

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



Center for Program Integrity

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To: All Medicare Advantage Organizations and Part D Sponsors

From: Zabeen Chong, Director
Provider Enrollment and Oversight Group (PEOG)

Amy Larrick, Acting Director
Medicare Drug Benefit and C & D Data Group

Subject: Medicare Part D Prescriber Enrollment Requirement Update

This memo announces a delay in the enforcement of the Medicare Part D prescriber enrollment requirement; describes pre-enforcement activities and Part D sponsor obligations under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); and summarizes the major changes to the prescriber enrollment regulation published on May 6, 2015.

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 (summarized further below).

The IFC’s effective date is June 1, 2015. The revised prescriber enrollment requirement applicability date is January 1, 2016. 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 this protection in a way that minimizes the potential for disrupting beneficiaries’ access to needed Part D medications and compromising continuity of care.

CMS is delaying enforcement of the requirements in 42 CFR § 423.120(c)(6) until June 1, 2016. This decision was made based on CMS’ analysis of current Part D prescriber enrollment trends, and the strong concerns expressed recently by Part D sponsors and pharmacy benefit

managers (PBMs) about their ability to make the complex system enhancements needed to comply with the prescriber enrollment requirement due to the changes made by the IFC. 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 Part D sponsors and their PBMs to **begin outreach activities no later than January 1, 2016** in accordance with the guidance in Attachment A to this memo. These outreach activities will enhance CMS' continuing prescriber outreach and ongoing monitoring of prescriber enrollment trends and potential beneficiary impact. This period will provide 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. Before engaging in outreach activities, Medicare advantage organizations that include a Part D benefit should review additional CMS guidance, which we expect to release in the near future.

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 January 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 from being denied by Part D plans beginning June 1, 2016. Prescribers can refer to the following CMS website to find their MAC: www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

Part D Claims January 1, 2016 – May 31, 2016

The Medicare Access and CHIP Reauthorization Act of 2015 (**MACRA**) was signed into law on April 16, 2015. Section 507 of MACRA requires that for plan year 2016 and thereafter, claims for covered Part D drugs must include a valid prescriber NPI.

More specifically, Section 507 of MACRA amends Section 1860D-4(c) of the Social Security Act (42 U.S.C. 1395w-104(c)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders. While 42 CFR 423.120(c)(5) will no longer be applicable on January 1, 2016, we believe that certain existing Part D claims procedures established by stakeholders through the National Council for Prescription Drug Programs (NCPDP) to comply with 423.120(c)(5) will also comply with the provision of Section 507 of MACRA that requires pharmacy claims for covered Part D drugs to include prescriber NPIs that are determined to be valid.

Currently, NCPDP Part D claims procedures support the following actions as to prescriber NPIs:

- A Part D sponsor communicates at POS whether or not a submitted prescriber NPI is active and valid.
- A sponsor pays a claim if the sponsor determines that the prescriber NPI is active and valid.
- If the sponsor communicates that the prescriber NPI is not active and valid, but the pharmacy corrects the NPI or confirms that the NPI is active and valid because the pharmacy has so determined through more up-to-date information, the sponsor pays the claim.

In addition to these existing procedures, we interpret Section 507 of MACRA to mean that beginning January 1, 2016, a Part D sponsor cannot pay a claim that the sponsor determines does not have an active and valid prescriber NPI, unless the pharmacy corrects the NPI or confirms that it is active and valid. Thus, existing procedures to comply with the requirement under 42 CFR §423.120(c)(5)(iii)(B)(2) that a Part D sponsor must pay a claim even when the pharmacy does not correct the NPI or confirm that it is active and valid will no longer apply.

Part D Claims Beginning June 1, 2016

Once the Medicare Part D prescriber enrollment requirement is enforced, the claims procedures described just above should continue to be followed for claims that contain NPIs of “Other Authorized Prescribers” (as defined in 42 CFR §423.100) and for claims when a Part D sponsor determines that it must cover a provisional supply in accordance with 42 CFR §423.120(c)(6) to comply with Section 507 of MACRA. However, when a Part D sponsor determines at POS that the prescriber is enrolled in Medicare in an approved status or has a valid opt-out affidavit on file, then the sponsor may rely on this determination to support that the prescriber also has an active and valid NPI. In other words, a sponsor does not have to also check the status of the prescriber NPI in the National Plan & Provider Enumeration System (NPPES), because a prescriber must have an active and valid NPI in order to be enrolled in an approved status or have a valid opt-out affidavit on file.

Beneficiary Notices

Section 507 of MACRA also requires the Secretary to establish procedures to ensure that an affected beneficiary be properly informed at the point of service (“POS”) when a claim for a covered Part D drug is not paid because it does not contain an active and valid NPI. CMS regulations – including revised 42 CFR §423.120(c)(6) – do not establish procedures for POS notification to the enrollee containing the reason a claim does not pay when the reason is because it does not include an active and valid NPI. Therefore, CMS is currently developing these notification procedures and expects to provide guidance to Part D sponsors in the near future related to compliance with this provision.

Major Changes of the IFC

As noted above, the prescriber enrollment requirement is a crucial program integrity and basic quality assurance protection for Medicare beneficiaries. The Medicare enrollment and opt-out

process provides CMS with the opportunity to verify the credentials of Part D prescribers. Even with the changes made by the IFC, the requirement still means that the vast majority of prescribers who write prescriptions for Part D drugs must be enrolled in Medicare in an approved status or have a valid opt-out affidavit on file for their prescriptions to be coverable under Part D.

However, “other authorized prescribers” are now exempt from the Medicare Part D prescriber enrollment requirement. “Other authorized prescribers” are defined as “individuals other than physicians and eligible professionals who are authorized under State or other applicable law to write prescriptions” for purposes of the prescriber enrollment requirement only. CMS believes “other authorized prescribers” are largely pharmacists who are permitted to prescribe certain drugs in certain states. Pharmacists are not able to enroll in or opt-out of Medicare. Part D sponsors and their PBMs must establish a system to identify pharmacy claims with “other authorized prescribers” at the point-of-sale (POS) in order to adjudicate them as exempt from the prescriber enrollment requirement. CMS will provide a list of identified specialties permitted to enroll in Medicare or opt-out in order to assist Part D sponsors and PBMs in this regard. The list will be available at go.cms.gov/PrescriberEnrollment.

Additionally, the IFC added provisions requiring Part D sponsors to cover a three month provisional supply of the drug and provide beneficiaries with individualized written notice before denying a Part D claim or beneficiary request for reimbursement on the basis of a prescriber’s being neither enrolled in an approved status nor validly opted out. The three month provisional supply is intended to give the prescriber time to enroll in Medicare or opt-out.

Part D sponsors should carefully review the IFC for additional detail and guidance concerning “other authorized prescribers” and the three month provisional supply provisions. **The IFC comment period closes at 5 p.m. on July 6, 2015.** Stakeholders are encouraged to submit comments. The IFC will be posted on the CMS Part D Prescriber Enrollment website at: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html>. Part D sponsors, PBMs, and pharmacies should periodically check this website for updated and added information.

Questions concerning this memo should be sent 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 Part D sponsors and their PBMs to **begin outreach activities no later than January 1, 2016** in accordance with this guidance.

- **No later than January 1, 2016 until May 31, 2016 – Part D Prescriber Outreach**
 - Part D sponsors (and their PBMs) should develop and implement a prescriber outreach strategy with the goal of achieving enrollment of the prescribers writing 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.
 - Before engaging in outreach activities, Medicare advantage organizations that include a Part D benefit should review additional CMS guidance, which we expect to release in the near future.
 - Examples of a what possible outreach strategies could be:
 - 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 bene 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. Sponsor re-contacts top prescribers 90-120 days after initial contact who are still not enrolled or opted-out.
 - 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/Medicare-Individual-Provider-List/u8u9-2upx>. This may assist plans in determining which

prescribers are already enrolled in or opted out of Medicare. Also, the NPPES downloadable file at <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/DataDissemination.html> includes prescribers' last self-reported addresses.

- 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 other 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 will continue to conduct prescriber outreach.
- CMS will provide a sample communication that sponsors can use for prescriber outreach by August 1, 2015.
- CMS will provide a comprehensive website for prescribers to reference about the enrollment requirement at go.cms.gov/PrescriberEnrollment.
- CMS has prepared 1-800-Medicare and MAC customer service representatives for inquiries from prescribers about the enrollment requirement.
- 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.

- **No earlier than April 1, 2016 until May 31, 2016 – Enrollee Outreach**

- Outreach dependent upon prescriber enrollment trends and further analysis of potential effectiveness.
- CMS to provide future guidance by 4th quarter 2015.

- **June 1, 2016 – Enforcement of the Part D prescriber enrollment requirement by CMS begins.**