

OIG REMINDS PHARMACIES OF PROPER SCHEDULE II BILLING PRACTICES

EXECUTIVE SUMMARY

On September 27, 2012, the Department of Health and Human Services Office of Inspector General ("OIG") issued its findings resulting from a study of Medicare Part D billings and payments for Schedule II drug refills. Schedule II drugs have the highest potential for abuse of any prescription drug in the United States as they have a strong potential for abuse and dependency. Schedule II drugs include many opiates, such as morphine, opium, oxycodone, codeine, Demerol and fentanyl; stimulants, such as amphetamine, Adderall and Ritalin; and some depressants and hallucinogenic substances.

Although federal law prohibits refilling prescriptions for Schedule II drugs,¹ the OIG found that Medicare Part D paid \$25 million for Schedule II drugs billed as refills in 2009. The OIG also found that over 25,000 Schedule II prescriptions did not have valid prescriber information. The OIG made recommendations to the Centers for Medicare & Medicaid Services ("CMS") based upon its findings. CMS concurred with some, but not all, of the recommendations. For a copy of the complete report, see the following [link](#).

STUDY FINDINGS

The OIG's study found that, in 2009, many pharmacies billed, and were reimbursed by, Medicare Part D Sponsors ("Sponsors") for 397,203 Schedule II refills, accounting for 2% of all Schedule II drugs dispensed during that year. Schedule II refills are unlawful under the Controlled Substances Act; therefore, the OIG determined that pharmacies should not have been reimbursed for any of these refills. Fentanyl and oxycodone-acetaminophen were found to account for over 50% of the unlawful Schedule II refills.

Seventy-five percent of the Schedule II refills were billed by long-term care pharmacies. The OIG acknowledged that some long-term care pharmacies may have incorrectly billed these drugs as refills when the drugs were actually dispensed as partial fills, which are allowed in the long-term care setting, assuming that certain conditions are met.² CMS responded to this portion of the study, noting that long-term care pharmacies do not have a consistent procedure for billing partial fills. Although this may account for a portion of the Schedule II refill data, the OIG still found that billing partial fills as refills raises several concerns. Beneficiaries may be paying multiple copayments. It also affects the accuracy of Prescription Drug Event ("PDE") data, which is the basis on which Sponsors are paid. Sponsors, CMS and the OIG use PDE data to identify and prevent fraud, waste and abuse, so inaccurate data is an obstacle to such efforts.

The study also revealed that 25,836 Schedule II refills (7% of the refills) were prescribed by invalid prescribers. Schedule II prescriptions must include the name, address and signature of the prescriber. Over 13,000 of these refills either listed no prescriber number or listed numbers that had not been assigned to a provider. Nearly 39,000 prescribers were associated with Schedule II refills. Though most of these prescribers were associated with only one or two refills, numerous prescribers were associated with hundreds of Schedule II refills.

Sponsors issue a PDE record to CMS for each prescription filled for their enrollees. CMS then uses these PDEs to calculate the necessary payments to Sponsors. Nearly three-quarters of Sponsors paid for Schedule II refills. The OIG concluded that Sponsors do not have adequate safeguards to ensure the accuracy of the data submitted to CMS. It also referenced recent audits of three sponsors that found the Sponsors did not have adequate controls in place to prevent Schedule II refills.

RECOMMENDATIONS BY THE OIG TO CMS AND CMS'S RESPONSE

The OIG made several recommendations to CMS based upon the results of this study, and CMS responded to the recommendations. The more relevant of these recommendations are described below.

- The OIG recommended that CMS exclude Schedule II refills when calculating payments to Sponsors. CMS concurred in part with the recommendation, stating that it agreed that procedures should be in place to prevent the billing of these refills, but that CMS would not exclude these payments to Sponsors.
- The OIG recommended that CMS monitor Sponsors to ensure that they validate prescriber numbers for Schedule II drugs. CMS concurred with this recommendation.

- The OIG recommended that CMS follow up on Sponsors and pharmacies with high numbers of refills. CMS partially concurred. It agreed to follow up with the industry to determine whether there is another acceptable standard that could be used to distinguish legally dispensed partial fills from illegally dispensed refills.

CONCLUSION AND PRACTICAL TAKEAWAYS

Based upon the OIG's report and CMS's response, prescribers and pharmacies should be reminded that it is not appropriate to bill for refills of Schedule II drugs. Long-term care facilities, particularly, should be aware of proper billing procedures for partial fills of Schedule II drugs. All pharmacies should confirm that prescriber numbers are active and valid and that any controlled substance is consistent with the schedule of drugs that the practitioner is authorized to prescribe.

In light of this report and the Drug Enforcement Agency's recent enforcement activities, pharmacies should be aware that the government is more closely scrutinizing pharmacies' practices concerning Schedule II. While the report does not require pharmacies to imminently change their procedures, the report indicates additional Schedule II enforcement avenues that may be used in the future. We recommend that pharmacies review their audit plans and update them to reflect these considerations, as appropriate. Depending upon their findings, corrective action may be appropriate.

If you have any questions or would like additional information about this topic, please contact Susan D. Bizzell at (317) 977-1453 or sbizzell@hallrender.com, Nicholas A. Gonzales at (414) 721-0486 or ngonzales@hallrender.com or your regular Hall Render attorney. We would like to thank Alyssa James, Law Clerk, for her assistance with this article.

¹ 21 U.S.C. §829(a).

² 21 C.F.R. §1306.13.