HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

JUNE 20, 2014

PRESCRIBERS MUST BE ENROLLED IN OR AFFIRMATIVELY OPTED-OUT OF MEDICARE IN ORDER FOR PRESCRIPTIONS TO BE COVERED BY PART D

EXECUTIVE SUMMARY

On May 23, 2014, the Centers for Medicare and Medicaid Services ("CMS") published a final rule addressing various changes to the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) Programs ("Final Rule"). Among other changes, the Final Rule enumerated new Medicare enrollment or opt-out requirements for prescribers of Part D covered drugs, effective June 1, 2015. These changes require Part D claim denials where the prescribing practitioner is neither enrolled with nor affirmatively opted-out from the Medicare program.

Specifically, Part D plans (and their prescription benefit managers ("PBMs")) will be required to deny claims for prescriptions written by eligible professionals(1) who either: i) do not have a national provider identifier ("NPI"); or ii) do not have a valid Medicare enrollment or opt-out affidavit on file with a Medicare A/B administrative contractor ("MAC"). Since this could result in point of sale denials that impact patient care, pharmacies and providers will want to consider the potential impact of the Final Rule on their patients and operations.

DISCUSSION

The Final Rule standards implement Section 6504 of the Affordable Care Act ("ACA") governing eligible professionals who prescribe Medicare Part D drugs. The ACA requires that eligible professionals who order durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") or certify home health care for Medicare beneficiaries be enrolled in Medicare and allows the Secretary to extend these requirements to Eligible professionals who prescribe Medicare Part D drugs. As such, under the Final Rule, a valid Part D prescription must now be written by an EP who has an NPI and is either enrolled in Medicare or who has a valid record of opting out of Medicare on file with the MAC.

The Final Rule has direct operational obligations for Part D sponsors, such as drug plans and PBMs, which are now required to deny claims for Part D drugs if the prescriber is not enrolled in Medicare or if there is not a valid opt-out on file with the MAC. Although unclear regarding operations, this may result in point of sale denials.

CMS stated that 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 the Medicare program requirements (*e.g.*, not excluded from Medicare or Medicaid participation). CMS stated that reports of prescriptions written by physicians with suspended licenses and similar weaknesses in verifying a prescriber's credentials are among the top concerns that prompted the Final Rule.

CMS plans to publish a list to plan sponsors that indicates who the qualified eligible professionals are for purposes of prescribing Part D drugs. CMS will issue sub-regulatory guidance on how exactly prescription verification will work before the June 15, 2015 implementation date. This guidance is expected to address, among other issues, the verification process, the specific contents of the list, the frequency with which the list will be updated and various other operational aspects of the requirement, including whether retroactive denials will be possible. CMS also stated it is considering a process to alert prescribers who are neither enrolled nor opted-out of the need to take action to comply with the Final Rule. CMS has not yet addressed how frequently it will publish the list of compliant eligible professionals nor how compliant and non-compliant eligible professionals will be tracked. However, CMS stated that it thinks the number of eligible professionals who are neither enrolled in Medicare nor opted-out of Medicare is very low, and as such, there should not be many hurdles to implementation.

Stakeholders have voiced various concerns about how the Final Rule will work in practice. These concerns include how plan sponsors will identify that a prescription was written by a prescriber who has not enrolled or who has not opted-out, whether retroactive denials or point of sale denials will be required, whose responsibility it is to educate patients about providers who fall out of compliance, how patients and plans will address the situation of a provider falling out of compliance between refills and whether there will be an emergency exception for urgent first time prescriptions and refills. Other concerns include whether unenrolled prescribers will be disproportionately reflected in various supplier types or geographic areas, whether plans will be penalized for filling prescriptions if the plan did not know at the time of dispensing

that the prescriber's enrollment was terminated and how foreign prescriptions will be addressed.

NEXT STEPS

In summary, it is critical that all prescribers writing prescriptions covered by Part D maintain a valid NPI and either enroll in Medicare or make sure they have a valid opt-out affidavit on file with their MAC. Affected pharmacies and providers will thus want to monitor potential patient care implications. Also, pharmacies must assess operational considerations, such as mechanisms for validating prescribers with their Part D Plan sponsors or PBMs, and the impact of point of sale denials, especially for refills where a prescriber has fallen out of compliance without the patient's knowledge.

If you have further questions about the information in this article, please contact

- Todd A. Nova at (414) 721-0464 or tnova@hallrender.com,
- Rachel S. Delaney at (414) 721-0448 or rdelaney@hallrender.com
- Your regular Hall Render attorney.

(1) Physicians and/or advanced practice clinicians authorized by state law to write prescriptions.