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Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
Attention: ICR Reference Number 202306-0938-013
725 17th Street NW,
Washington, DC 20503

RE: Novo Nordisk Comments on *CMS-10847 Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (ICR Reference Number 202306-0938-013)*

Dear OMB Desk Officer:

On May 22, 2023, Novo Nordisk Inc. ("Novo Nordisk") provided comments in response to the information collection request ("ICR") issued by the Centers for Medicare & Medicaid Services ("CMS" or the "Agency"), entitled *Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act*. We thank CMS for reviewing our previous comments and issuing a revised ICR for comment on June 30, 2023. We also appreciate the opportunity to provide further comments to CMS on the revised ICR.

We remain disappointed and concerned that the Agency did not adequately address many of the issues we raised in our May 22 comment letter, which is incorporated here by reference. We refer the Agency back to our previous ICR comment letter for a thorough explanation of these issues. We reiterate key concerns here in brief and highlight where we believe the Agency's responses and existing guidance are insufficient. We respectfully request that the Agency make further revisions to the ICR consistent with our initial ICR comment letter, these additional comments, and to the extent applicable, our comment letter in response to CMS's *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (the "Initial Guidance"), which is also incorporated here by reference.

Additionally, Novo Nordisk is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), and these comments incorporate by reference the comments submitted by PhRMA in response to the revised ICR.

CMS DID NOT ADEQUATELY ADDRESS CONCERNS THAT MANUFACTURERS NEED MORE THAN 30 DAYS TO SUBMIT DATA

We are disappointed by the Agency's staunch commitment to a 30-day timeframe in which manufacturers must submit data. CMS responded to public comments on this issue, stating that although the Agency "appreciates commenters' concerns regarding deadlines," it "is abiding by the statutory deadlines in this revised guidance." *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* (the "Revised Guidance") § C: Negotiation Factors (Section 50); *see also* CMS Response to Public Comments Received for CMS-10847: Burden to Report the Information Required and/or Requested ("Response to Public Comments"). Novo Nordisk continues to believe that the statute affords CMS flexibility to implement the data submission timelines with respect to the manufacturer-specific data elements enumerated in section 1194(e)(1) and the evidence about alternative treatments detailed in section 1194(e)(2). We again urge CMS to permit manufacturers to make rolling data submissions, based on timelines that would be agreed to by CMS and each affected manufacturer.

CMS DID NOT ADEQUATELY ADDRESS CONCERNS THAT MANUFACTURERS MUST HAVE SUFFICIENT MEANS TO EXPLAIN THEIR ASSUMPTIONS IN PREPARING MANUFACTURER-SPECIFIC DATA

CMS's revised ICR largely fails to address manufacturers' needs for sufficient means to explain the reasonable and necessary assumptions that they must make in preparing manufacturer-specific data submissions. In its Response to Public Comments, the Agency repeatedly stated that it would not adopt the recommendation that manufacturers submit a statement of reasonable assumptions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. *See, e.g.*, Response to Public Comments § C: Research and Development (R&D) Costs and Recoupment. To be clear, Novo Nordisk did not and does not suggest that manufacturers should be permitted to "use reasonable assumptions *in lieu of* the definitions in Appendix C," which was how CMS characterized a public comment to which CMS responded in the Revised Guidance. Revised Guidance § C: Monitoring Compliance and Civil Monetary Penalties (Sections 90.1 and 100) (emphasis added). Rather, manufacturers need sufficient opportunity and space to explain the manufacturer-specific data that they will provide *based on* the definitions in Appendix C and the related guidance in the ICR. Manufacturers will need to make myriad decisions in preparing their data submissions based on the limited guidance that CMS has provided for many of the data elements at issue. CMS has acknowledged this inevitability by including in the ICR fields for manufacturers to provide explanations of the data they submit (e.g., free-text explanation fields to explain the applicable direct costs that manufacturers included in various data elements). Indeed, for several data elements, such as non-FAMP, research and development costs and recoupment, current unit costs of production and distribution, and prior Federal financial support, CMS expressly invites manufacturers to use the explanation fields to describe the "assumptions" and methodologies underlying their reported data. Having sufficient space to provide these

explanations and assumptions will be particularly important for purposes of price applicability year 2026 because of the newness of these obligations and in the absence of informed and detailed guidance from CMS that meaningfully addresses the myriad decisions and related complications that manufacturers will face in compiling and providing this data based on CMS's definitions. We emphasize that these complications will exist despite the definitions in Appendix C and the ICR. Novo Nordisk again requests that CMS remove any word limit on the explanations that manufacturers will provide for each data element. Alternatively, CMS could use expanded word limits and also permit manufacturers to upload exhibits and related documents to further explain and clarify their good faith, reasonable assumptions throughout the ICR.

CMS Did Not Adequately Address Concerns and Complications that Primary Manufacturers Should Not Be Responsible for Collecting Data from Secondary Manufacturers

As a threshold matter, Novo Nordisk reiterates its opposition to the ill-conceived concept of Primary and Secondary Manufacturers, which not only presents significant Constitutional and practical concerns but also violates the IRA, as further described in our comments provided in response to the Agency's Initial Guidance. We echo these comments now, and in the context of the revised ICR, Novo Nordisk emphasizes its view that Primary Manufacturers should not be responsible for collecting data from Secondary Manufacturers. In its Revised Guidance, CMS stated that it "believes the Primary Manufacturer, based on its arrangements with Secondary Manufacturer(s), can reasonably ensure that the Primary Manufacturer can comply with its negotiation program obligations with regarding [*sic*] to data submission and ensuring the availability of MFP for selected drug sold by Secondary Manufacturer(s)." Revised Guidance § C: Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data. Yet, the Agency offered no substantive basis for this belief and revealed its misunderstanding of the complex relationships and interactions that exist in the pharmaceutical industry. We again request that the Agency require that Secondary Manufacturers—not Primary Manufacturers—be responsible for submitting their own data. CMS's willingness to "provide an opportunity for corrective action in certain instances of potential violation prior to imposing [civil monetary penalties], which may provide Primary Manufacturers an opportunity to mitigate noncompliance related to Secondary Manufacturers in applicable situations" does not adequately assuage our concerns on this point. Revised Guidance § C: Monitoring Compliance and Civil Monetary Penalties (Sections 90.1 and 100).

CMS Did Not Adequately Address Concerns that the Agency Must Protect the Confidentiality of Manufacturer-Specific Data

Novo Nordisk acknowledges that CMS further clarified its proposed approach to protecting the confidentiality of manufacturers' data, as stated in the Agency's Revised Guidance, but we believe the proposal still lacks strong protections and clear expectations on which manufacturers can confidently rely. For example, when addressing such data security and confidentiality concerns

raised in response to the initially published ICR, CMS merely assured commenters that, among other vague protections, its Health Plan Management System (which will be used to collect information from manufacturers) "adheres to [HHS]/CMS policies, procedures, controls, and standards for information security and privacy." Response to Public Comments: Confidentiality of Information Submitted Under This ICR and Its Storage by CMS. Without more, we cannot be certain of CMS's ability to protect our highly confidential and competitive information.

We also reiterate our belief that CMS should afford manufacturers deference in making good faith determinations as to which specific data and information are proprietary and thus must be protected from public disclosure and subject to the protections around its use. Further, we request that if CMS would consider disclosing or using information that a manufacturer has designated confidential and proprietary, then the Agency must provide manufacturers a reasonable opportunity to object to such disclosure or use in advance, and to allow them sufficient time to take measures to prevent such unauthorized disclosure or use. On this last point, although CMS acknowledged that several commenters had requests of this nature, the Agency failed to provide a meaningful response. Instead, CMS reiterated that it is empowered by the IRA to make determinations of what constitutes "proprietary information" and largely echoed a vague intention that it "is committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process." Revised Guidance § C: Manufacturer Data Submission, Proprietary Information, and Confidentiality (Section 40.2). Novo Nordisk is not comforted by this amorphous commitment; accordingly, we respectfully request additional clarity and cooperation on this issue.

CMS DID NOT ADEQUATELY ADDRESS THE PROBLEMS AND CHALLENGES RELATED TO MANUFACTURER-SPECIFIC DATA ELEMENTS

Research & Development Costs and Recoupment (Section C)

With respect to Research & Development Costs and Recoupment (Section C), we reiterate that there are some data elements for which it could be difficult or impossible for manufacturers to determine based on the significant time—several decades, in some cases—that has passed since the research and development costs were incurred. In those cases, to approach directionally accurate figures for these data elements that reflect the decades of work invested in the research and development of the products, Novo Nordisk would be required to rely on a series of assumptions and allocation methodologies. We again note that manufacturers should not face the threat of fines or False Claims Act liability based on good faith assumptions to provide the data requested, including in cases where there are substantial limitations in the data available.

Further, with respect to the element of abandoned and failed drug costs specifically (Question 4), we remain firm in our belief that it is myopic, unfair, and in some cases, practically infeasible, to only consider the costs of research and development that are associated with the

"same active moiety / active ingredient or mechanism of action" and "same therapeutic class" as the selected drug. We note that in its Revised Guidance, CMS addressed comments on this important issue by simply (and unhelpfully) responding that it believes its revised definitions related to research and development costs are "sufficiently broad." Revised Guidance § C: Publication of the MFP (Section 60.6). The Agency provided no evidence to support such belief, and we encourage CMS to revisit our previous ICR comment letter for a deeper understanding of this point and others. The Agency also did not provide a definition for "therapeutic class," despite that the first page of the Negotiation Data Elements ICR Crosswalk of Changes Between 60-Day Notice and 30-Day Notice includes the following note: "Section C, Question 4 definition: Added definition of therapeutic class for purposes of reporting costs of failed or abandoned products related to the selected drug." However, without a definition to review, we are unable to comment on what CMS might be proposing for that term.

With respect to global and U.S. total lifetime net revenue for the selected drug (Question 6), we previously commented that it would be unfair of CMS to make a determination as to whether research and development costs have been recouped for a selected drug by considering/comparing a narrow set of research and development costs (generally, those associated with FDA-approved indications) against the global, total lifetime net revenue for the selected drug. In its Revised Guidance, CMS addressed concerns that "CMS' approach for calculating recoupment of R&D costs by comparing global net lifetime revenue for the selected drug with R&D costs attributable to FDA-approved indications of the selected drug is imprecise or flawed and disadvantages the manufacturer." Revised Guidance § C: Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data. In response, CMS reconsidered and revised its guidance and ICR "to clarify that CMS will consider both a Primary Manufacturer's global and also U.S. revenue when determining whether to adjust the preliminary price based on manufacturer-submitted data." *Id.*; *see also* Response to Public Comments § C: Research and Development (R&D) Costs and Recoupment. CMS devised the data element of U.S. Lifetime Net Revenue for the Selected Drug (Question 6b) in the revised ICR.

But the mere addition of another data element related to U.S. Lifetime Net Revenue in CMS's revision does not fully address our primary concern. CMS will still consider global revenue figures in comparison to research and development costs narrowed to FDA-approved indications. Instead, if the Agency is determined to consider global revenue figures, then it should also consider global costs. More specifically, CMS should at least consider lifetime, global costs that are associated with researching, developing, producing, distributing, and selling the product, including related indirect costs, as well as comprehensive research and development costs associated with failures well beyond those associated with the "same active moiety / active ingredient or mechanism of action" and "same therapeutic class." We again note that, as a fundamental matter, Novo Nordisk strongly opposes the concept of considering whether research and development costs have been recouped for purposes of setting a Maximum Fair Price, as the IRA contemplates, because it is based on an inherent misunderstanding of the operations of a large and complex global

pharmaceutical company like Novo Nordisk. CMS's persistent limitations exacerbate our concerns that such an unfair concept also will be unfairly implemented. By failing to make balanced and fair revisions to its guidance and ICR, CMS proposes to truncate the true value of the actual costs invested in bringing successful pharmaceutical products to market.

Current Unit Costs of Production and Distribution category (Section D)

Novo Nordisk previously expressed our concerns regarding CMS's proposal that manufacturers report these unit costs for the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year 2026). In Section D of its Response to Public Comments, CMS responded to this concern and claimed that the Agency chose this time period to align with the statute. Yet, we again note that our organization does not maintain or devise a unit cost of production or distribution in the ordinary course of business in this manner. As mentioned, these challenges will necessitate that the data submitted will be based on myriad important assumptions, and manufacturers should not face the threat of fines or False Claims Act liability based on good faith assumptions to provide the data requested.

Prior Federal Financial Support (Section E)

Novo Nordisk emphasizes its view that as the conduits that provide Federal funding to manufacturers, government agencies are already cognizant of the funds they expended to support pharmaceutical development. Accordingly, manufacturers should not bear the burden of supplying to CMS information that is readily accessible to the Agency from these other sources. Further, we note that manufacturers' financial and recordkeeping systems have evolved and turned over since Federal financial support may have first been granted. In light of this challenge, manufacturers should be permitted to conduct reasonable due diligence of their information and data to determine whether prior Federal financial support might have been provided that is within the scope of the reporting obligation, without the looming threat of fines or False Claims Act liability for such diligence. Additionally, as explained in our previous ICR comment letter, the Agency should revise its definition of prior support to include only funding that resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency for an invention directly related to the development of the selected drug. CMS should also only consider those patents and patent applications that are directly related to the selected drug.

Patents, Exclusivities, and Approvals (Section F)

Novo Nordisk appreciates CMS's clarification regarding the types of patents and patent applications that CMS considers to be "related to" the selected drug, which was a point raised in our previous ICR comment letter. We also appreciate CMS's withdrawal of the requirement that manufacturers list all pending patent applications for which a claim of patent infringement could reasonably be asserted. While these revisions are responsive to some of our concerns, we again

ask that CMS address the other issues we raised, such as the challenges we foresee in gathering information regarding expired patents and the need for robust confidentiality protections to safeguard manufacturers' responses.

Market Data, Revenue, and Sales Volume Data (Section G)

The revised ICR does not provide clarity on how to ascertain or calculate many of the data elements listed in Section G (e.g., CMS does not specify whether manufacturers should report the wholesale acquisition cost in effect on the first or last day of the quarter, or in some other way). Importantly, we urge CMS to abandon its demand for the three novel price points "U.S. commercial average net unit price," "U.S. commercial average net unit price—without patient assistance program," and "U.S. commercial average net unit price—best." The Agency should not rely on these price points to develop an initial offer, as the revised ICR does not provide nearly enough guidance on how to calculate them. There remain numerous substantial, unanswered questions about how these metrics are to be calculated, and what CMS means by certain terminology used (e.g., "free or reduced-priced services"). The revised ICR simply does not define these pricing points with sufficient specificity to facilitate competent, compliant, reliable government price reporting. In addition, Novo Nordisk specifically objects to the inclusion of discounted sales to 340B covered entities in "commercial" net unit prices. These sales are not commercial and should not be included in metrics that are intended to reflect commercial sales. Because the revised ICR fails to adequately define these three novel price points, CMS is almost certain to receive highly variable, non-standard, and ultimately unilluminating responses from manufacturers. Accordingly, CMS's demand for "U.S. commercial average net unit price," "U.S. commercial average net unit price—without patient assistance program," and "U.S. commercial average net unit price—best" should be withdrawn.

Evidence About Alternative Treatments (Section I)

Novo Nordisk appreciates CMS's addition of manufacturer and patient-focused meetings in Fall 2023 to discuss topics such as section 1194(e)(2) data. To further enhance the usefulness of the data gathered under this section, we repeat our previous request that CMS provide clarification on the terms "therapeutic advance" (Question 28) and "unmet medical need" (Question 30). We note that in the case of "unmet medical need," CMS revised the definition to encompass situations where "existing treatments do not adequately address the disease or condition" (Definitions for Question 30), and the Agency stated in a footnote that it will consider the U.S. Food and Drug Administration's nonbinding recommendations related to this concept. These edits, however, fail to provide the clear and meaningful guidance we requested and require on this point.

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Thank you for considering Novo Nordisk's comments. We would be pleased to discuss these comments with you in further detail. If you have questions, please contact Jennifer Duck, VP, Public Affairs at JEDK@novonordisk.com.