



CENTER FOR MEDICARE

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TO: Drug Manufacturers

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SUBJECT: Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)

Drug manufacturers must establish access to HPMS in order to participate in various Medicare program areas, including, but not limited to, the following:

- Coverage Gap Discount Program (CGDP) ¹
- Manufacturer Discount Program (MDP)
- Drug Price Negotiation Program, including Small Biotech Exception requests and submission of Negotiation Data Elements

This memo provides technical instructions for obtaining access to HPMS: (1) as a direct manufacturer employee, (2) as a consultant employed by the manufacturer, and/or (3) as a signatory for a manufacturer.

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

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

¹ All manufacturers participating in CGDP will retain their current P numbers. Existing manufacturer users will also retain their current HPMS user accounts, as long as the account remains active and is in good standing per CMS IT requirements (e.g., password is being reset timely and annual recertification process has been completed).

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

In accordance with the 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 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 EFI:
<https://youtu.be/LeLlCfJZJYg>

2. After receipt of the CMS user ID:
 - a. Change the default password at <https://eua.cms.gov>.
 - b. Complete the CMS computer-based security training at <https://www.cms.gov/cbt/login/default.aspx>.
3. Log into HPMS at <https://hpms.cms.gov> and complete the user account information.

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 HPMS on their behalf. CMS requires those sponsoring manufacturers to submit official letters to authorize HPMS access for these designated consultant users.

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

Establishing HPMS Electronic Signature Access as a Manufacturer

CMS requires that authorized officials of the manufacturer organization sign documents and complete attestations using the electronic signature process in HPMS.

These signatures include, but are not limited to, the following:

- CGDP Agreements;
- Small Biotech Exception requests;
- Drug Price Negotiation Manufacturer Agreements;
- Negotiation Program Data Elements; and
- MDP Agreements.

Eligibility for Electronic Signature Access

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.
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.

CMS **strongly encourages** manufacturers to establish multiple signatories in HPMS, as CMS will **not** accept signatures outside of the HPMS electronic signature process.

An individual that fails to meet the criteria noted above is ineligible for electronic signature access. **If CMS discovers that a signatory does not meet these criteria, documents signed and attestations completed by that signatory may be deemed invalid.**

Appendix C outlines the steps for establishing electronic signature access as a manufacturer in HPMS.

Requesting Elevated Privileges

CMS automatically assigns certain HPMS access types to a manufacturer user's account upon account creation (e.g., the management of basic drug manufacturer information such as manufacturer contacts, EINs, and labeler codes).

However, where a function has been deemed sensitive, CMS will require the manufacturer user to request access. For example, CMS will treat access types governing the submission and view of drug negotiation data elements as sensitive. Prior to the release of sensitive functionality, CMS will provide manufacturers with instructions for requesting these elevated privileges for individuals whose positions require the access.

Part B-Only Drug Manufacturers

Later in 2023, CMS will begin issuing P numbers to Part B-only drug manufacturers, upon request. Having a CMS-issued P number will allow Part B-only drug manufacturers to maintain general information about their organization in HPMS and receive CMS communications targeted to manufacturers. CMS will release instructions on this process under separate cover.

For questions about this memo, please contact Kristy Holtje at Kristy.Holtje@cms.hhs.gov.

For technical assistance with HPMS, please contact the HPMS Help Desk at either hpms@cms.hhs.gov or 1-800-220-2028.

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 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. Click the "Information Systems Security and Privacy Awareness Training" link.
5. Click the "Click here for CMS Information Systems Security and Privacy Awareness (ISSPA) Training" link. Then select the "Click to launch the course" link.
6. Once complete, click the "Click to complete Course" button and print a copy of your certificate for your records, as it may be needed later in the process. Please note that you may need to log in a second time in order to generate your certificate. Your CBT is not considered to be complete until you obtain the certificate.

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 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 HPMS Help Desk cannot reset passwords.

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.

Appendix C - Establishing HPMS Electronic Signature Access as a Manufacturer

Once the prospective signatory has obtained a CMS user ID with HPMS access, the manufacturer 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. CMS recommends the use of the following sample language:

(Name of manufacturer) hereby requests that (Name of individual, role, and CMS user ID) be granted electronic signature access for the following P number(s): (list specific P numbers).

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 e-mail.

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