

Date: July 3, 2023
To: Interested Parties
From: Meena Seshamani, MD, PhD, Deputy Administrator and Director of the Center for Medicare, Centers for Medicare & Medicaid Services
Subject: General Instructions for Completing the Medicare Drug Price Negotiation Program Agreement

Introduction

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (hereinafter referred to as the “Negotiation Program”), codified in sections 1191 through 1198 of the Social Security Act (the Act). The Act establishes the Negotiation Program under which manufacturers and CMS may negotiate to determine a price (referred to as maximum fair price in the Act and “MFP” in this instructions document) defined at section 1191(c)(3) of the Act, with manufacturers for certain high expenditure, single source drugs¹ covered under Medicare Part B and Part D.

Pursuant to section 1193 of the Act and in accordance with applicable guidance and regulations, following the selected drug publication date, CMS and the manufacturer² (“Manufacturer”) of a selected drug (“Selected Drug”) may enter into a Medicare Drug Price Negotiation Program Agreement (“Agreement”) for a price applicability period. Pursuant to this Agreement, the Manufacturer shall submit information to CMS for the negotiation period (and renegotiation period, as applicable), negotiate (and renegotiate, as applicable) to determine the MFP for the Selected Drug, provide access to the MFP, and comply with the requirements determined by CMS to be necessary for administering and monitoring compliance with the Negotiation Program. Any MFP negotiated pursuant to section 1194 of the Act will be incorporated into the Agreement through an addendum executed by CMS and the Manufacturer (“Addendum”). Any MFP renegotiated pursuant to section 1194 of the Act will be incorporated into the Agreement through an additional Addendum that will supersede any prior Addendum.

This document sets forth instructions for identifying authorized representative(s) and effectuating the Agreement and any Addenda reached pursuant to the Negotiation Program.

¹ Hereinafter, “drug” includes drugs and biologics pursuant to the definition of a “qualifying single source drug” at section 1192(e)(1) of the Act.

² Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with “the manufacturer” of a selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug, CMS will enter into an agreement with the manufacturer of the selected drug in accordance with applicable guidance and regulations.

Instructions: Identifying an Authorized Representative

To help ensure timely execution of the Agreement, CMS requests that, within 5 days following publication of the list of selected drugs for an initial price applicability year, the Manufacturer submit to CMS all names, titles, and contact information for representatives authorized to execute the Agreement, inclusive of Addenda (herein referred to as “authorized representative”). The authorized representative or representatives must be legally authorized to bind the Manufacturer to the terms and conditions contained in the Agreement, including any Addenda.

Identification and system approval of an authorized representative(s) will occur within CMS Health Plan Management System (CMS HPMS). Once signatory system access for an authorized representative is approved, he or she may effectuate the Agreement in the Drug Negotiation Agreement module. If the authorized representative(s) changes, the Manufacturer must notify CMS of the new authorized representative(s). This notification must be sent via email to IRAREbateandNegotiation@cms.hhs.gov unless CMS specifies a different email address in writing. Instructions for becoming an authorized representative, requesting signatory access, and adding CMS HPMS Manufacturer Consultant Access are here: <https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-hpms.pdf>.

Instructions: Signing the Agreement and Addenda, As Applicable

Once an authorized representative is approved for signatory access, that person may effectuate the Agreement and any Addenda. Detailed instructions for signing the Agreement in CMS HPMS will be available in the Documentation section of the Drug Price Negotiation module. In the event that the CMS HPMS is not available for this purpose, CMS will provide further instructions to the authorized representative(s) on executing the Agreement.

CMS will send all notice and communications related to the Agreement and Addenda via email to the email addresses associated in CMS HPMS with the authorized representative(s). All notices and communications to CMS regarding the Agreement must be sent via email to IRAREbateandNegotiation@cms.hhs.gov unless a different policy is specified by CMS in writing.