Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

August 24, 2023

VIA ELECTRONIC FILING - REGINFO.GOV

OMB Desk Officer
Office of Management and Budget (OMB)
725 17th St NW
Washington, DC 20503

RE: Information Collection Request (ICR) Form for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10849, OMB 0938-NEW)

To Whom it May Concern:

Eli Lilly and Company appreciates the opportunity to respond to the recent Information Collection Request (ICR) regarding the Maximum Fair Price (MFP) counteroffer process for the Medicare Drug Price Negotiation Program provision of the Inflation Reduction Act (IRA).[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

CMS Should Make Substantial Changes to the Counteroffer Form and Process

While the IRA itself imposes many requirements on CMS that are incompatible with a genuine negotiation process (e.g., signing an agreement before agreeing to price, one-sided transparency requirements, the imposition of ruinous excise taxes, etc.) Lilly has nonetheless encouraged CMS to use the opportunities where the agency has some discretion to move toward a more genuine bilateral negotiation between manufacturers and CMS. The Counteroffer form and process presents such an opportunity.

First, CMS should provide its Initial Offer on an NDC-11 by NDC-11 basis and adopt the same standard for purposes of the Counteroffer Form. As CMS knows, each NDC-11 represents a unique product and package size. Some NDCs contain more or less active ingredient, some require more or less frequent dosing, some cost more or less to make, etc. CMS's present approach of identifying a Qualified Single Source Drug (QSSD) at the per unit level for a 30-day supply ignores all of these realities.

CMS's proposed counteroffer approach is also wholly inconsistent with standard industry practice. All standard discount and rebate agreements negotiated in the "real world" allow for different prices at the NDC-11 level. This occurs either via tables that set out specific price schedules or via a fixed

[1] 88 Fed. Reg. 47880 (July 25, 2023)

discount or rebate percentage that is applied to each NDC-11, even if those NDC-11s have variable list prices. Lilly also has concerns that the "single price" dynamic for MFP will create unintended, misaligned financial incentives and arbitrage opportunities in the distribution and supply chain. For example, if the unitary price agreed to in Question 2 on the Counteroffer form is re-transformed into an MFP for a particular unit for a Medicare beneficiary at the pharmacy counter and one NDC-11 either results in a better business choice for the pharmacist or allows the pharmacist to make a better "margin" than a different NDC-11 would, the pharmacist is likely to steer the beneficiary to one product presentation over another. Similarly, we can foresee a scenario where one NDC-11 is actually "underwater" (i.e., costs more to make and ship than is reflected in the MFP). In those cases, manufacturers would be undoubtedly harmed, which in turn could impact patient access.

Second, CMS should allow greater flexibility in the flow of information and in the cadence of manufacturer-government interactions. In standard negotiations, neither party typically imposes word, pagination, or interaction limits on counterparties. In the MFP context, however, manufacturers are limited in the manner and number of interactions allowed with CMS. This inhibits the manufacturer's ability to engage in meaningful dialog on issues of misalignment. Imposing a 2,500-word limit on the counteroffer justification creates an uneven playing field where manufacturers of drugs with multiple indications or multiple presentations may struggle to provide a justification that accounts for the breadth of their innovation. If CMS is concerned that the Health Plan Management System (HPMS) system lacks the capacity for more data, CMS should solicit manufacturer justifications via the same process used for Initial Delay Requests for biosimilar manufacturers: tendered via email to IRARebateandNegotiation@cms.hhs.gov and/or uploaded to a secure Box site.[2]

Third, CMS has been appropriated 3 billion dollars (that are not time limited) to implement the IRA. The agency has stated that it is hiring over 100 new employees to support IRA negotiation.[3] As part of the MFP program, the government need only negotiate 10 contracts in the first year. This is an incredibly manageable caseload given these resources and CMS should retain much more flexibility for responding to individual concerns and engaging in meaningful dialogue, especially as the program is getting established and both CMS and manufacturers will need to learn a lot.

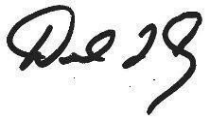
Finally, as a practical matter, we would note that commercial negotiations typically do not feature text formatting conditions that would somehow nullify the exchange of information. In the ICR, CMS states that "[d]ata that are not in a visual form, such as a table or chart consisting only of text, will not be considered by CMS."[4] Some data and charts may include non-text data elements. Where this occurs, CMS should simply work with a manufacturer to adjust the data presentation rather than ignore the potentially helpful information provided by a manufacturer.

***

[2] CMS, Revised Guidance, p. 180.
[3] https://www.reuters.com/business/healthcare-pharmaceuticals/hiring-data-how-us-will-set-up-new-medicare-drug-price-talks-2022-08-22/
[4] ICR at 4.

Lilly sincerely appreciates your thoughtful consideration of our feedback on the MFP Counteroffer ICR. Please do not hesitate to contact Chad Barker (barker_chad@lilly.com) with any questions.

Sincerely,



Derek Asay
Senior Vice President, Government Strategy

Shawn O'Neail
Senior Vice President, Government Affairs