

PRESCRIBER ENROLLMENT REQUIREMENTS FOR PART D PRESCRIPTIONS: ENFORCEMENT TO BEGIN IN EARLY 2017

The Centers for Medicare & Medicaid Services (“CMS”) announced that it will delay enforcement of its final rule (“Final Rule”) requiring physicians and other prescribing health care clinicians to either enroll in or opt out of Medicare in order for the prescriptions they write to be covered by any Medicare Part D prescription drug benefit plan.

Beginning in early 2017, CMS will move forward with a phased implementation of the Final Rule. While full implementation and enforcement of the Final Rule and Part D prescriber enrollment requirement is delayed until January 1, 2019, current prescribers who write prescriptions for Part D covered drugs should as soon as possible either: (i) ensure that they maintain a valid national provider identifier (“NPI”) and corresponding Medicare enrollment; or (ii) submit a valid opt-out affidavit to their Medicare Administrative Contractor (“MAC”). Irrespective of the CMS full implementation schedule, beginning in the second quarter of 2017, Part D prescriptions written by certain sanctioned providers^[1] will be denied at the point of sale in all cases. We discuss in greater detail below the timeline for implementation of this newer standard.

Discussion

The Final Rule, published by CMS in 2014, sets forth new standards requiring that prescribers of Part D covered drugs either enroll in Medicare or affirmatively opt out. Specifically, Part D claims will be denied where the prescribing practitioner is neither enrolled with nor affirmatively opted out from the Medicare program. As a result, Part D plans and their pharmacy benefit managers (“PBMs”) must deny claims for prescriptions written by eligible prescribing practitioners^[2] who either: (i) do not have an NPI; or (ii) do not have a valid Medicare enrollment or opt-out affidavit on file with a MAC.

The purpose of the Final Rule is to ensure that Part D drugs are prescribed by qualified practitioners who are eligible to prescribe under state law and under Medicare program requirements (e.g., are not excluded from Medicare or Medicaid participation). Reports of prescriptions written by physicians with suspended licenses and similar weaknesses in verifying a prescriber’s credentials also prompted CMS’s enactment of the Final Rule.

Recognizing the potential beneficiary impact of the Final Rule and the need for continued access to care among the Part D population, CMS announced a delay in full implementation and enforcement of the Final Rule until January 2019. To allow sufficient time for prescribers to enroll or opt out of Medicare and for Part D plan sponsors and PBMs to make necessary enhancements to their claims processing systems, CMS will implement a multifaceted, phased timeline for implementation of the Final Rule. The following is a list of CMS’s planned incremental actions related to the Final Rule and corresponding implementation dates.

- *Second Quarter 2017.* The prescriber enrollment requirement will be enforced with respect to certain sanctioned providers (noted above). Prescriptions written by such providers will be denied at the point of sale.
- *Second Quarter 2017.* CMS will make an easy enrollment application process available to providers for quick enrollment in Medicare. This process will allow providers to review, update, electronically sign and submit a prepopulated enrollment application online.
- *Second Quarter 2017.* CMS will begin targeted, prioritized risk-based outreach and education to providers. This prioritized approach will include direct mailings and coordination with the Part D plans to enroll prescribers.
- *Third Quarter 2017.* CMS will target and send direct mailings via email and/or paper to all prescribers that are not enrolled in the Medicare program. In addition, direct mailing notifications will be triggered for unenrolled providers based on prescription drug events.
- *January 1, 2019.* Full implementation and enforcement of the Final Rule.
- *Continuously Ongoing.* CMS will continue its current education and outreach efforts related to the prescriber enrollment requirements, including hosting stakeholder meetings and conferences, assembly meetings and presentations.

Providers may visit the [CMS website](#) for additional information regarding how to enroll or opt out of Medicare and to confirm their Medicare enrollment status via the CMS enrollment file. Note that the CMS enrollment file does not specify if a particular prescriber is eligible to prescribe, as prescribing authority is largely determined by state law.

Practical Takeaways

Providers who write prescriptions for covered Part D drugs who are not already enrolled in Medicare in an approved status or have a valid record of opting out should submit an enrollment application or opt-out affidavit to their MAC as soon as possible to ensure that Part D prescriptions they write are not denied at the point of sale. Medicare Advantage Organizations, Part D plan sponsors and PBMs should consider developing and implementing a provider outreach strategy to ensure that prescribers who write prescriptions for enrollees meet the prescriber enrollment requirements as set forth in the Final Rule. Finally, pharmacies should assess operational considerations such as mechanisms for validating prescribers with Part D plan sponsors or PBMs and the impact of point of sale denials, especially for refills where a prescriber falls out of compliance without the patient's knowledge.

If you have questions or would like additional information about this topic, please contact:

- Todd A. Nova at (414) 721-0464 or tnova@hallrender.com;
- Julie K. Lappas at (317) 977-1490 or jlappas@hallrender.com;
- Kristen H. Chang at (414) 721-7923 or kchang@hallrender.com; or
- Your regular Hall Render attorney.

[1] These include those who are currently excluded by OIG, revoked by the Medicare program or are otherwise unenrolled with Medicare and have been convicted of a felony within the last 10 years.

[2] Eligible practitioners include, but are not limited to, physicians, advanced practice clinicians and dentists who are authorized by state law to prescribe prescription drugs. The prescriber enrollment requirements also apply to physicians and non-physician practitioners employed by Part A institutional providers such as hospitals, federally qualified health centers or rural health centers that write Part D prescriptions. Pharmacists who are permitted to prescribe certain drugs in various states but are not able to enroll in or opt out of Medicare based on applicable law are exempt from the prescriber enrollment requirements.