



Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development  
Attention: Document Identifier/OMB Control Number: CMS-10849  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244

Re: CMS-10849 Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Mr. Parham:

The Coalition for Government Procurement (“the Coalition”) appreciates the opportunity to respond to *Information Collection Request (ICR) for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*.

The Coalition is a non-profit association of over 350 Federal contractors, including leading pharmaceutical manufacturers potentially affected by Sections 11001 and 11002 of the IRA. Our member companies’ portfolios cover healthcare, information technology, professional services and other industries and account for over \$115 billion dollars in Federal contract obligations. For more than 40 years, the Coalition has promoted common sense in Federal procurement and best value solutions for Government, industry and American taxpayers.

Our comments on the ICR solely pertain to the proposed framework for Government and industry interactions in the price setting process outlined in the ICR. As proposed, the price setting process puts unnecessary limitations on the open dialogue and collaboration between Government and industry needed to establish maximum fair prices for covered drugs that meet the needs of Medicare patients, while minimizing unintended consequences for all patients and in the broader market.

Per the Supporting Statement accompanying the ICR, the price setting process begins after the submission of an initial Maximum Fair Price (MFP) offer from CMS to the Primary Manufacturer and is composed of the following steps:

- (1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer from the Primary Manufacturer (if CMS’ written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer;*
- (2) in accordance with Section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written counteroffer;*
- (3) if the Primary Manufacturer’s written counteroffer is not accepted by CMS, up to three possible in-person or virtual negotiation meetings between the Primary Manufacturer and CMS;*
- (4) a final written offer made by CMS to the Primary Manufacturer; and*

*(5) a response by the Primary Manufacturer to CMS' final written offer, either accepting or rejecting this final offer.*

Proposed CMS guidance<sup>1</sup> from March clarifies that in the third step, CMS intends to hold at least one in-person or virtual negotiation meeting with the manufacturer prior to a final written offer. The manufacturer and CMS then may each request one more negotiation meeting, but they are limited during negotiations to a total of three meetings. The guidance does not require or suggest meetings between manufacturers and CMS at any other point in the drug selection, initial offer development, and price setting process.

The Coalition recognizes the opportunity for CMS and industry to meet in the third stage of the process to allow both parties to exchange information about each other's offers and the benefits and risks of any potential agreement. We are concerned, however, that placing a cap on the number of meetings could impose an artificial constraint, and we believe that the Drug Price Negotiation Program could benefit from guidance that promotes greater communication and collaboration between the Government and manufacturers.

**Therefore, we recommend that CMS revise the proposed price setting process for the Drug Price Negotiation Program to ensure that CMS representatives and industry can engage in constructive dialogue, to include sharing CMS's evaluation and interpretation of industry's input. CMS and industry should be encouraged to engage in open communications in the best interest of patients and innovation, without arbitrary limits (e.g., the number of meetings and the length of dossier submissions) established through regulation.**

## The Federal Procurement System Provides a Model for How CMS can Engage with Industry

Congress, Federal regulators, and acquisition officials have long recognized the value of open communication between Government and industry in driving best value pricing and solutions for American taxpayers in the Federal procurement system, which purchased over \$1.1 trillion dollars of goods and services in FY 2022. Open dialogue between Government and industry in the pre-solicitation process is encouraged by the Federal Acquisition Regulation (FAR) and in guidance from the Office of Management and Budget (OMB). Contract programs within the U.S. Department of Veterans Affairs, the Defense Health Agency, and the Defense Logistics Agency that procure and negotiate prices for pharmaceuticals for millions of military service members and their beneficiaries, provide opportunities for industry to meet and engage with the Government throughout the acquisition process.

The Medicare Drug Price Negotiation Program is not an acquisition program, though it requires industry and Government to agree on prices subject to a set of terms and conditions. Therefore, it stands to reason that there may be best practices for the negotiation of drug pricing under Federal contracts that are also pertinent to CMS's price setting. Guidance on Government and industry communication from the FAR and OMB suggests that CMS and manufacturers should engage in an open dialogue throughout

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<sup>1</sup> Center for Medicare and Medicaid Services, "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," March 15, 2023, <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>.

the entire process from selection to price setting, that CMS should be open to meeting requests, and remove artificial caps on the number of meetings and types of engagement.

The FAR is the primary regulation used by Executive agencies in the procurement of products and solutions and ensures that all procurement procedures are standard and conducted in a fair and impartial manner. In Part 15<sup>2</sup> of the FAR, “Contracting by Negotiation,” contracting officers are encouraged to participate in pre-proposal discussions and post-proposal negotiations with industry. There is no specific mandate in the FAR that limits the number of times a contracting officer can meet with industry during negotiations.

In addition to Part 15, FAR Part 1 was amended in December 2022 to emphasize the importance of effective communication between Government and industry in the negotiation of Federal contracts in accordance with Section 887 of the National Defense Authorization Act (NDAA) for FY 2016. Per FAR Part 1.102-2 (a)(4):

*The Government must not hesitate to communicate with industry as early as possible in the acquisition cycle to help the Government determine the capabilities available in the marketplace. Government acquisition personnel are permitted and encouraged to engage in responsible and constructive exchanges with industry (e.g., see 10.002 and 15.201), so long as those exchanges are consistent with existing laws and regulations, and do not promote an unfair competitive advantage to particular firms.*

In the spirit of the FAR Part 1 and 15, we recommend that CMS encourage responsible and constructive informal exchanges between CMS and manufacturers, early in the price setting process and often, while doing so consistent with law and regulation and in a manner that does not promote unfair competitive advantage.

Further, in its series of governmentwide memoranda refuting “myths” in Federal contracting, beginning with the “*Myth-Busting: Addressing Misconceptions to Improve Communication with Industry during the Acquisition Process*” memo in February 2011, OMB emphasized that having access to current market information is critical to the Government as they define contract requirements and negotiate associated terms and conditions. OMB also recognized that:

*“our industry partners are often the best source of this information, so productive interactions between federal agencies and our industry partners should be encouraged to ensure that the Government clearly understands the marketplace and can award a contract or order for an effective solution at a reasonable price.”*

Arbitrary limits on Government and industry communications in the price setting process run contrary to the spirit of FAR and OMB guidance. They risk depriving the Government of important information about the risks and benefits of prices set, and the potential impacts on areas beyond each individual agreement that are critical to *all* patients, like clinical research and innovation.

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<sup>2</sup> FAR Part 15.201 Exchanges with industry before receipt of proposals, [https://www.acquisition.gov/far/part-15#FAR\\_15\\_201](https://www.acquisition.gov/far/part-15#FAR_15_201)

## Recommendations

In short, the Coalition recommends that CMS revise the proposed price setting process for the Drug Price Negotiation Program to:

1. Ensure that CMS representatives and industry have an opportunity to engage in constructive dialogue, without arbitrary or artificial limitations to such dialogue, during the price setting process, so that meaningful information sharing occurs between CMS and industry partners, including but not limited to CMS's evaluation and interpretation of industry's input.
2. Focus on achieving the maximum price for negotiated drugs, in the best interest of patients so as to not jeopardize access to innovation, as the desired outcome of the price setting process (versus meeting certain requirements on the number, type and scope of industry communications).
3. Eliminate arbitrary limits on achieving this objective, including limitations on the number of meetings and limits to the length of dossier submissions.

We believe that these revisions to the price setting process will help to ensure that Medicare beneficiaries continue to receive access to covered drugs and that all patients continue to benefit from the pharmaceutical industry's investments in critical drug research and innovation.

Thank you for considering industry's comments in response to the Drug Pricing Negotiation Counteroffer Information Collection request. If you have any questions, please contact Roger Waldron at [rwaldron@thecgp.org](mailto:rwaldron@thecgp.org) or (202) 331-0975.

Sincerely,



Roger Waldron  
President