HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

MAY 14, 2012

OIG STUDY PERCEIVES QUESTIONABLE PART D BILLING BY RETAIL PHARMACIES

BACKGROUND

Throughout the existence of the Medicare Part D program, the Office of Inspector General ("OIG") has issued several reports concerning the vulnerability of the Medicare Part D program in regards to its potential for fraud and abuse. On May 9, 2012, the OIG released a report identifying eight questionable billing practices of retail pharmacies throughout the country and making six recommendations to the Centers for Medicare & Medicaid Services ("CMS") in order to strengthen the integrity of the Medicare Part D program ("Report"). A full copy of the Report is available here.

OIG'S FINDINGS

To detect potential areas of fraud and abuse, the OIG based its most recent study on the analysis of the 73.3 million prescription drug events ("PDE") records for all Part D drugs billed to Medicare by retail pharmacies in 2009. The OIG analyzed PDE records to identify questionable billing practices of individual pharmacies. The eight measures used in its analysis were: (1) average amount billed per beneficiary; (2) average number of prescriptions per beneficiary; (3) average amount billed per prescriber; (4) average number of prescriptions per prescriber; (5) percentage of prescriptions that were for Schedule II drugs; (6) percentage of prescriptions that were for Schedule III drugs; (7) percentage of prescriptions that were for brand name drugs; and (8) percentage of prescriptions that were refills. For each of these eight measures, the OIG set a threshold. Pharmacy metrics that measured above the threshold indicated that the pharmacy had billed an extremely high amount. The OIG acknowledges that there may be legitimate reasons for a pharmacy to bill high amounts in a particular category, but concluded that pharmacies above the threshold should be scrutinized further.

Of the 59,307 retail pharmacies that were studied, 2,637, approximately 4%, were identified as having questionable Part D billing. For example, nearly 800 pharmacies billed high dollar amounts per beneficiary (each with an average of over $4,050 per beneficiary, which is nearly three times the national average for this same metric). One particular pharmacy billed an average of $23,145 per beneficiary. Some of these pharmacies also billed for an extremely high number of prescriptions per beneficiary, each averaging at least 66 prescriptions per beneficiary, while the national average was 28 prescriptions per beneficiary. The OIG believes that this may indicate that the pharmacies are billing for drugs that were not medically necessary or drugs that were never provided to the beneficiary.

Additionally, over 1,000 pharmacies billed for extremely high percentages of Schedule II and/or Schedule III drugs. One pharmacy billed 75% of its prescriptions as Schedule II drugs; most of these prescriptions were ordered by one particular physician. The OIG also identified pharmacies that bill for a high percentage of brand name drugs, which may indicate that such pharmacies are billing for brand names but dispensing generics or that they are billing for prescriptions that were never dispensed. The OIG found that independent pharmacies were eight times more likely than chain pharmacies to have questionable billing. Although only 34% of pharmacies are independent, they accounted for 80% of the pharmacies with questionable billing. In addition to independent pharmacies, the OIG also found that certain geographic regions were more likely to have questionable billing. These regions included Miami, Los Angeles, Detroit, New York, Baltimore and Tampa.

OIG'S RECOMMENDATIONS TO CMS

Due to the perceived vulnerabilities in the oversight of the Part D program, the OIG made several recommendations to CMS in order to combat potential fraud and abuse in this area. CMS concurred with the following four recommendations by the OIG:

1. CMS should strengthen the Medicare Drug Integrity Contractor's ("MEDIC's") monitoring of pharmacies and ability to identify pharmacies for further review. This would allow the MEDIC to more readily determine pharmacies with questionable billing.
2. CMS should provide additional guidance to sponsors on monitoring pharmacy billing based upon input from sponsors and the MEDIC.
3. CMS should further strengthen its compliance plan audits. These audits should include in-depth reviews of how sponsors monitor and oversee pharmacies.
4. CMS should follow up on pharmacies identified as having questionable billing, as referred to them by the OIG. This additional follow-up

will most likely occur through CMS's use of the MEDIC.

There were two additional OIG recommendations in which CMS partially concurred.

1. The OIG recommended that CMS require sponsors to refer potential fraud and abuse incidents that may warrant further investigation to CMS and other pertinent entities. CMS responded that its regulations currently do not require self-reporting of potential fraud and abuse incidents; however, it determined that it would explore the option of placing additional burden on plan sponsors.

2. Additionally, the OIG suggested that CMS should develop risk scores for pharmacies. CMS responded that the MEDIC currently identifies pharmacies that present a fraud risk, although it said it would consider developing a high, medium and low risk assessment for pharmacies and sharing that information with sponsors, as appropriate.

IMPLICATIONS FOR PHARMACIES

In light of this study, pharmacies should be aware of the factors that may be used to "flag" pharmacies as having questionable billing. To that end, pharmacies must take great care in ensuring compliance with federal and state fraud and abuse laws. It is evident that the OIG is making efforts to eliminate as much fraud and abuse in retail pharmacies as possible. While pharmacies should continue to conduct audits pursuant to their compliance programs, pharmacies may wish to add to their current audit the following items to determine whether they exceed the thresholds set out in the Report (or more conservative thresholds, such as 90th percentile): (1) amounts billed per beneficiary; (2) number of prescriptions per beneficiary; (3) amounts billed per prescriber; (4) number of prescriptions per prescriber; (5) percentage of prescriptions for Schedule II drugs; (6) percentage of prescriptions for Schedule III drugs; (7) percentage of prescriptions that are for brand name drugs; and (8) the percentage of prescriptions that are refills. Any factor determined to be above the OIG threshold (or pharmacy-selected threshold) should be thoroughly scrutinized to evaluate whether there is a legitimate explanation.

For pharmacies that identify a problematic factor that is dependent upon a prescriber's actions (for example, the amount of Schedule II and III drugs prescribed by a particular prescriber), they will need to consider how to address this through their compliance programs.

As the OIG and CMS continue to develop processes for the agencies, sponsors and MEDICs to identify fraud and abuse by retail pharmacies, pharmacies should be aware of any trends in billing that may seem suspicious and take steps to correct such billing, where appropriate.

If you have any questions or would like additional information about this topic, please contact Susan Bizzell at 317.977.1453 or sbizzell@hallrender.com, Nicholas Gonzales at 414.721.0486 or ngonzales@hallrender.com or your regular Hall Render attorney.

Special thanks to Alyssa James, Law Clerk, for her assistance with the preparation of this Health Law News article.