

2021 Manufacturer Agreement Process

NOTE: *These instructions are for manufacturers who do not currently participate in the Coverage Gap Discount Program (Discount Program) and wish to become part of the program beginning with the 2021 calendar year. A manufacturer with an existing Discount Program agreement need not re-contract to continue to participate in the program as its existing agreement remains in force unless terminated by either party.*

Manufacturers who wish to participate in the Discount Program beginning with the 2021 calendar year must submit a signed Manufacturer Agreement and a signed Third Party Administrator Agreement (Agreements) to the Centers for Medicare & Medicaid (CMS) by January 30, 2020. The Agreements are administered and signed electronically through CMS' Health Plan Management System (HPMS) system. To initiate the contracting process, manufacturers must first request a pending contract "P" number by completing the following steps:

- Submit the following information via email to CGDPandManufacturers@cms.hhs.gov:
 - Manufacturer Name
 - DUNs Number
 - Primary Contact First and Last Name
 - Primary Contact Email Address
 - Primary Contact Phone Number
- The subject line of the email should read "[manufacturer name] Request for P Number".

P numbers will be issued beginning May 7, 2019. We recommend that manufacturers submit P number requests by October 17, 2019 to allow sufficient time to obtain P numbers and submit the necessary forms to gain access to the HPMS system.

Once CMS receives the Request for P Number email, the primary contact will receive an email containing the pending contract "P" number and the instructions to obtain access to HPMS. Manufacturers' Primary Contacts and those persons with authority to enter into contracts with CMS on behalf of the manufacturer must have access to HPMS to complete the contracting process.

The model Discount Program and TPA agreements are available on the CMS website in the Downloads section. Once your organization has access to HPMS the person identified with authority to enter into the Agreements will be allowed to electronically sign the documents until the January 30, 2020 deadline.

Labeler Code Maintenance- Manufacturers are responsible for keeping their labeler codes current on an ongoing basis. A manufacturer that does not yet have a valid labeler code is encouraged to sign the 2021 agreement. Once logged into the HPMS module the company representative will have an opportunity to indicate that the organization does not have any approved codes. Once new codes are received the company will update HPMS. New codes must be updated within HPMS as soon as possible but no later than 3 business days after having received written notification of the codes from the FDA. This must be done to both comply with the terms of the Discount Program agreement and to make sure that the manufacturer's drugs can be covered by Part D.

Any questions regarding the Agreements should be sent via email to CGDPandManufacturers@cms.hhs.gov.

Thank you for your interest in the Discount Program.