DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: June 30, 2025

TO: Interested Parties

FROM: Christina Ritter, PhD, Acting Deputy Director

Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Drug Price Negotiation 60-Day

Information Collection Request Open for Public Comment

CMS is announcing the publication of an information collection titled the Negotiation Program Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Redaction Act Information Collection Request (hereinafter, the "Drug Price Negotiation ICR"). The Drug Price Negotiation ICR can be found in the <u>Federal Register</u> and is available for a 60-day comment period. The full text of the ICR can also be found at CMS' PRA website. Comments are due by **August 29, 2025**.

This package contains two parts: 1) the *Negotiation Data Elements Form*, which includes the data CMS will consider as the basis for determining offer(s) and counteroffer(s) throughout the negotiation and renegotiation (if applicable) processes based on the submissions required from a participating drug company and the optional submissions from the public on the selected drug and its therapeutic alternative(s), and 2) the *Drug Price Negotiation Process Form*, which includes the data and information CMS will consider if a participating drug company submits a counteroffer for a selected drug during the negotiation and renegotiation (if available) processes.

Participating drug companies will submit their information through the CMS <u>Health Plan</u> <u>Management System (HPMS) website</u>. Instructions for participating drug companies to gain access to the CMS HPMS are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess. Members of the public may optionally submit evidence about therapeutic alternatives of the selected drugs via a publicly available web link that will be available through CMS.gov.

For initial price applicability year 2028, submission of the Negotiation Data Elements by participating drug companies and the public is due by March 1, 2026. CMS will issue initial offers to the participating drug companies by June 1, 2026, and counteroffers, if applicable, will be due 30 days after receipt of the initial offer.