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VIA ELECTRONIC DELIVERY

William N. Parham III
Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Notice of Agency Information Collection Activities: Submission for OMB Review; Comment Request (CMS-10110): *Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals*[1]

Dear Director Parham:

Amgen Inc. ("Amgen") appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services ("CMS") regarding the above-referenced Notice of Agency Information Collection Activities (the "Notice"). We applaud CMS's efforts to modernize the ASP reporting system and documentation, and we are pleased to provide feedback on the Notice and its supporting materials.[2]

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics, and promoting high-quality care for patients. Amgen develops innovator medicines and biosimilar biological products, and our interest is to ensure a robust market for, and improve patient access in the United States to both innovator and biosimilar biological products. We believe that clear average sales price ("ASP") reporting guidance is one important means by which CMS can help to ensure that all manufacturers, including Amgen, are able to report accurate ASP data using the same rules and standards. Such guidance will support more consistent pricing and reporting decisions across the market. And effective systems to implement such guidance are critical.

[1] 89 Fed. Reg. 41,968 (May 14, 2024).
[2] Supporting materials available at: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10110 (last visited May 30, 2024).

As an initial matter, we understand that CMS has already rolled out much of the supporting system documentation relevant to the Notice in connection with its April 2024 updates to the ASP Module. And, while we are generally supportive of CMS's updates, we believe there are a number of issues in the documentation and related systems that could use additional clarification and/or revision. In summary we believe that CMS should:

- Subject any affirmative restatement obligation to formal notice/comment rulemaking;
- Clarify its guidance and configure the ASP Module to: (1) allow more than one individual per Submitter or Certifier role per Labeler code (with access to historic data), (2) allow manufacturers to voluntarily limit system access for certain individuals, similar to what is permitted in the Medicaid Drug Products System, and (3) develop and publicize a process by which a manufacturer may expeditiously terminate and/or add a user;
- Clarify the "Notes" to the "Instructions" in the New Financial Data Template, and confirm no manufacturer liability for submitting/certifying data under the previous template in connection with the apparently deleted "Notes" descriptions;
- Update the Average Wholesale Price (AWP) field "Notes" to the "Instructions" in the New Financial Data Template;
- Expedite processing of new "Generic Names," and update fields as soon as possible (at a minimum with new medications within same calendar quarter as requested);
- Provide detailed instruction on how to select among the "Unit of Volume Per Item" unit types;
- Provide detailed instruction on how to select among the "Unit for Strength" unit types;
- Clarify "Notes" to "Instructions" in the New Product Data Template and delete "Must be after the First Marketing Date" from the Note to "Date of First Sale;" and
- Update its systems and guidance to expressly permit the extension of the ASP reporting deadline to the next business day, where the deadline otherwise falls on a federal holiday or weekend.

Each of these recommendations are described in more detail below.

I. SUBMITTER AND CERTIFIER USER GUIDES

A. CMS should subject any affirmative restatement obligation to formal notice/comment rulemaking.

The draft "Submitter User Guide" includes the following statement: "Manufacturers of drugs and biologicals payable under Medicare Part B have an obligation to report accurate ASP data to CMS, including addressing data miscalculations and other errors in previously submitted data. *Upon* identifying an error, manufacturers *must* submit corrected data through the ASP Module."[3] We are not aware of a statutory or regulatory obligation that affirmatively requires restatement of previously submitted ASP data. And, as the HHS Office of Inspector General has noted previously, manufacturers have specifically expressed a need for additional guidance regarding "[t]he circumstances under which manufacturers should or must refile ASP data or the historical period for

[3] CMS, Medicare Part B ASP Module: Submitter User Guide, ver. 0.1, § 3.4 (Jan. 22, 2024) (emphasis added). It is not entirely clear which version of the Submitter User Guide is subject to comment as part of the Notice. This is because the supporting materials for the Notice link to a file containing "Version 0.1, Date January 22, 2024" of the Guide, but CMS's current CMS's ASP Education & Outreach website links to an apparently newer version of the file, containing "Version 1.0, Date: March 15, 2024" of the Guide. Our comments below apply to either version of the Guide, but *we recommend CMS confirm the version numbers and dates are accurate*.

which such refiling should be considered."[4] This sub-regulatory guidance does not address these concerns. Rather, the Submitter User Guide appears to impose a new affirmative obligation that has not been subject to full notice and comment rulemaking. We further note that an obligation to restate data into perpetuity is not practical, given that there is no guidance regarding record retention requirements applicable to the ASP calculation, and also given that restatements outside of a certain period of time would have no impact on any outstanding Medicare payment obligations. Moreover, we are concerned that the "upon" language suggests an immediacy that is not reasonable, given that manufacturers will generally need to test and vet potential errors carefully before calculating and submitting revised ASP data, in order to ensure such restated data can be certified as regulation requires.[5]

Separately, CMS has been clear, in connection with Medicaid average manufacturer price ("AMP") restatement regulations, that restatement is not required "when the revision would be solely as a result of data pertaining to lagged price concessions."[6] Given the similar calculation mechanics applied in calculating both AMP and ASP—in which lagged price concessions are estimated using a data from a 12-month/4-quarter period[7]—we believe it is reasonable to assume that restatement of ASP is *also* not required solely on the basis of lagged transactions. However, the Submitter User Guide is unclear on this point.

We are concerned by the lack of clear timing and process implied by the Submitter User Guide language regarding restatement, and ***we believe that any affirmative ASP restatement requirement, if adopted, represents a new obligation on manufacturers that should be subject to formal notice/comment rulemaking as a "substantive rule," consistent with the Administrative Procedures Act.***[8] By analogy, we note that the 3-year affirmative restatement obligation in connection with the Medicaid Drug Rebate Program was adopted pursuant to such notice and comment rulemaking,[9] indicating that CMS, itself, understands that such an obligation should be subject to formal rulemaking.

B. CMS should clarify its guidance and configure the ASP Module to: (1) allow more than one individual per Submitter or Certifier role per Labeler code (with access to historic data), (2) allow manufacturers to voluntarily limit system access for certain individuals, similar to what is permitted in the Medicaid Drug Products System, and (3) develop and publicize a process by which a manufacturer may expeditiously terminate and/or add a user.

Amgen appreciates CMS for acknowledging in its ASP Module update that manufacturers may use vendors in connection with some operational aspects of ASP data processes, and including a "Contractor" role, as an alternative to a "Direct Employee" role, in connection with data certification.[10] These roles are addressed in the Medicare Part B ASP Module Certifier User Guide.[11] We appreciate

[4] *See* U.S. Dep't of Health & Human Servs., Off. of Inspector Gen., Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices, OEI-BL-21-00330, 14 (Dec. 2022).
[5] 42 C.F.R. § 414.804(7).
[6] 42 C.F.R. § 447.510(b)(2).
[7] *See* 42 C.F.R. § 447.510(d)(2)(iii) (AMP), and 42 C.F.R. § 414.804(a)(3) (ASP).
[8] *See* 5 U.S.C. § 551 et seq.; *see also* Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979).
[9] *See* 68 Fed. Reg. 51,912 (Aug. 29, 2003); *see also* 81 Fed. Reg. 5169, and 85 Fed. Reg. 87.000 (Dec. 31, 2020) (revising the Medicaid restatement obligations at 42 C.F.R. § 447.510).
[10] Additional clarification regarding how a manufacturer may use a Contractor to satisfy its certification obligation under 42 C.F.R. § 414.804(a)(7) would be helpful.
[11] CMS, Medicare Part B ASP Module: Certifier User Guide, ver. 0.1, §§ 3.4.1-3.4.2 (Jan. 22, 2024). It is not entirely clear which version of the Certifier User Guide is subject to comment as part of the Notice. This

this acknowledgement of the need for more flexibility in the ASP reporting process. However, the creation of the Contractor role, without more detail how a manufacturer may use this role, will not fully permit the flexibility that manufacturers need to best ensure the right individuals have system access to input and/or view appropriate data.

We recommend CMS further clarify its guidance and configure the ASP Module in such a way as to permit a manufacturer to have multiple "Direct Employees" and/or "Contractors" complete the "Certifier" role in the system. Similarly, we believe CMS should clarify and configure the ASP Module to permit a manufacturer to have multiple ASP "Submitters" with the ability to view historical data. Neither the Certifier User Guide nor the Submitter User Guide is clear with respect to whether the number of manufacturer users and/or ability to view historical data is limited in the updated system, but the Certifier role has historically been limited to a single user per labeler code, and the Submitter role has historically been limited in the ability to view historic data or data entered by others. Those limitations have created real operational challenges for manufacturers. Redundancy of reporting and/or certification roles is necessary for manufacturers to accommodate for out-of-office time and/or personnel transitions. Further, in larger manufacturers, different key personnel and/or contractors may be responsible for price reporting with respect to different products and/or labeler codes. Permitting multiple system users/broader data access for each role in the ASP Module would permit manufacturers to better ensure timeliness and accuracy of ASP reporting.

We also request that CMS permit manufacturers to voluntarily limit system access for certain individuals to certain NDCs and/or time periods, as compared to the entire labeler portfolio. There are numerous business reasons that manufacturers may desire to limit the ASP pricing information available to particular individual(s) to a particular NDC(s). For example, a manufacturer may use a particular contractor for one product but not another. Or, in connection with a product—but not labeler code—sale to another manufacturer, it is common for there to be remaining inventory of the product under the original manufacturer's labeler code sold into the market by the acquiring manufacturer (prior to the acquiring manufacturer selling the product under its own labeler code). In such situations, the parties may agree to various business terms to ensure appropriate ASP reporting, but one option that has been historically available in the Medicaid Drug Rebate Program system, but *not* the Medicare Part B ASP Module, has been the ability to delegate reporting and/or certification for a single NDC, such that the delegate can view/report pricing only with respect to that NDC and not with respect to the entire labeler code.[12] Such an option would be tremendously helpful in the ASP system as well.

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is because the supporting materials for the Notice link to a file containing "Version 0.1, Date January 22, 2024" of the Guide, but CMS's current CMS's ASP Education & Outreach website links to an apparently newer version of the file, containing "Version 1.0, Date: March 15, 2024" of the Guide. Our comments below apply to either version of the Guide, but *we recommend CMS confirm the version numbers and dates are accurate*. That said, we note that Version 0.1, which, despite the relatively earlier version number and date, appears to be linked in the Notice, includes what appear to be real manufacturer and product names in some of the Figures, but that those figures appear to have genericized such references in Version 1.0 of the Guide. While we assume that the pricing data included in the Figures does not reflect actual product pricing, *we recommend that CMS ensure it is not including any manufacturer's proprietary information in the final Guide*.

[12] *See* CMS, Medicaid Drug Programs [MDP] User Manual, ver. 1.7, § 1.2.1 (Nov. 9, 2023) ("If workload or business factors make it appropriate, the [Technical Contact ("TC")] for a drug manufacturer may identify one or more additional MDP users called Labeler Designees. Labeler Designees are typically responsible for maintaining some or all product data and either monthly or quarterly pricing data for one or more specific labeler National Drug Code (NDC1) codes. The data maintained by each Labeler Designee will contribute to the product and monthly and/or quarterly data submitted by the labeler to CMS through MDP. CMS recommends that each TC establish at least one Labeler Designee … as a backup to submit data. This role can also be configured to be read-only, to be time-limited by month or quarter, and to include or exclude

Finally, we recommend that CMS develop and publicize a process by which a manufacturer may expeditiously terminate and/or add a user for any reason. It is a business reality that employees and contractors turnover from time to time, and it is critically important for manufacturers to ensure that *current* employees and/or contractors (and *only* current employees and/or contractors) have system access and may certify ASP data. Given that failure to change system users in a timely manner could cause delays in submissions, Amgen requests that CMS create a user change process that can be effectuated quickly, and that can be flexible to allow an authorized representative of a manufacturer other than the currently-listed certifier(s) to approve such a change, if needed.

II. NEW FINANCIAL DATA TEMPLATE

A. CMS should clarify the "Notes" to the "Instructions," and confirm no manufacturer liability for submitting/certifying data under the *previous* template in connection with the apparently deleted "Notes" descriptions.

The Notice's supporting materials[13] include a portable document file ("pdf") (dated 5/14/2024) titled: "FinancialData Template Instructions.pdf." Pages 3-4 of those Instructions include a number of "Notes," but the pdf file format does not make it clear which Note modifies which fields. Separately, CMS's ASP Education & Outreach website currently links to a version of the "Financial Data Template" (dated 3/18/2024) including a tab for "Instructions."[14] Those 3/18/2024 Instructions are available in Microsoft Excel format, and, in that version, there is a column titled "Notes," in which each note is linked to a particular field.[15] Accordingly, we have used the 3/18/2024 version to attempt to ascertain which "Notes" link to which field in the newer 5/14/2024 version. Based on that review, it *appears* that the 5/14/2024 pdf file does *not* include in the "Notes" various text descriptions that are included in the 3/18/2024 Excel file. Assuming the relevant text has, in fact, been deleted, Amgen supports those deletions.

Amgen asks CMS to: (1) clarify which "Notes" link to which fields, (2) confirm that the deletion of the additional text in the "Notes" column (as compared to the current 3/18/2024 version) is intentional, and not merely a product of file conversion, and (3) confirm that manufacturers will not be liable for submitting/certifying data under the current template in connection with the apparently deleted "Notes" descriptions. The latter confirmation is particularly important, as we are concerned by several of the Notes in the 3/18/2024 Excel file, including the following statements, which we believe to be inaccurate and confusing descriptions of the relevant pricing fields, for reasons summarized below, and which we are hopeful to confirm have been deleted:

- CMS "Note": "Manufacturer's Average Sales Price" is "[a] manufacturer average sales price for all National Drug Codes ["NDCs"] assigned to the drug or biological product."

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access to specific products (NDC2s)…Certifiers have access to view and certify product and either monthly or quarterly pricing data for a labeler code, but they cannot modify the data. This role can also be configured to include or exclude access to specific products. CMS recommends that each TC establish at least one Labeler Certifier… as a backup to certify submitted data."

[13] *See:* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof 1995/pra-listing-items/cms-10110 (last visited May 30, 2024).

[14] *See:* https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-education/financial-data-template (last visited May 30, 2024).

[15] *See id*.

    - Inaccuracy: In general, we understand that CMS's regulations require that ASP is calculated and reported distinctly for each NDC-11, *not* as an average across all NDCs.[16]
- CMS "Note": "ASP is the volume-weighted average of the manufacturers' average sales prices for all [NDCs] assigned to the drug or biological product."
    - Inaccuracy: Same as above. Further, the volume-weighted average of ASPs for all NDC-11s assigned to the billing or payment code for a drug or biological product is used to calculate the payment amount for that billing or payment code, not the ASP itself.
- CMS "Note": "Average Wholesale Price" ("AWP") is the "Average price paid for a drug from a manufacturer for a corresponding ASP unit."
    - Inaccuracy: AWPs are calculated by third party pricing compendia and may or may not relate to actual prices paid to manufacturers.

B. CMS should update Average Wholesale Price (AWP) "Notes."

As noted above, CMS's revised Financial Data Template includes a new "optional" field for reporting AWP. Amgen supports and appreciates that this field is "optional," as the subset of products subject to AWP-based reimbursement is limited,[17] there is no statutory AWP reporting obligation, and, as noted above, we understand AWPs are generally calculated by third party compendia. And while we strongly support the apparent removal of the "definition" of AWP that appeared in the 3/18/2024 Financial Data Template Instructions, ***we ask that CMS further revise the "Note" linked to the AWP field to expressly state that: "AWPs are calculated by third party pricing compendia, are subject to change without manufacturer input, and may or may not relate to actual prices paid to manufacturers."*** This clarification is important, given that manufacturers are required to certify the AWP data (even if it is voluntarily reported), and manufacturers are not generally in a position to know whether AWPs are "accurate" as compared to any particular definition, but rather are reliant on third parties to supply these data as of a point in time.

III. NEW PRODUCT DATA TEMPLATE

A. CMS should expedite processing of new "Generic Names," and update fields as soon as possible (at a minimum with new within same calendar quarter as requested).

Amgen understands that CMS has added a Product Data Template field for "Generic Name" and that the proposed Product Data Template included in the Notice's supporting materials includes a finite list of generic names from which manufacturers may choose. The ASP Submitter User Guide, also included in the Notice's supporting materials, proposes a process to *request* a new generic name be added to list.[18] We understand CMS is intending for this to "reduce[] the chances of data entry errors."[19]

[16] 42 C.F.R. § 414.804(a)(1).
[17] *See* 42 U.S.C. §§ 1395u(o)(1)(A) and 1395l(t)(15).
[18] *See* ASP Submitter User Guide, ver. 0.1 § 3.1.3.1 (Jan. 22, 2024).
[19] CMS Part B Drug Technical Support (DTS) Data Collection System Crosswalk Document (Jan. 30, 2024).

We appreciate the intent behind this change, but we are concerned that any delays in approval of new generic names would impede a manufacturer's ability to timely report data. Accordingly, ***we encourage CMS to expedite processing of new generic name requests, and to commit to update "Generic Name" fields, as applicable, at a minimum within the same calendar quarter that the request is made.***

B. CMS should provide detailed instruction on how to select among the "Unit of Volume Per Item" unit types.

In CMS's revised Product Data Template (dated 5/14/2024), CMS lists seventeen different "valid values" for "Unit of Volume Per Item" types, namely: Ampule, Capsule, Cells, Disc, EACH, G, Implant, MCG, MG, ML, Pack, RcoF, SQ CM, Syringe, TABLET, Units, and Vial. In many cases, more than one unit type may potentially apply to a particular product, but CMS offers no directions as to how to choose among these unit types. In particular, it would be helpful for additional CMS clarification regarding when a "ML" unit type would be appropriate, given that the statute defines "unit" to be determined "exclusive of any diluent without reference to volume measures pertaining to liquids."[20] In addition, these unit types do not correspond to the unit types that manufacturers report with respect to "average manufacturer price" or "best price" under the Medicaid Drug Rebate Program, and thus there are no parallels that can be drawn between the two programs to help identify the appropriate unit type. ***To encourage consistency in reporting across manufacturers and products, Amgen urges CMS to provide detailed direction on how to select among these unit types.***

C. CMS should provide detailed instruction on how to select among the "Unit for Strength" unit types.

The revised Product Data Template (dated 5/14/2024) also lists well over 100 different unit types for "Unit for Strength." Despite the relatively large number of unit types, this list does not appear comprehensive. In addition, where there is not an exact unit type for a particular product, CMS does not provide any guidance on how to select among the unit types that are available. ***To encourage consistency in reporting across manufacturers and products, Amgen urges CMS to provide detailed direction on how to select among these unit types.***

D. CMS should clarify "Notes" to "Instructions," and delete "Must be after the First Marketing Date" from the Note to "Date of First Sale."

As with the Financial Data Template Instructions, discussed above, the 5/14/2024 pdf file format of the Product Data Template Instructions do not make it clear which "Notes" link to which fields. Amgen has therefore referred to the current website version of the Product Data Template Instructions (updated 4/24/2024).[21] Based on that comparison, there appears to be a "Note" to the "Date of First Sale" stating that this date "Must be After the First Marketing Date."

We understand the "Date of First Sale" field is intended to be used for Part B inflation rebate purposes. CMS's Part B inflation rebate guidance notes that CMS will use the "date of first sale" associated with

[20] 42 U.S.C. § 1395w-3a(b)(2)(B).

[21] *See:* https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-education/product-data-template (last visited May 30, 2024).

the HCPCS code to define "first marketing date."[22] Meaning that for the first NDC(s) within a HCPCS code, the First Marketing Date and the Date of First Sale would presumably be the same. ***Accordingly, we ask CMS to clarify the "Notes" to the "Instructions" and delete "Must be After the First Marketing Date" from the Note to "Date of First Sale."***

IV. WEBSITE "FREQUENTLY ASKED QUESTIONS"

A. CMS should update its systems and guidance to expressly permit the extension of the ASP reporting deadline to the next business day, where the deadline otherwise falls on a federal holiday or weekend.

The Notice does not include CMS's 3/11/24 "Frequently Asked Questions" ("FAQ") document[23] in the linked supporting materials. However, that FAQ document includes substantive content that appears to be directly relevant to the current data collection. Among other things, the FAQ document includes a table indicating that the ASP reporting deadline is the 30th of the month following the reporting quarter, *regardless of whether it falls on federal holiday or weekend.*[24] However, the ASP statute does not expressly require the strict application of the 30-day time period where the deadline falls on a federal holiday or weekend, and there is abundant precedent for extending federal reporting deadlines in such cases.[25] And the Social Security Act, as it relates to Medicare, *requires* that:

> Where this subchapter, any provision of another law of the United States (other than the Internal Revenue Code of 1986) relating to or changing the effect of this subchapter, or any regulation issued by the Commissioner of Social Security pursuant thereto provides for a period within which an act is required to be done which affects eligibility for *or the amount* of any benefit *or payment* under this subchapter or is necessary to establish or protect any rights under this subchapter, and such period ends on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order, then such act shall be considered as done within such period if it is done on the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.[26]

Moreover, manufacturers—like the federal government—typically observe federal holidays and weekends as non-work days, and staffing is significantly limited on such days. Amgen believes allowing for an extension of ASP submission deadlines in such cases would permit more meaningful review and certification of ASP data, consistent with the statute, and ***CMS should thus update its ASP systems and guidance to expressly permit the extension of the ASP reporting deadline to the next business day, where the deadline otherwise falls on a federal holiday or weekend.***

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[22] CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act, 16 (Dec. 14, 2023), available at: https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.

[23] *See* CMS, Average Sales Price (ASP) Quarterly Publication Process Frequently Asked Questions, ver. 1.1 (Mar. 11, 2024), available at: https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.

[24] *See id.* at 4 ("When must data be reported?").

[25] *See, e.g.,* 42 C.F.R. § 447.511(b) (Medicaid state utilization data); CMS, Medicaid Drug Rebate Program Data Guide § 4.2 (Jul. 2023) (Medicaid manufacturer pricing data); 42 C.F.R. § 424.44(c) (Medicare claims). *See also* Executive Order 11582 (Observance of Holidays by Government Agencies, February 11, 1971).

[26] 42 U.S.C. § 416(j) (emphasis added).

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We appreciate CMS's consideration of these comments. Please do not hesitate to contact Yola Gawlik at (202)320-1159 or ygawlik@amgen.com if you have any questions.

Sincerely,

Yola Gawlik
Executive Director
Global Government Affairs & Policy