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

CENTER FOR MEDICARE

DATE: January 10, 2025

TO: Drug Manufacturers

FROM: Vanessa S. Duran, Director
Medicare Drug Benefit and C & D Data Group

Christina Ritter, Director
Medicare Drug Rebate and Negotiations Group

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

In August 2022, the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) was signed into law. The IRA authorized Medicare to directly negotiate prices for certain high expenditure, single source drugs covered under Medicare Part B or Part D. As instructed by section 1191(b)(3) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) will announce drugs selected for negotiation no later than February 1 of the year that begins two years prior to the initial price applicability year (e.g., February 1, 2025 for initial price applicability year 2027).

Primary Manufacturers of selected drugs, which are the entities that hold the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the 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 February 28, 2025, and submit certain information by March 1, 2025. Between June 1 and October 31, 2025, negotiations for maximum fair prices (MFPs) between CMS and participating manufacturers will occur. CMS is using the CMS Health Plan Management System (CMS HPMS) to facilitate many of the activities involved in the Negotiation Program (further outlined in the table below). The following forms are available in the Drug Price Negotiation module of the CMS HPMS to facilitate these actions; to access these forms, navigate to the Drug Price Negotiation module within the CMS HPMS and click on a form displayed on the list shown on lefthand side:

Form	Description
Agreements	In accordance with section 1193(a) of the Act, the Secretary shall enter into Agreements with manufacturers of selected drugs for a price applicability period. This form allows both Primary Manufacturers and CMS to enter electronic signatures to effectuate Agreements.
Manufacturer-Specific Data Form (Sections A-H)	After entering into an Agreement with CMS, the Primary Manufacturer of each selected drug must submit to CMS certain information with respect to the selected drug, including the non-Federal average manufacturer price (non-FAMP) and related data, as outlined in section 1193(a)(4)(A) of the Act, and the negotiation factors outlined in section 1194(e)(1) of the Act. This form facilitates entry of required data elements for negotiation.
Evidence About Selected Drugs and Their Therapeutic Alternatives Form (Sections I-J)	CMS is seeking input from the public and from Primary Manufacturers under section 1194(e)(2) of the Act to consider information on the selected drug and its therapeutic alternative(s). This form facilitates entry of optional information about selected drugs and their therapeutic alternative(s).
Negotiation Process	Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with the Primary Manufacturer of the selected drug. This form facilitates exchange of offers and counteroffers for a selected drug.

CMS is sharing this memo to provide technical instructions for obtaining user access to the CMS HPMS and the Drug Price Negotiation module in the CMS HPMS. This memo supersedes the previous CMS HPMS memos related to the Negotiation Program.

Gaining Access to HPMS

In order to access the CMS HPMS, each manufacturer user must have the following:

1. An active CMS user ID with the CMS HPMS production job code assigned (HPMS_Prod_AWS);
2. One or more P Numbers assigned to the user ID in CMS HPMS; and the
3. Applicable HPMS access types assigned to the user ID.

The process to obtain a CMS user ID can take up to five business days.

Please note that there is **no limit** on the number of users permitted access to CMS HPMS per manufacturer. In fact, CMS strongly encourages manufacturers to establish multiple CMS HPMS users to ensure that the organization retains 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.

Requesting a CMS User ID and HPMS Access

To obtain a CMS user ID with the HPMS job code, a prospective manufacturer user must:

1. Submit a request for a CMS user ID via the ICT (formerly known as EFI) system. Manufacturers must use the "direct plan employee" workflow.

Instructions are available in the Download section on: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html
Users can also visit the YouTube video created for accessing ICT: https://youtu.be/LeLlCfJZJYg

2. After receipt of the CMS user ID:
    a. Complete the CMS computer-based security training to activate your account at https://www.cms.gov/cbt/login/default.aspx activation of your account will add the HPMS job code to your profile.
    b. Change the default password at https://eua.cms.gov

3. Log into CMS HPMS at https://hpms.cms.gov and complete the user account information. You will know you are set up when you receive the email from the HPMS mailbox.

An individual must have a Social Security Number (SSN) in order to obtain a CMS user ID.

Appendix A provides instructions on CMS' annual user ID recertification and password maintenance requirements.

Obtaining HPMS Access as a Manufacturer Consultant

Manufacturers may employ consultants to perform business functions in the CMS HPMS on their behalf. CMS requires those sponsoring manufacturers to submit official letters to authorize CMS HPMS access for these designated consultant users.

Appendix B outlines the steps for authorizing manufacturer consultant access in the CMS HPMS after the consultant has obtained a CMS user ID.

Gaining Access to the Drug Price Negotiation Module

Drug Price Negotiation Module Access Types

There are three access types available for manufacturer users in the Drug Price Negotiation module:

- Drug Price Negotiation Data Submission – Manufacturer
- Drug Price Negotiation Signatory Access – Manufacturer
- Drug Price Negotiation View/Reports – Manufacturer

To check what access a user currently has, they should log in to the CMS HPMS and navigate to the User Resources module and select "My Account." Once on the My Account page, a user can check their current access type(s) by clicking on the User Access Report tab (as these access types are specific to the Drug Price Negotiation module, please ensure that you look under the Drug Price Negotiation heading when checking current access).

Depending on 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 single manufacturer user would like to create, populate, certify, and submit a counteroffer, that user must be assigned *both* the Drug Price Negotiation Signatory Access – Manufacturer and Drug Price Negotiation Data Submission – Manufacturer access types (see below for details).

Please note that any user granted access to the Drug Price Negotiation module can see information submitted through the module, such as the Manufacturer-Specific Data Form (Sections A-H). 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 Drug Price Negotiation module.

The following sections describe the functionality that each access type provides for each post-selection form in the Drug Price Negotiation module.

Agreements

Access Type Name and Code	Access Type Description
Drug Price Negotiation Data Submission – Manufacturer	N/A (no functionality is associated with this access type within this form)
Drug Price Negotiation Signatory Access – Manufacturer	Allows designated users to perform electronic signatures for the Agreement and any Agreement Addenda for their assigned P number(s) and selected drug(s).
Drug Price Negotiation View/Reports – Manufacturer	Allows designated users to access reports for the Agreement and any Agreement Addenda and view Agreements and any Agreement Addenda for their assigned P number(s) and selected drug(s).

Manufacturer-Specific Data Form (Sections A-H)

Access Type Name and Code	Access Type Description
Drug Price Negotiation Data Submission – Manufacturer	Allows designated users to enter information into the fields available for each negotiation data element for their assigned P number(s) and selected drug(s).

Drug Price Negotiation Signatory Access – Manufacturer	Allows designated users to certify and submit negotiation data elements for their assigned P number(s) and selected drug(s).
Drug Price Negotiation View/Reports – Manufacturer	Allows designated users to access reports for the negotiation data elements and view submissions for their assigned P number(s) and selected drug(s).

Evidence About Selected Drug and Their Therapeutic Alternatives Form (Sections I-J)

Access Type Name and Code	Access Type Description
Drug Price Negotiation Data Submission – Manufacturer	Allows designated users to enter information into the fields available for each negotiation data element for their assigned P number(s) and selected drug(s).
Drug Price Negotiation Signatory Access – Manufacturer	Allows designated users to certify and submit negotiation data elements for their assigned P number(s) and selected drug(s).
Drug Price Negotiation View/Reports – Manufacturer	Allows designated users to access reports for the negotiation data elements and view submissions for their assigned P number(s) and selected drug(s).

Please note, respondents who are not Primary Manufacturers do not need a CMS User Type to access the questions in Sections I and J. These respondents will answer these questions via a separate web application, which is publicly accessible at https://hpms.cms.gov.

Negotiation Process

Access Type Name and Code	Access Type Description
Drug Price Negotiation Data Submission – Manufacturer	Allows designated users to create and enter information into manufacturer-initiated offers for their assigned P number(s) and selected drug(s).
Drug Price Negotiation Signatory Access – Manufacturer	For each of their assigned P number(s) and selected drug(s): - For CMS-initiated offers, allows designated users to reject an offer or navigate to the Agreements section of the Drug Price Negotiation module to accept an offer by signing the Agreement Addendum. - For manufacturer-initiated offers, allows users to certify manufacturer-initiated offers and share them with CMS.
Drug Price Negotiation View/Reports – Manufacturer	Allows designated users to view CMS- and manufacturer-initiated offers and counteroffers for their assigned P number(s) and selected drug(s).

Access to the Drug Price Negotiation Module

For a user to have one or more of the three access types available for manufacturer users in the Drug Price Negotiation module, access must be requested via email.

The process to add an access type to an existing user in the CMS HPMS generally takes at least 1-2 business days. Manufacturers may reference the table below for guidance on requesting access to each access type:

Access Type Name and Code	How to Obtain Access
Drug Price Negotiation Signatory Access – Manufacturer	To be eligible for electronic signature access in the CMS HPMS, the prospective manufacturer signatory must meet one or more of the following criteria: 1. Serve as the Primary Manufacturer's CEO, where the individual has been duly appointed by the organization's board or other governing body. 2. Serve as the Primary Manufacturer's CFO, where the individual has been duly appointed by the organization's board or other governing body. 3. Serve in a role other than the Primary Manufacturer's CEO or CFO, where the individual has authority that is equivalent to a CEO or CFO. 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 above. 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, manufacturer name, P number(s), and that electronic signature access is required. The letter must be provided on the Primary 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 for Drug Price Negotiation Program" in the subject line of the email. Note: Due to potentially sensitive or proprietary information in the Drug Price Negotiation module, CMS will require the manufacturer to gain elevated privileges. Thus, Signatory Users for other Drug Manufacturer functionality (e.g., Drug Manufacturer Discount Program - Manufacturer Signatory) must still request Signatory access for the Drug Price Negotiation module (*the Drug Price Negotiation Signatory Access – Manufacturer user access type is distinct from both the Drug Manufacturer Discount Program - Manufacturer Signatory (0397) user access type and the Signatory Contact*

	and Secondary Signatory Contact in the Drug Manufacturer Contract Management module). If a user is newly requesting the Signatory Access user role, please ensure that that documentation is provided to the CMS HPMS. If a user already has the Signatory Access user role, but that role was granted on the basis of a role or delegation of authority from a Primary Manufacturer different from the role or delegation of authority used in the initial request, please submit appropriate documentation to the CMS HPMS prior to signing an Agreement. CMS may periodically review which users have the Drug Price Negotiation Signatory Access – Manufacturer user access type and remove such access if the documentation provided does not meet the requirements (e.g., if the official letter was not on the Primary Manufacturer's letterhead).
Drug Price Negotiation Data Submission – Manufacturer	To make this request, a user with the Drug Price Negotiation Signatory Access – Manufacturer access type 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"
Drug Price Negotiation View/Reports – Manufacturer	To make this request, a user with the Drug Price Negotiation Signatory Access – Manufacturer access type 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"

CMS HPMS user accounts become inactive after one year if a user has not logged on to their account. 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 Drug Price Negotiation 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.

Contact Information for Negotiation Program

CMS looks forward to working with manufacturers as CMS implements the Negotiation Program. CMS is providing the ability for manufacturers to designate a Primary and Secondary Drug Price Negotiation Contact for communications related to the Negotiation Program. CMS

will send all communications related to the Negotiation Program via email to these contacts, if designated. Additionally, CMS will send all communications related to the Negotiation Program via email to the Drug Price Negotiation Signatory User(s) using the email addresses associated with those users in the CMS HPMS. These contacts will not be used if a manufacturer (1) has not submitted a Small Biotech Exception (2) has not submitted a Biosimilar Delay request or (3) is not a Primary Manufacturer with a drug selected for negotiation.

To add or update the Primary or Secondary Drug Price Negotiation Contacts in CMS HPMS, a HPMS User may take the following steps:

1. Log into CMS HPMS here: https://hpms.cms.gov/app/ng/home/
2. Hover over the "Drug Manufacturers" tab at the top of the screen and navigate to the "Drug Manufacturer Contract Management" module
3. Select the P Number of the Primary Manufacturer
4. Navigate to the Manage Contact Data page
5. Input or update information into the "Primary Drug Price Negotiation Contact" field and, as feasible, the "Secondary Drug Price Negotiation Contact" field.
6. Keep these contacts up to date to ensure designated individuals receive all relevant correspondence from CMS.

For questions related to the Negotiation Program that are not directly related to accessing the CMS HPMS, please contact IRARebateandNegotiation@cms.hhs.gov

Appendix A - CMS User ID Recertification and Password Maintenance Requirements

Annual Recertification Process

CMS user IDs must be recertified electronically on an annual basis using CMS' System Access Certification (SAC) application at https://eua.cms.gov/eurekify/portal/login. For assistance with the SAC, the security computer-based training (CBT), and passwords, please contact the **CMS IT Service Desk at 1-800-562-1963 or 410-786-2580**.

If you do not complete the recertification in a timely manner, your CMS user ID will be revoked, and you will have to re-apply as a new user.

Upon receipt of a recertification email notice from eua@cms.hhs.gov, you must complete both Steps 1 and 2:

Step 1: System Access Review

1. Log into the SAC at https://eua.cms.gov/eurekify/portal/login using your CMS HPMS credentials.
2. If you find a certification item on your home screen, select the "Certify" button to proceed.
3. Select the check box that appears next to your name. This action will automatically select the check boxes for all of your associated job codes.
4. Select the "Keep" button in order to retain access to the selected job codes.
5. On the summary page, select the "Submit" button to continue.
6. On the confirmation pop-up window, select the "X" that appears in the upper right-hand corner in order to complete the system access review step.

Step 2: Security Training

1. Access the CMS security CBT (Information Systems Security and Privacy Awareness Training) at the following URL: https://www.cms.gov/cbt/login/
2. Log in using your CMS credentials and complete the training.
3. Set up your multi-factor authentication (MFA) preference for the CMS IDM. Note: This MFA process is different than the process for establishing MFA preferences for accessing HPMS.
4. Agree to the Terms & Conditions and click on Sign In.
5. Select the Information Systems Security and Privacy Awareness Training link on your dashboard.
6. Once on the course page, click on "Launch ISSPA Course", then select "Enter" to begin the ISSPA training course.
7. Once you have completed the training, sign and upload the Rules of Behavior to the "Rules of Behavior Upload" on the course page.
8. Once you have uploaded the Rules of Behavior, you are required to complete a short post-course evaluation.

9. Once you have completed the evaluation, your status will be updated to completed and you will have access to the certificate of completion.

Step 3: Checking Your Status

You can check your System Access Review (SAC) and security CBT status in EUA at any time.

1. Log into EUA at https://eua.cms.gov using your CMS HPMS credentials.
2. Click on the "View My Identity" button or use the link from the left-hand navigation bar under the "Home" header.
3. Your identity information will appear on the subsequent page.

If the SAC Recert Status is "OK," the SAC Recert Completion Date has changed to the day you completed your system access review, and the SAC Recert Due Date changed to the following year, you have completed the system access review step successfully.

If the SAC Recert Status is "Pending," you have completed the system access review, but it is pending CMS approval.

If the SAC Recert Status is "Due," you must complete the system access review as described in Step 1 above. Upon completion, your system access review will be sent to CMS for approval.

If your CBT Recert Status is "OK," you have completed the CBT and no further action is required on this step. The CBT Completion date should reflect the day you completed your CBT, while the CBT Recert Due Date should reflect the following year.

If your CBT Recert status is "Due," you must complete the security CBT as described in Step 2 above. Please note that your CBT status will be updated overnight, not immediately. However, if the CBT status remains unchanged, send a copy of your CBT certificate to CBT@cms.hhs.gov and request that CMS update your CBT status manually in EUA.

Password Maintenance

CMS passwords must be reset every 60 days. You can reset your password using the CMS EUA system at https://eua.cms.gov. To change your password, select the "Change My Password" link in the left menu and follow the instructions listed on the page.

For technical assistance with this process, please contact the CMS IT Service Desk at either 1-800-562-1963 or 410-786-2580. If your account locks and your password must be reset by the CMS IT Service Desk, your password will be reset to the default (i.e., first letter of your last name in upper case, second letter of your last name in lower case, followed by the last six digits of your social security number). You are required to change the default password immediately via EUA.

Please note that the CMS HPMS Help Desk cannot reset passwords. Additionally, if a user fails to update their password within the 60-day period, their account will only remain revoked for a

month and then will be deleted. It is imperative users keep their account in a good status to retain their ID.

For additional information, please visit https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/RecertAndPwdProcess.html.

Appendix B - Establishing HPMS Manufacturer Consultant Access

To authorize a consultant's access, the manufacturer must perform the following steps:

1. Prepare an official letter that states the user's name, CMS user ID, consultant company name, the type of consultant access being requested, and the P number(s) for which consultant access is needed. The letter must be provided on the sponsoring manufacturer's official letterhead **and** signed by a senior official of the organization. Manufacturers can submit one letter and include multiple consultants on that letter if they are all obtaining the same consulting access type. CMS recommends the use of the following sample language:

   (Name of manufacturer) hereby requests that *(name of consultant user, the CMS user ID, and consultant company name)* be granted consultant access for the following P number(s): *(list P number(s) here)*.

2. Submit the official letter via e-mail in scanned PDF format to HPMSConsultantAccess@cms.hhs.gov. To facilitate timely processing, please indicate the type of consultant access in the subject line of the e-mail.

   NOTE: If a user is serving multiple manufacturers, only **one** CMS user ID is required. However, an official letter must be provided from **each** manufacturer for which the user will be serving as an agent in HPMS.

Manufacturers may direct questions regarding consultant access to HPMSConsultantAccess@cms.hhs.gov.