

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



CENTERS FOR MEDICARE & MEDICAID SERVICES

DATE: March 1, 2016
TO: All Part D Sponsors
FROM: Zabeen Chong, Director
Provider Enrollment and Oversight Group (PEOG)
Center for Program Integrity

Jennifer R. Shapiro, Acting Director
Medicare Drug Benefit and C&D Data Group (MDBG)
Center for Medicare

SUBJECT: Delay in Enforcement of the Medicare Part D Prescriber Enrollment Requirement to February 1, 2017

Delay in Enforcement of the Medicare Part D Prescriber Enrollment Requirement

The Centers for Medicare & Medicaid Services (CMS) finalized CMS-4159-F *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (“Final Rule”) on May 23, 2014. On May 6, 2015 CMS published CMS-6107-IFC *Medicare Program; Changes to the Requirements for Part D Prescribers*, an interim final rule with comment (“IFC”) that made changes to the Final Rule. These regulations are codified at 42 CFR § 423.120(c)(6). We refer to these rules in this memo as the “Part D Prescriber Enrollment Requirement.”

CMS is delaying enforcement of the Part D Prescriber Enrollment Requirements until **February 1, 2017**. We have a responsibility to enforce this crucial program integrity and basic quality assurance protection for Medicare Part D beneficiaries as soon as possible. However, we also have a responsibility to enforce it in a way that minimizes the potential for disrupting beneficiaries’ access to needed Part D medications.

With the revised date, prescribers will have sufficient time to complete their enrollment activities. In addition, this delay will provide Part D sponsors and pharmacy benefit managers (PBMs) and Medicare Advantage Organizations (MAOs) offering MA-PDs additional time to finalize the system enhancements needed to comply with the Part D Prescriber Enrollment Requirement and various guidance documents released by CMS since publication of the IFC, in particular the comprehensive Technical Guidance released on December 29, 2015. These various guidance documents are available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html>.

Prescriber Outreach Activities

In order to continue to make meaningful and measurable progress toward a minimally disruptive implementation of the Medicare Part D Prescriber Enrollment Requirement, CMS strongly encourages MAOs and Part D sponsors and their PBMs to **begin or continue prescriber outreach activities** in accordance with the guidance in Attachment A to this memo, which is an updated version of the same Attachment A to the June 1, 2015 memo, “Medicare Part D Prescriber Enrollment Update.” These outreach activities enhance CMS’ continuing prescriber outreach and ongoing monitoring of prescriber enrollment trends and potential beneficiary impact. This period will provide MAOs, Part D sponsors and their PBMs with an opportunity to address potential enrollee impact and specific business considerations arising from prescriber enrollment trends. Such activities will in turn inform CMS’ ongoing outreach, monitoring, and implementation of the prescriber enrollment requirement. CMS appreciates the efforts of stakeholders to work cooperatively with the agency to implement the requirement in this manner.

CMS also strongly encourages prescribers of Part D drugs (except those who meet the definition of “other authorized prescribers”) to **submit their Medicare enrollment applications or opt-out affidavits to their Medicare Administrative Contractors (MACs) before August 1, 2016**. This should provide the MACs with sufficient time to process the prescribers’ applications or opt out affidavits and thus prevent prescription drug claims associated with their prescriptions from being rejected by Part D plans beginning February 1, 2017. Prescribers can refer to the following CMS website for more information go.cms.gov/PrescriberEnrollment.

Additional Forthcoming Guidance

CMS will continue to provide additional guidance as appropriate, such as a template for the required individualized written communication that must be sent to beneficiaries who receive a provisional supply, and guidance on how Part D plan sponsors should process enrollee inquiries and complaints related to the prescriber enrollment requirement.

Questions concerning this memo may be addressed to PartDPolicy@cms.hhs.gov.

ATTACHMENT A

Part D Prescriber Enrollment Requirement - Sponsor Outreach Activities

In order to continue to make measurable and meaningful progress toward a minimally disruptive implementation of the Medicare Part D prescriber enrollment requirement, CMS strongly encourages MAOs, Part D sponsors and their PBMs to begin or continue prescriber outreach **activities** in accordance with this guidance.

- **No later than January 1, 2016 until January 31, 2017 – Part D Prescriber Outreach**
- MAOs, Part D sponsors (and their PBMs) should develop and implement a prescriber outreach strategy with the goal of achieving enrollment of the prescribers (except other authorized prescribers “OAPs”, who cannot enroll) who write prescriptions for their enrollees.
- The outreach strategy should be tailored to be the most effective for a sponsor’s plans.
- The strategy should include timely review of effectiveness and results and adapt as warranted.
- MAOs should consider the additional guidance memo of June 10, 2015 “Requirement for Part D Coverage: Prescriber Requirements”.
- Examples of possible outreach strategies:
 - Rolling Outreach:
 - *First Month*: Contact prescribers associated with the top XX% of impacted Part D claims within a certain time period. (*Note*: One communication per prescriber, not per beneficiary or per claim).
 - *Second Month*: Contact prescribers associated with the next XX% of impacted claims.
 - *Third month*: Contact prescribers associated with the remaining impacted claims, excepting prescribers associated with a nominal percentage of claims.
 - *Fourth month*: Re-contact the top prescribers who have not yet filed an enrollment application or opt-out affidavit.
 - Simultaneous Outreach: Sponsor contacts all prescribers simultaneously. 90-120 days after initial contact, sponsor re-contacts top prescribers who are still not enrolled or opted-out.
- CMS recognizes that outreach strategies may vary. For instance:
 - Sponsors may base their outreach strategy on the number of impacted enrollees versus number of claims, or a combination of the two.
 - Sponsors may engage in prescriber outreach at the plan or contract level.
 - Sponsors may adopt strategies that vary by geographical region.
 - Sponsors may involve network pharmacies in their outreach strategies, for example, to educate them on the upcoming prescriber enrollment requirement and depending on the potential impact of the requirement to a particular network pharmacy; however, CMS

would expect that a sponsor would not unduly burden any pharmacy with respect to prescriber outreach.

- CMS has provided a sample communication that sponsors can use and have used for prescriber outreach, which is updated to address the new enforcement date and is included as an attachment. As with the prior version, this template outreach communication may only be reproduced and used by sponsors/plans/PBMs without changes, except that it may be reproduced in black and white or in color. Sponsors/plans/PBMs may draft and include a separate letter with the template copy to convey the additional information that they believe is important to motivate the targeted prescribers to enroll in Medicare.
- Sponsors should note that they may compare NPIs of prescribers currently writing prescriptions for enrollees in their plans to the NPIs listed on the Medicare Individual Provider File available at <https://data.cms.gov/dataset/MedicareIndividual-Provider-List/u8u9-2upx>. This list indicates which prescribers are already enrolled in or opted out of Medicare, and sponsors can thus use the list to eliminate outreach to prescribers who are already enrolled or opted out.

In addition, two lists indicating which prescribers have pending applications are available at go.cms.gov/PrescriberEnrollment under “Check Your Enrollment Status” - one for physicians and one for non-physicians, both also by NPIs. Sponsors may also compare the NPIs of these latter two lists to the NPIs of prescribers currently writing prescriptions for enrollees in their plans to eliminate outreach to prescribers who already have pending applications. Finally, the NPPES file includes prescribers’ last self-reported addresses and taxonomy(ies) and is available at http://download.cms.gov/nppes/NPI_Files.html.

- CMS has provided a comprehensive website about the enrollment requirement at go.cms.gov/PrescriberEnrollment that providers can reference.
- CMS has prepared 1-800-Medicare and MAC customer service representatives for inquiries from prescribers about the enrollment requirement.
- CMS will continue to conduct prescriber outreach. It is understood that prescribers will receive multiple communications about the Part D prescriber enrollment requirement due to CMS outreach and outreach from multiple sponsors.
- CMS is evaluating the potential effectiveness of enrollee outreach before enforcement and will provide future guidance on this topic.
- **February 1, 2017 – Enforcement of the Part D Prescriber Enrollment Requirement by CMS begins.**

**Important official message for providers
who prescribe drugs for Medicare patients.**



ENROLL IN MEDICARE AS A PROVIDER NOW!

Dear Prescriber. You have been identified as a provider who currently prescribes drugs for Medicare patients, but who is not enrolled in (or validly opted-out of) Medicare. **Because of a new Medicare requirement, it is crucial for your patients' health that you enroll in Medicare to prescribe (or validly opt out, if appropriate) as soon as possible.** Please follow the below steps. A delay on your part could result in your Medicare patients not being able to obtain drugs you prescribe for them.

What's changed & when?

We have published rules that will soon require nearly all providers (for example, dentists, physicians, psychiatrists, residents, nurse practitioners, and physician assistants), including Medicare Advantage providers, who prescribe drugs for Part D patients to enroll in Medicare (or validly opt out, if appropriate). In the near future, we will enforce a requirement that Medicare Part D prescription drug benefit plans may not cover drugs prescribed by providers who are not enrolled in (or validly opted out of) Medicare, except in very limited circumstances.

Why is this important to my patients and me?

Unless you enroll (or validly opt out), Medicare Part D plans will be required to notify your Medicare patients that the Part D drugs you prescribe cannot continue to be covered. Please also note that if you opt out, you cannot receive reimbursement from traditional Medicare or a Medicare Advantage plan, either directly or indirectly (except for emergency and urgent care services; see 42 CFR 405.440 for details.)

What steps do I need to take?

To help your Medicare patients, please enroll in Medicare for the limited purpose of prescribing Part D drugs. There are no fees to complete the process. You can do so electronically or on paper:

1. *Electronic process:* Use the PECOS system at go.cms.gov/pecos. For limited enrollment, we recommend using the step-by-step instructions at go.cms.gov/PECOSsteps and a video tutorial at Go.cms.gov/PECOSVideo; or
2. *Paper process:* Complete the paper application for limited enrollment at go.cms.gov/cms855o and submit it to the MAC in your geographic area. To locate your MAC, please refer to the MAC list at: go.cms.gov/partdmaclist.

If you need assistance with the process of enrolling in (or validly opting out) of Medicare, please contact the MAC within your geographic area.

Thank you for your prompt and careful attention to this important matter, and for serving Medicare beneficiaries. These new CMS rules will enable federal officials to better combat fraud and abuse in the Part D program through verification of providers' credentials via the Medicare enrollment/opt-out process.

The Centers for Medicare & Medicaid Services

QUESTIONS? NEED ASSISTANCE?

Please contact CMS at **providerenrollment@cms.hhs.gov** if you have questions about this letter, you do not prescribe drugs, or if you believe that:

- You are already enrolled in (or validly opted out of) Medicare.
- You have a pending application.
- You are not eligible to enroll in Medicare (for example, you are a pharmacist).

If you need assistance with the process of enrolling in (or validly opting out) of Medicare, please contact the MAC within your geographic area. To locate your MAC, please refer to the MAC list on the CMS website at: go.cms.gov/partdmaclist.

Please visit the CMS Part D Prescriber Enrollment website at go.cms.gov/PrescriberEnrollment for helpful information about the new requirement, such as resources to check your application status, or to sign up for the listserv to receive updates.

Background Information

The Medicare program is administered by the Centers for Medicaid & Medicare (CMS) within the U.S. Department of Health and Human Services. The Medicare program is divided into four parts: 1) Part A generally covers inpatient hospital services; 2) Part B generally covers physician services; 3) Part C (Medicare Advantage) refers to Medicare-approved private health insurance plans for individuals enrolled in Parts A and B; and 4) Part D covers the cost of most prescription medications.

The Part D prescriber enrollment rules referred to in this notice are CMS-4159-F *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (79 FR 29843; May 23, 2014); and CMS-6107-IFC *Medicare Program; Changes to the Requirements for Part D Prescribers* (80 FR 25958; May 6, 2015).