, or to provide responses if the dispensing entity has not opted to authorize use of the NCPDP dataQ Pharmacy Database. J&J asks CMS / the MTF to provide manufacturers with any data provided in response to these questions that is not present in the dataQ Pharmacy Database. This information should be provided to all manufacturers of selected drugs, including those opting out of participating in the MTF-PM.

J&J also asks CMS to clarify that the payment information provided by dispensing entities in this form, including Section 3: Dispensing Entity Financial Information, will not inform how the dispensing entity will appear on the ledger, and that the payment destination and ledger functionality will be distinct from one another.

Manufacturer Payment Elements Form

In addition to the issues raised in our previous ICR comments, we ask CMS to address the following questions.

- General Instructions - Submission Method

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- We ask CMS to clarify its process for receiving MFP refund amount payments and payment elements on Banking Holidays and non-banking business days and recommend that non-banking business days be excluded from the 14 day prompt MFP payment window.

- Section 1: Payment Element 3: (Method for Determining MFP Refund Amount)
  - J&J asks CMS to further clarify Code 4 (No Refund Transmitted – Section 1193(d)(1) Exception), and Code 7 (Refund Transmitted Consistent with Alternative Reconciliation). Specifically, we ask CMS to clarify which code should be used to identify an incorrect MFP refund amount payment when the claim is later identified as 340B.
- Section 1: Payment Element 4:
  - We ask CMS to clarify that there will be no negative values in the Quantity of a selected drug payment element, and that zero values are allowed.
  - Moreover, we are aligned to PhRMA's recommendations to expand Code 4 to to include the scenario where the 340B ceiling price equals the MFP; add an additional payment element code for manufacturer payment of the difference between the 340B ceiling price and the MFP when the 340B ceiling price is higher than the MFP. We also recommend CMS clarify that manufacturers utilizing the MTF PM can use the credit/debit ledger system to make these adjustments for claims identified as 340B outside of the 14-day prompt MFP payment window.
- Section 1: Payment Element 5: (Amount of Payment Transmitted as the MFP Refund)
  - J&J urges CMS to explicitly clarify and ensure that the MTF will never pull funds from manufacturer bank accounts, including for adjustments, unless the Manufacturer approves the withdrawal.

Johnson & Johnson appreciates the opportunity to provide these comments. For questions or more information, please contact jroche8@its.jnj.com.

Sincerely,

Jacqueline Roche

Jacqueline Roche, DrPH
Head Payment and Delivery Policy
Johnson & Johnson

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Appendix A

December 23, 2024

VIA Electronic Filing – http://www.regulations.gov

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) (CMS-10912, OMB 0938-NEW)

Dear Director Parham:

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J&J is committed to collaborating with CMS to achieve a workable model for the effectuation of the "Maximum Fair Price" ("MFP") for IPAY 2026. We appreciate our ongoing engagement with CMS to work collectively toward our shared implementation goals; however, we are deeply concerned about the significant work ahead to achieve a successful implementation model that is workable for all stakeholders. As we move closer to January 1, 2026, J&J strongly urges CMS and the Medicare Transaction Facilitator(s) (MTF) to collaborate closely with manufacturers of selected products to co-create and test the MTF processes for IPAY 2026. Urgency in establishing a governance model and cadence for meaningful collaboration is critical, as clarity on specific MTF requirements and process flows is needed to inform manufacturer process design and build for operational readiness.

CMS must act now to advance joint decision-making to define critical MTF system and process requirements, implement a CMS solution for 340B data transparency, and adopt a pre-fund model to address pharmacy cashflow concerns. Comments on these recommendations are below.

I. CMS Must Act Now to Advance Joint Decision Making on System and Process Requirements

Clarity on operational requirements is needed so manufacturers can build, test, and execute systems effectively for January 1, 2026 "go-live." The MTF and manufacturers must collaborate to define these requirements to ensure successful process integration and system operability. To promote alignment on critical decisions for the "MFP" effectuation process, CMS should form a joint governance model that prioritizes transparency with manufacturers. For example, manufacturers need visibility to CMS' detailed development timeline with clear development milestones for MTF systems and processes (for example, data exchange to and from the manufacturer). MTF requirements should be shared transparently with manufacturers and should not be considered proprietary because this level of transparency is needed for manufacturer system builds and to and enable successful integration between manufacturers and the MTF.

- *Immediate Alignment on MTF Requirements Needed to Enable Fully Operational Manufacturer Systems by September 1, 2025*

Given the September 1, 2025 deadline for manufacturers to submit MFP effectuation plans to CMS, and the need for testing and implementation prior to "go-live," manufacturer systems must be fully operational by September 1, 2025. Despite this urgent timeline, we are concerned that foundational components of the effectuation process remain unclear, undeveloped, or otherwise still need to be addressed by CMS, which will delay the manufacturer development process and the ability for manufacturer compliance. Manufacturers cannot design and build systems without clearly understanding CMS submission requirements.

To enable manufacturer process design, manufacturers need visibility to MTF technical requirements, including the MTF's capabilities to receive payment data, details of the credit/debit ledger including its design and functionality, the MTF DM data transmission process including format (i.e. Secure File Transfer Protocol (SFTP) or other methods), transmission cadence details (i.e. day of transmission = day zero), clarification on when CMS will provide list of NPIs of participating dispensing entities to manufacturers, and details on the dispute and

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appeals process. We stress that the time is now for joint decision-making on these system and process for a successful go live on January 1, 2026.

- *CMS Should Commit to Providing CMP Relief to Manufacturers Making Good Faith Efforts to Comply if MTF Systems and Requirements Are Not in Place*

Section 1197 of the Act states that manufacturers may be subject to civil monetary penalties (CMPs) for failure to ensure access to the MFP for MFP eligible individuals.[2] CMS Guidance further specifies that manufacturers may be subject to CMPs for failure to process timely and complete reimbursement under a retrospective reimbursement structure as provided in the Guidance.[3] CMS has stated that it will establish an MTF to facilitate effectuation of the "MFP" for IPAY 2026. If CMS does not define critical details required for manufacturers to build and test systems to effectuate the "MFP" through the MTF (including MTF processes and data submission requirements), manufacturer compliance with the statute will be infeasible. This will result in significant risk to beneficiary access to selected drugs and CMPs for manufacturers, despite manufacturers' good faith efforts and willingness to meet compliance obligations and provide access to the "MFP".

Manufacturers cannot be subject to CMPs on the basis that they failed to ensure access to the MFP or process timely and complete reimbursement under a retrospective reimbursement structure for factors outside of their control, including if CMS has not defined critical requirements before March 1, 2025. J&J asks CMS to clarify that the Agency will establish a safe harbor from CMPs for manufacturers making good faith efforts to comply with the statute if the Agency fails to define by March 1, 2025 the critical requirements and/or the Agency fails to establish an operational MTF before January 1, 2026.

II. CMS Must Provide a Solution for 340B Claims Transparency to Enable Statutory Compliance

The IRA stipulates that the "MFP" for a selected drug must be provided in a nonduplicated amount to the 340B ceiling price when a CE or contracted pharmacy of a CE dispenses or administers a selected drug to an eligible patient.[4] We strongly urge CMS to provide a solution to enable 340B claim transparency required for manufacturers to comply with the statute and avoid duplicate discounts on the same claim.

Without a CMS solution for 340B transparency, manufacturer efforts to meet statutory requirements and maintain fiduciary responsibility will require the use of unregulated, incomplete, and non-standardized third-party data. Most 340B data received from third-party agreements will not be available to deduplicate payments in the 14-day payment window envisioned by CMS. Data that may be made available through third-party agreements is typically received up to 6 months after a claim (if at all), and not all manufacturers have access to this third-party 340B data. As a result, avoiding duplicate discounts in compliance with the statute

[2] Social Security Act (SSA) § 1197(c)
[3] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf
[4] SSA § 1193(d)(1)

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will not be possible for all claims. This will result in a high volume of disputes, and certain 340B duplicate claims will never be identified due to data challenges.

- *Mandatory 340B Modifiers Paired with the Establishment of a Comprehensive 340B Data Repository Are Needed to Support Program Integrity and Statutory Compliance*

J&J strongly urges CMS to establish a 340B Part D Claims Repository that has utility across CMS programs and is not limited to the Inflation Rebate Program. We urge CMS to act with urgency to establish this Repository that can also be used to support compliance with the statutory prohibition of duplicate 340B and "MFP" discounts under "MFP" Effectuation. In establishing the Repository, we recommend that CMS require CE participation, including mandating accurate and complete CE reporting of claims data to the Repository, and that CMS ensure manufacturers receive claim level transparency to enable audits and data validation.

To ensure the accuracy of claims added to the Repository, J&J also urges CMS to mandate the use of 340B modifiers on all pharmacy claims that are applied consistently across all channels to help verify 340B claims. Voluntary use of modifiers is insufficient because, in our experience, a very limited number of CEs voluntarily provide the 340B modifier. We are concerned that a lack of sufficient 340B data transparency will impede program integrity and result in a high volume of future disputes. Mandatory and timely use of 340B claim modifiers is critical to enable manufacturers and CMS to accurately identify 340B claims to avoid duplicate discounts, as required by statute.

- *CMS Must Ensure Covered Entity Compliance and Accountability for Data Accuracy*

We note that a successful 340B data transparency solution will requires CE compliance and accountability for data accuracy. Flawed data and improper use of required modifiers introduce program integrity risks. Therefore, to ensure the accuracy and completeness of data added to the Repository, we encourage CMS to require attestations from CEs on the accuracy and completeness of data, conduct periodic audits of data in the Repository, and establish data validation processes. Additionally, to enforce CEs' compliance with required modifiers, we recommend that CMS reject Part D claims submitted without required modifiers and that CMS conduct periodic audits on their appropriate use.

III. CMS Should Pre-Fund the "MFP" Discount Amounts to Address Dispensing Entity Cash Flow Concerns

A workable model for MFP effectuation is critical to ensuring beneficiary access to their medications and adequate pharmacy reimbursement. Cash flow risks facing dispensing entities will negatively impact beneficiaries. J&J is concerned that as a result of these cash flow risks, over 90% of independent pharmacists have stated they cannot provide patients with access to their medications when the program goes into effect.[5] In meetings with CMS and in our past comment letters, J&J has urged the Agency to leverage its statutory authority to pre-fund the "MFP" discounts to mitigate these risks and other significant operational issues. We are very

[5] https://ncpa.org/newsroom/news-releases/2024/10/15/independent-pharmacies-reluctant-stock-drugs-medicare-negotiation

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concerned that CMS has not implemented our proposed solution and instead intends for manufacturers to address these cashflow concerns through its guidance.

- *Manufacturers Have No Statutory Mandate and Lack the Ability to Address Pharmacy Cashflow Concerns*

CMS' envisioned process of requiring manufacturers to submit plans to address pharmacy cashflow concerns is perfunctory, as manufacturers have no capability or mandate to mitigate these concerns. Instead, a meaningful solution is for CMS to pre-fund the "MFP" discounts. Under a CMS pre-fund model, dispensing entities would receive the "MFP" discount amount on eligible claims in a timely manner while enabling a reconciliation process with manufacturers for those amounts on a regular quarterly billing cycle. A CMS pre-fund model reduces financial risk for pharmacies, thereby reducing negative consequences on beneficiary access. A CMS pre-fund improves workability for all stakeholders and also supports program sustainability as the number of manufacturers and selected products grows.

J&J's comments on the ICR Forms are below.

Supporting Statement Appendix:

- *CMS Is Underestimating Burden to Complete the ICR Forms*
  J&J is concerned that CMS is significantly underestimating the burden required of manufacturers to complete the ICR forms. CMS estimates do not reflect the considerable system demands, time, and personnel resources required to prepare and submit the manufacturer plans. This will involve significant effort and input from internal teams, outside legal counsel, and consultants. In addition, given the anticipated high volume of claims and disputes, CMS is also underestimating the burden of sampling and analyzing data for the MTF DM payment elements form and preparing and submitting disputes. We urge CMS to engage with manufacturers to provide more realistic burden estimates.

Drug Price Negotiation Program MTF DM Primary Manufacturer "Maximum Fair Price" Effectuation Plan Form (Appendix B)

- *Question 3: Primary Manufacturer's Process for Communicating with Dispensing Entities*

  J&J urges CMS to expressly recognize that Primary Manufacturers can use the MTF's credit/debit ledger to communicate "MFP" effectuation information to dispensing entities.

- *Question 4: Primary Manufacturer's Process for Identifying 340B Eligible Claims*
  CMS requires Primary Manufacturers to describe their "valid and reliable" process for identifying 340B eligible claims. Given that manufacturers lack visibility to data required to identify 340B eligible claims, as described in our comments above, we ask CMS to

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acknowledge that it will defer to the Primary Manufacturer's definition of "valid and reliable", which will include reliance on non-standardized data sets that are not available to all manufacturers. Additionally, we note that a 340B reconciliation should not be considered a dispute, and manufacturers should be able to seamlessly reopen the claim and process 340B reconciliation offsets via the ledger.

Furthermore, we note that CMS has alluded to inconsistent standards for identifying 340B eligible claims through its various guidance documents and rules. In defining the Inflation Rebate Program in the CY2025 Physician Fee Schedule Rule, CMS noted that NPIs can be used to identify 340B claims.[6] However, CMS notes that NPI would not be sufficient in the IPAY 2027 Guidance.[7] We ask CMS to clarify this inconsistency and to adopt a standardized approach.

- *Question 5 – Frequency of Manufacturer Transmission of Payment Elements to the MTF DM*
  Primary Manufacturers are required to describe their planned frequency for transmitting claim-level payment elements to the MTF DM. To provide this information, manufacturers need CMS to provide details on the MTF DM's data capabilities and requirements for receiving data. We also recommend that CMS acknowledge that manufacturers cannot submit claim-level payment elements during certain times, such as banking holidays.

- *Question 6: Primary Manufacturers' Plans for Calculating the "MFP" Refund Amount*
  J&J urges CMS to clarify that "MFP" refunds should never exceed the Standard Default Refund Amount (SDRA, i.e., WAC—"MFP"). This is important not only because manufacturers have no control over the price at which dispensers purchase drugs from supply chain intermediaries that may exceed WAC, but also to remove potential perverse incentives for supply chain actors to improperly inflate prices to increase "MFP" refund amounts artificially. J&J is aligned with PhRMA's comments on this issue.

  Further, J&J recommends that CMS monitor how the Medicare Drug Price "Negotiation" Program impacts plan reimbursement to dispensers. For example, CMS should monitor and mitigate formulary tactics that would reduce patient access to or result in higher patient cost sharing for selected products, including increasing utilization management, requiring non-medical switching, or moving products to lower / coinsurance formulary tiers.

- *Questions 14 – 18: Information on "MFP" Effectuation for Selected Drugs with Secondary Manufacturers*

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[6] 89 FR 97710; https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other

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

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J&J continues to assert that Primary Manufacturers cannot be held responsible for secondary manufacturers or third-party manufacturers with whom they have no contracts. We have reiterated this concern in our comments on the CMS' IPAY 2026 and 2027 Guidance. We continue to urge CMS to abandon the Primary and Secondary Manufacturer construct.

- *Question 22: Dispensing Entities with Material Cashflow Concerns*
  As outlined above, J&J is opposed to the requirement for manufacturers to develop mitigation plans for dispensing entities with cash flow concerns. We urge CMS to remove this question or make it optional for manufacturers.

  In addition, Question 22 requires the Primary Manufacturer to acknowledge that it "will be provided" a list of dispensing entities with material cashflow concerns. We note that manufacturers cannot acknowledge that something "will be" provided. Manufacturers can only provide this acknowledgment once the list is provided.

- Other Topics for Appendix B:

  Manufacturers have no visibility into CMS Confidentiality Practices to protect the confidentiality of manufacturer plans, including, for example, manufacturer-contracted prices outside of the standard default refund amount. We ask CMS to 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 dispensing entities through the MTF DM.

  In addition, we ask CMS to allow Primary Manufacturers to upload documents for a broader number of questions, including Questions 4, 10, 15, 16, 17, 21, and 22.

Drug Price "Negotiation" Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)

As with other aspects of this ICR, many details that Primary Manufacturers require clarity around are not addressed. For example, we ask CMS to clarify how many log-on credentials a manufacturer will be provided to the MTF DM system. This is important to inform the design of Primary Manufacturer processes. We note that manufacturers will require technical instructions to access the MTF DM. Furthermore, Primary Manufacturers should have ample opportunity to submit test transmissions of payment and claim-level data elements.

We also ask CMS to clarify the process for manufacturer transmission of updated payment elements when adjustments are needed. In instances when a previously paid claim requires an adjustment to the corresponding payment amount, as determined by the Primary Manufacturer, we recommend that manufacturers should be able to retransmit the claim elements, with the

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ledger subsequently adjusting automatically to reflect the adjustment. This capability would minimize the manufacturer's burden in the adjustment process.

Drug Price "Negotiation" Program Complaint and Dispute Intake Form (Appendix D)

- *Overview*

  CMS notes that complaints and disputes must be submitted to CMS no later than 120 days after the subject of the complaint or dispute. We ask CMS to provide greater clarity by defining “date of the subject of the complaint or dispute”. For example, it could be the date of the claim for Rx fulfillment or the date of manufacturer payment.

  CMS outlines its plan for the MTF to route issues to either a “dispute” or “complaint” route. J&J asks CMS to clarify how the MTF will determine if a submission is routed as a complaint or dispute and to provide details on the timeline for making that determination.

- *Question 1: Contact Information*

  J&J recommends that CMS add Question 1C to require the submitter to identify whether they are a 340B Covered Entity or a Contract Pharmacy working for a Covered Entity. This should be required in the CMS form.

- *Question 3: Issue Category*

  J&J recommends that CMS reorder Questions 2 and 3 and that the issue category identified in Question 3 determine which responses under Question 2 (Selected Drug & Claim Information) are either optional or required. For example, if the submitter identifies the issue category as related to a claim issue, then responses to Questions 2A through 2I should be required and not optional. However, if the submitter identifies the issue category as related to a technical process issue, then Questions 2A through 2I could be optional.

  CMS provides an issue category for identifying issues related to the relationship between the “Negotiation” and 340B Programs. When this category is indicated for disputes involving a manufacturer-applied justification code of “4” for 340B, J&J recommends that CMS require the dispensing entity to provide evidence that the claim is not a 340B claim or has not already been paid via 340B payment.

- *Question 5: Supporting Documentation*

  J&J recommends that CMS add zipped files and other archival/compression file types to the list of allowed extensions for document upload.

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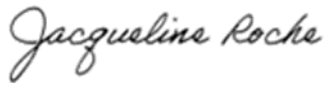
- *Other Complaint and Dispute Topics*
  J&J asks CMS to clarify the details of the complaint and dispute process. For example, manufacturers require details to understand how the dispute system will function, and we recommend that CMS clarify that the centralized complaint and dispute intake system will provide manufacturers with the ability to create, upload, download, and respond to disputes, including the ability to respond to thousands of lines at a time if needed. We note that to respond to disputes related to payment information, manufacturers will require visibility of claims level details and supporting documentation (redacted) to verify and resolve.

  Lastly, we ask CMS to clarify how it will protect patient-identifying information, including when supporting documentation is uploaded. We also ask CMS to provide the proper venue for encrypting, exchanging, and protecting any potential proprietary or confidential information.

Johnson & Johnson appreciates the opportunity to provide these comments. For questions or more information, please contact jroche8@its.jnj.com.

Sincerely,



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