

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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TO: Drug Manufacturers

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SUBJECT: Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (HPMS) for the Medicare Drug Price Negotiation Program

SUMMARY

In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. The IRA authorizes Medicare to directly negotiate prices for certain high expenditure, single source drugs covered under Medicare Part B or Part D. As instructed by section 1192(a)(1) of the Social Security Act (the Act), the Centers for Medicare and Medicaid Services (CMS) will announce up to 10 drugs selected for negotiation by September 1, 2023. Manufacturers¹ of selected drugs who choose to participate in the Medicare Drug Price Negotiation Program (Negotiation Program) have a statutory deadline to enter into a Medicare Drug Price Negotiation Program Agreement (Agreement) by October 1 and submit certain information by October 2 as described in the [revised guidance](#) published on June 30, 2023. These actions will take place in the CMS Health Plan Management System (CMS HPMS), so manufacturers may wish to ensure they have the proper user permissions in place in the CMS HPMS by September 1 in the event that one of the manufacturer's drugs is selected for participation in the Negotiation Program, since adding new users or changing user permissions can take several days.

CMS is sharing this memo to provide technical instructions for obtaining user access to the Drug Price Negotiation module in CMS HPMS and describe actions manufacturers may wish to take in the CMS HPMS.

¹ In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate a maximum fair price with "the manufacturer" of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer").

A manufacturer may wish to:

1. Review the Drug Price Negotiation module user types (see section below) and determine who would need to access the CMS HPMS in the event of drug selection and whether those individuals currently have access to the CMS HPMS. If an individual does not have a CMS HPMS account, they may register for CMS HPMS access using the instructions provided in the [May 4, 2023 memo](#) entitled “Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS).” Because this process may take up to five days, individuals should start that process as soon as practicable. If an individual already has CMS HPMS access, they should make sure they are able to log in. As a reminder, a user account in the CMS HPMS becomes inactive after one year of inactivity. If an account is inactive, that user should send an email to HPMS_Access@cms.hhs.gov with the CMS user ID to reactivate the account.
2. Confirm and update, as needed, the Signatory User(s) in the Coverage Gap Discount Program (CGDP) module. In the event a manufacturer’s drug is selected for negotiation, the Primary Manufacturer’s Signatory Users with an active CMS HPMS account will *automatically* be granted signatory access to the Drug Price Negotiation module on September 1, 2023, and on a rolling basis thereafter. Accordingly, manufacturers may wish to make changes to their Signatory User(s) before September 1, 2023. To establish new signatories, manufacturers should follow the instructions provided in the [May 4, 2023 memo](#) pertaining to electronic signature access.
3. CGDP Signatory Users may email the CMS HPMS to request access to other user types (Drug Price Negotiation Data Submission and/or View/Reports) for themselves and for other existing CMS HPMS users associated with the same P number. This email must include the following information for each user: user’s name, CMS user ID, manufacturer name, P number, and the access type name and code for which access is needed. To facilitate timely processing, ensure that the email subject line includes “Drug Price Negotiation User Access.” If a manufacturer believes that one of their drugs may be selected for participation in the Negotiation Program, this email can be sent prior to September 1, 2023. Please note that Primary Manufacturers will not have access to the Agreement and Data Element Submission in the Drug Price Negotiation module until September 1, 2023, but requests can be submitted early to allow for timely processing. See the “How to Obtain Access” section below.
4. Once CMS publishes the selected drug list, CMS intends to contact the Signatory User(s) in the Drug Price Negotiation module and the Primary Point(s) of Contact as recorded in the CMS HPMS Drug Manufacturer Contract Management module, so Primary Manufacturers may wish to prioritize adding those users and contacts, as necessary. A manufacturer that believes one of their drugs may be selected may also email the IRA inbox the name, email, and phone number of their Primary Point of Contact for the Negotiation Program.
5. Be on the lookout for more information from CMS by adding IRAREbateandNegotiation@cms.hhs.gov and HPMS@cms.hhs.gov to your contact list.

Please note: Any action taken in the CMS HPMS or response from CMS HPMS help resources does not indicate a manufacturer is the Primary Manufacturer of a selected drug. CMS will continue to process requests to add and remove users and contacts as requested by manufacturers consistent with typical CMS HPMS practice.

DRUG PRICE NEGOTIATION MODULE USER TYPES

The Drug Price Negotiation module will be available starting September 1, 2023. There will be three access types available for Primary Manufacturer users in the Drug Price Negotiation module, each of which is described in the table below.

Access Type Name and Code	Access Type Description
Drug Price Negotiation Signatory Access - Manufacturer (2154)	Allows designated users to perform electronic signatures for the Agreement and any Addenda for their assigned P number(s) and selected drug(s) and certify and submit negotiation data elements.
Drug Price Negotiation Data Submission - Manufacturer (2160)	Allows designated users to enter negotiation data elements for their assigned P number(s) and selected drug(s).
Drug Price Negotiation View/Reports - Manufacturer (2161)	Allows designated users to access reports for the Agreement and the negotiation data elements for their assigned P number(s) and selected drug(s).

Depending upon their responsibilities, *a single user may be assigned one or more of these three access types* (see section below for how to request access to these user types). For example, if a manufacturer would like a single user to both sign the Agreement and input certain section 1194(e)(1) data elements, that user must be assigned *both* the Drug Price Negotiation Signatory Access user role and the Drug Price Negotiation Data Submission user role.

Please note that any user granted access to the Drug Price Negotiation module can see the information submitted through the module, such as the section 1194(e) factors. Primary Manufacturers may wish to consider the nature of this potentially sensitive or proprietary information when determining which users to include in a request for Drug Price Negotiation module access.

There is **no limit** on the number of users permitted access to the CMS HPMS per manufacturer. In fact, CMS **strongly encourages** manufacturers to establish multiple CMS HPMS users for each access type to ensure continuous coverage to meet program deadlines.

In accordance with the CMS HPMS Rules of Behavior, the sharing of CMS user IDs is **strictly prohibited**. If CMS determines that individuals are sharing a user ID, the user ID will be revoked immediately. Please request a new user ID in the CMS HPMS for each individual that must access the CMS HPMS.

ACCESS TO THE DRUG PRICE NEGOTIATION MODULE

This section discusses two pathways for potential users: new users who do not have access to the CMS HPMS at this time and existing CMS HPMS users who will need to request access to the Drug Price Negotiation module.

New Users:

In the May 4, 2023 memo, CMS provided detailed instructions for requesting new user CMS HPMS access for various Medicare programs, including the Negotiation Program. Three options are available for

requesting CMS HPMS drug manufacturer access: (1) as a direct manufacturer employee, (2) as a consultant employed by the manufacturer, and/or (3) as a signatory for a manufacturer.²

A new CMS HPMS user should follow the instructions in the May 4, 2023 memo for creating a CMS user ID and requesting the CMS HPMS job code. Since this process can take up to five business days, CMS strongly encourages Primary Manufacturers to make these requests as early as practicable. **Please note that Primary Manufacturers will not have access to the Agreement and Data Element Submission in the Drug Price Negotiation module until September 1, 2023, but requests can be submitted early to allow for timely processing.**

Once a new user has access to HPMS, they should follow the steps outlined in the “Existing Users” section below.

Existing Users:

In order to facilitate access to the Drug Price Negotiation module, **CMS will automatically grant users that have active signatory access in the CMS HPMS for the manufacturer in the CGDP module access to the Drug Price Negotiation module as a Signatory User.** This will occur automatically on September 1, 2023, and on a rolling basis thereafter for any new user with signatory access added to the P Number of the Primary Manufacturer.

The two other access types require a Signatory User to request access via email. Manufacturers may reference the table below for guidance on requesting access to each user type:

Access Type Name and Code	How to Obtain Access
Drug Price Negotiation Signatory Access - Manufacturer (2154)	<p><i>This access type will be automatically granted to individuals that have active signatory access in the CMS HPMS for the CGDP. This will occur automatically on September 1, 2023 and on a rolling basis after.</i></p> <p>To make this request, a prospective signatory must: (1) Prepare an official letter that states the user’s name, role (e.g., CEO), CMS user ID, P number(s), and that electronic signature access is required. The letter must be provided on manufacturer’s official letterhead and signed by a senior official of the organization. Manufacturers can request electronic signature access for more than one signatory on a single letter; and (2) Submit the official letter via e-mail in scanned PDF format to HPMSconsultantAccess@cms.hhs.gov. To facilitate timely processing, please indicate “Manufacturer Electronic Signature Access” in the subject line of the email. These instructions are available in the May 4, 2023 memo.</p>

² As described in the May 4, 2023 CMS HPMS memo, to be eligible for electronic signature access in HPMS, the prospective manufacturer signatory must meet one or more of the following criteria: (1) Serve as the primary manufacturer’s Chief Executive Officer (CEO), where the individual has been duly appointed by the organization’s board or other governing body; (2) Serve as the primary manufacturer’s Chief Financial Officer (CFO), where the individual has been duly appointed by the organization’s board or other governing body; (3) Serve in a role other than as the primary manufacturer’s CEO or CFO, where the individual has authority that is equivalent to a CEO or CFO; or (4) Serve in a role with the primary manufacturer, where the individual has been granted directly delegated authority to perform electronic signatures on behalf of one of the individuals noted in 1-3.

Access Type Name and Code	How to Obtain Access
Drug Price Negotiation Data Submission - Manufacturer (2160)	<p><i>This access type is only assigned upon an email request by a Signatory User of the Primary Manufacturer.</i></p> <p>To make this request, a Signatory User must send an email to HPMS_Access@cms.hhs.gov that contains the following information for each user: user's name, CMS user ID, manufacturer name, P number(s), and the access type name and code for which access is needed. To facilitate timely processing, ensure that the email subject line includes "Drug Price Negotiation User Access."</p>
Drug Price Negotiation View/Reports - Manufacturer (2161)	<p><i>This access type is only assigned upon an email request by a Signatory User of the Primary Manufacturer.</i></p> <p>To make this request, a Signatory User must send an email to HPMS_Access@cms.hhs.gov that contains the following information for each user: user's name, CMS user ID, manufacturer name, P number(s), and the access type name and code for which access is needed. To facilitate timely processing, ensure that the email subject line includes "Drug Price Negotiation User Access."</p>

CMS HPMS user accounts become inactive after one year if a user has not logged on to their account. CMS encourages a manufacturer that believes that one of their drugs may be selected for participation in the Negotiation Program to ensure that the necessary users can access their CMS HPMS accounts. If an account is inactive, send an email to HPMS_Access@cms.hhs.gov with the CMS user ID to reactivate the account.

If a user no longer requires access to the Drug Price Negotiation module, a Signatory User must send an email to HPMS_Access@cms.hhs.gov with the user's name, CMS user ID, and manufacturer name to request removal of access.

HELPFUL LINKS:

- For accessing CMS HPMS: <https://hpms.cms.gov/app/ng/home/>.
- For instructions on creating a CMS User ID and establishing a Signatory User: <https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-hpms.pdf>.
- Instructions on using the Drug Price Negotiation module, including accessing and signing the Agreement, submitting negotiation data elements, reviewing the Initial Offer from CMS, reviewing any Negotiated Maximum Fair Price Addendum, submitting any Counteroffer and completing its associated Addendum, and reviewing any Final Offer from CMS and completing its associated Addendum, will be forthcoming and available in the module itself.

ADDITIONAL QUESTIONS AND COMMUNICATION

CMS looks forward to working with you as CMS implements the Negotiation Program. CMS will send all communications related to the Negotiation Program via email to the Signatory User(s) identified in the

CMS HPMS using the email addresses associated with those users in the CMS HPMS. CMS may also contact the Primary Contact on file in the CMS HPMS Drug Manufacturer Contract Management module. If there is a Primary Point of Contact that a Primary Manufacturer would like CMS to contact related to the Negotiation Program, CMS requests that a Primary Manufacturer email the name and contact information for that person within five business days of the selected drug list being published to IRAREbateandNegotiation@cms.hhs.gov. A manufacturer that believes it may be a Primary Manufacturer of a selected drug may email their name, email, and phone number in advance of September 1, 2023. These contacts will not be used if a manufacturer is not a Primary Manufacturer for initial price applicability year 2026.