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August 23, 2023

Via Electronic Delivery
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-10849
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Information Collection Request (ICR) for the Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10849)

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) Information Collection Request for the counteroffer process under the Inflation Reduction Act (IRA).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The Proposed Counteroffer Process is Inconsistent with the Spirit of the Paperwork Reduction Act; the Proposed Process Places an Undue Burden on Manufacturers, Results in Duplicative Requests for Information, and Lacks any Practical Utility in Providing the Information to CMS.

The Paperwork Reduction Act was established to ensure that proposed collections of information was "the least burdensome necessary [,]…is not duplicative of information otherwise accessible to the agency [,]… and has practical utility." [1] The current proposed counteroffer process requirements are not aligned with the spirit of the Paperwork Reduction Act. CMS's proposed requirements are overly burdensome on manufacturers, require manufacturers to surmise what data CMS requires in certain places, and put the onus on manufacturers to accurately report information that is already held by the Agency.

Additionally, the form has some duplicative requests for information, including information that CMS already has and is making manufacturers calculate themselves to then submit to CMS. This includes Question 2, which asks manufacturers to establish a "single price per 30-day equivalent supply" as opposed to price per unit. CMS has already calculated the 30-day equivalent supply for each NDC-9; this question is one example where manufacturers are left to try and determine what CMS is looking for and then figure out how to calculate the data to ensure it matches the information that CMS already has on hand.

This highlights the lack of practical utility in providing the requested information to CMS. It is a fruitless exercise for manufacturers to be left guessing as to what data CMS is looking for when CMS already has the data available. These proposed requirements for submission as part of the counteroffer process go beyond any reasonable bounds of what the Agency might need in implementing the IRA and against the spirit of the Paperwork Reduction Act.

The Certification Requirement is Problematic and Unclear

As currently constituted, the certification requirement is overly burdensome on manufacturers, with harsh penalties and unclear requirements. This combination leads to a great risk that manufacturers will be punished because of an unclear requirement or simply because of the nature of scientific research and development.

In establishing the final rulemaking regarding the certification requirement, CMS must remove requirements for completeness, instead requiring that manufacturers provide accurate information that is prepared in good faith and after reasonable efforts. Despite a manufacturer's best efforts, there are certain factors in the certification requirement that go beyond a manufacturer's control and can affect

[1] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

what CMS deems to be "complete." If CMS insists on deeming a form "complete," then the word should be defined as that all sections of the form were filled out.

Additionally, we also ask that CMS removes the requirement for timely notification of changed information. Manufacturers participating in this process will assuredly be working diligently to submit the requested information. However, it is possible that with the ongoing nature of clinical research and scientific discovery, the data that arises from such proceedings develops over time and new data is continually made available. Taking CMS's current requirements literally would result in an ongoing requirement to continually update the counter-offer explanation to represent the latest data. This is an overly burdensome requirement, and we ask that CMS remove it, while leaving the option open for manufacturers to submit additional information as it develops.

It is Difficult to Respond to the Counteroffer Process When We Do Not Yet Know What the Initial Offer and Justification Will Look Like

In soliciting feedback on the Counteroffer process, CMS is perplexingly soliciting feedback on a part of an overall process that has not yet been released. It is, quite frankly, nearly impossible for stakeholders to provide substantive feedback on the counteroffer process when we do not know what the initial offer and justification will look like.

CMS should provide manufacturers with a confidential report during the initial offer process to show the evidence they used in establishing the initial offer and how they evaluated said evidence, alongside a detailed explanation of each factor they weighed. Manufacturers should have the ability to review that justification in the confidential report, and it should be more detailed than what reports CMS might make public facing. However, CMS should also work to release some guidance on how it will approach its initial justification, so manufacturers who are selected are better able to work ahead of time to understand the Agency's approach.

Without any information as to what the initial justification for the offer will be, responding to the ICR seems to be a futile exercise. At the outset of the process of implementing the IRA, CMS said that it would work with manufacturers and other stakeholders to incorporate their feedback into the process that the Agency would eventually establish. However, CMS has left stakeholders unable to provide any actual comprehensive feedback on various aspects of the process by refusing to share any information about the details of the "negotiation" process. This black box approach in turn allows CMS to continue with its pre-determined approach without having to incorporate any feedback from manufacturers and other stakeholders, which could inform the processes in a meaningful way.

We have been urging CMS to release information on the overall "negotiation" process in a timely manner in order to allow for substantive and meaningful engagement with stakeholders. While we continue to believe that a transparent

process with opportunity for stakeholder review and feedback is the most appropriate approach, we note that CMS is running out of time to allow for such an approach. At this juncture it appears that the Agency is operating with limited transparency in implementing its preplanned process, to the detriment of patients, manufacturers, and the future of American biopharmaceutical innovation.

Manufacturers Should Be Able to Supplement Their Timely Submissions if New Data Arises (Or Other Good Cause)

Notwithstanding our comments above regarding certification and timely notification of changed information, we do note that there will be situations where information relevant to the negotiation arises after the submission deadline has passed. Such late-breaking developments will often be completely unforeseeable at the time of submission but highly relevant to the setting of the MFP. The potential scenarios are virtually limitless: for example, new therapeutic alternatives may come to market; production costs may shift due to ingredient shortages or supply chain issues; or new comparative effectiveness studies may become available.

The thirty-day data submission period is already an onerous requirement for manufacturers, especially with the number of questions and data that they must answer and submit. It is therefore highly possible that additional, relevant data will become available after this short timeline to submit.

Moreover, with just one day provided between the deadline to submit the agreement for "negotiation"—which we reiterate is not an actual negotiation process, but rather government price setting— and the deadline for when all data must be submitted to CMS, the ability to submit pertinent data that may arise after a timely submission is critical. This ICR on the counteroffer process does not highlight any way in which supplemental information can be provided in advance of, or even during, the counteroffer process.

CMS should not blind itself to highly pertinent new information, simply because the submission deadline has passed. In the initial negotiation guidance, the Agency proposed to limit the presentation of such information to the negotiation meetings during the period after the rejection of a counteroffer. Because such information can equally inform an initial offer, the Agency should provide the manufacturer the option to supplement its timely submission when there is good cause to do so during the initial negotiation period, including when new information relevant to the negotiation process becomes available after the October submission deadline.

CMS should establish a procedure that would allow manufacturers (and other stakeholders) the option to submit pertinent new information even after the

deadline should the need arise. The current uncertainty for manufacturers on their ability to submit pertinent supplemental information in advance of potential negotiation meetings is another way in which the "negotiation" process has proven to be anything but fair and predictable.

Permitting supplemental submissions is well warranted. Under the statute, manufacturers are given only one month from publication of the selected drug list to prepare a voluminous submission of complex information, including information regarding Non-Federal average manufacturer price (Non-FAMP); research and development costs; production and distribution costs; federal financial support for discovery and development; pending and approved patent applications, FDA exclusivities, NDAs or BLAs and approvals thereof; market data; and revenue and sales volume data. In some cases, requested data may also not exist in a format required by CMS, such that the manufacturer will need to painstakingly convert raw data from multiple sources into such a format. CMS should require less data to be submitted, and instead rely as much as possible on existing data sources. CMS is planning to rely on new metrics that need to be reported, such as the US commercial average net unit price, and not price reporting metrics that manufacturers already have access to in the course of normal business.

Manufacturers will assuredly work with utmost diligence to comply with CMS's submission requirements. Still, they may need the flexibility of a supplement to their timely submission for legitimate reasons. Ultimately, more generally permitting the manufacturer to supplement its timely submission where there is good cause would help ensure that the information required to be submitted as part of establishing the MFP is the best available information, as well as helping to make the "counteroffer" process smoother.

Remove Limits on the Ability of Manufacturers to Respond

We are concerned that CMS's approach in this data collection form may be too limiting in practice and will not allow for a robust submission of information - including any supplementary material – by manufacturers. In particular, we are concerned with the data fields outlined in the proposed question asking for the justification of the manufacturer's counteroffer, which has a word limit of only 2,500 words. While we appreciate the change to slightly increase the word limit, we still believe that manufacturers should be able to submit as much information as possible that is necessary for them to make an argument that they believe will be comprehensive and not limited to artificial constraints. Our concern also extends to the fields for the additional materials manufacturers are allowed to submit to

support their counteroffer justification, with artificial caps of 50 citations and 10 tables or graphs.

We strongly recommend that CMS reconsider its approach and permit manufacturers to submit any information they determine relevant to the "negotiation" process (including information not related to the negotiation factors enumerated in the statute). CMS should consider all such information submitted by a manufacturer for the counteroffer, not limiting the response to just the negotiation factors in sections 1194(e). Removing these limits will allow for manufacturers to adequately respond and provide apposite supporting information that can help inform CMS's decision making.

CMS Underestimates the Amount of Time It Will Take for Manufacturers to Complete Submission of the Form

In the Supporting Statement attached to the ICR, CMS provides its estimate of the burden for collecting information for the 10 selected drugs for IPAY 2026. In Section 12 (with table 1) attached, CMS estimates the burden to be 204.25 hours per Primary Manufacturer per selected drug at a base estimate cost of $32,731.39 per manufacturer per drug. [2] We believe these numbers are dramatic underestimates of the actual cost in time and money for each submitting manufacturer to create a robust counteroffer.

In particular, the difficulty a manufacturer will have in crafting a counteroffer is further exacerbated by the as-yet unreleased initial justification for the initial offer. If the initial justification is not released until the initial offer is provided to manufacturers, manufacturers will have to work to both comprehend CMS's rationale for the offer and suitably address it in their statement (which is already constrained by arbitrary word limits).

The counteroffer will be much more cumbersome for manufacturers than CMS currently estimates, and we ask CMS to reconsider these estimates of the substantial burden.

[2] Counteroffer Process Revised ICR Supporting Statement at 8-9.

More Specification is Needed on CMS's Safeguards for Confidential and Sensitive Information

BIO acknowledges CMS's stated commitment to confidentiality, but recommends that CMS establish more fulsome safeguards to ensure that the Agency is adequately protecting the confidentiality of all proprietary information submitted to CMS as part of the "negotiation" process. BIO recommends the following minimum controls and safeguards to give full meaning to the confidentiality requirement:

First, CMS should confirm that, in "implement[ing] a confidentiality policy that is consistent with existing requirements for protecting proprietary information,"[3] it will ensure protections comparable to, not only those under FOIA, but also those under government price reporting law and policy.

We appreciate CMS's confirmation that the protections under FOIA, including the prohibition on disclosure of information designated as confidential without providing a pre-disclosure notification and an opportunity to raise objections to disclosure,[4] will apply to information to be submitted under the program.[5] We continue to seek confirmation that the protections under government price reporting law and policy will also apply.

Second, CMS should implement robust storage and access controls and safeguards to protect the confidentiality of sensitive information. Confidentiality requirements are only as meaningful as the data privacy and security protections that are implemented to safeguard sensitive information against inadvertent or malicious[6] improper disclosure. Accordingly, CMS should implement robust systems and protocols, including by ensuring that all proprietary information stored in the Health Plan Management System (HPMS) and in electronic communications with the Agency is secure and accessible only to CMS staff and only where there is a legitimate programmatic need for access to such information.

In doing so, CMS should look to the safeguards it has already established under MDRP. Under MDRP, CMS has implemented a system with numerous privacy and security protections to safeguard sensitive product and pricing data submitted by manufacturers. For example, the online interface allows a manufacturer to view its pricing data, such as its Baseline Average Manufacturer Price (AMP) data, while disallowing states, which do not have a programmatic need to view such

[3] Initial Guidance at 29.
[4] *See* 45 C.F.R. §§ 5.41, 5.42.
[5] Counteroffer Process Revised ICR Supporting Statement at 4.
[6] Malicious third-party cyber activities have increasingly targeted the federal government—in, part, because its databases are repositories of significant amounts of sensitive information. *Cf.* David E. Sanger, *Russian Hackers Broke into Federal Agencies, U.S. Officials Suspect*, N.Y. Times, https://www.nytimes.com/2020/12/13/us/politics/russian-hackers-us-government-treasury-commerce.html (last updated May 10, 2021).

information, from doing likewise.[7] CMS should ensure that similar controls are in place with respect to HPMS, given CMS's intent to transition most information submissions to that system.

CMS should also specify how it will maintain the confidentiality of the subset of information that is required to be submitted via Box. With regard to Box (a third-party commercial platform), BIO asks CMS to specify how submitted information will be kept confidential, including against misuse by Box personnel.

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We thank you for the opportunity to register our thoughts and concerns on this topic and look forward to future discussions. Please do not hesitate to contact us with any questions at (202) 962-9200.

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[7] CMS, *Medicaid Drug Programs User Manual* 1 (Nov. 3, 2021).