QUI TAM RULING MAY RESULT IN PART D SPONSORS AND PHARMACY BENEFIT MANAGERS INCREASING THEIR AUDIT ACTIVITIES

EXECUTIVE SUMMARY

On December 20, 2012, a Federal District Court judge allowed a False Claims Act ("FCA") case to continue against a Pharmacy Benefits Manager[1] ("PBM"), related to PBM services it furnished to an unrelated Medicare Part D Sponsor ("Sponsor"). In 2007, the Sponsor engaged a third party auditor to audit the Part D claims processed by the PBM on behalf of the Sponsor. The auditor believed that, based on the audit findings, the PBM was improperly submitting Prescription Drug Event ("PDE") claims for prescriptions that were not allowed under the Part D program. Specifically, the auditor-turned-qui tam relator ("Relator") alleges that there were six areas in which claims had been improperly adjudicated, paid and submitted to the Centers for Medicare & Medicaid Services ("CMS"), including:

- Failure to apply the maximum allowable cost ("MAC");
- False physician identifiers;
- Gender specific deviations;
- Exceeding approved limits;
- Dispensing drugs without prior authorizations; and
- Billing for expired drugs.

The Relator alleges that such claims resulted in over $4 million in fraudulent claims submitted to CMS.

WHISTLEBLOWER SUIT

In 2009, the Relator who performed the audit on behalf of the Sponsor filed a whistleblower lawsuit against the PBM and related organizations[2] on behalf of the Government, alleging that the PBM maintained a nationwide scheme to defraud the Medicare Part D program through the submission of fraudulent PDE data to CMS. Although the Government has declined to join the Relator's lawsuit, it later filed a statement of interest in the case.

The Relator has alleged that the PBM violated the FCA based on two theories: the false certification theory and the worthless services theory.

FALSE CERTIFICATION THEORY

The PBM argued to have the Relator's false certification claim dismissed based on the following points:

1. The requirement that PDEs be certified as true, accurate and complete does not apply to PBMs as a condition of payment; such requirement applies only to Medicare Part D Sponsors.
2. None of the alleged violations involved data related to payment.
3. The Relator did not adequately allege how the PBM's PDE submissions were false.

The Court did not agree with any of the PBM's arguments. It found that the regulations should be interpreted broadly and that a PBM, when acting on behalf of a Sponsor, does certify to the accuracy and truthfulness of PDE data. The Court also found that "data related to payment" is a much more expansive term than the PBM argued. Finally, the Court found that the Relator adequately alleged that certain PDE submissions were false (failure to apply MAC pricing and inaccurate identification of prescribers).

WORTHLESS SERVICES THEORY

The Relator also alleged that the PBM failed to provide the required drug utilization review ("DUR") for medications dispensed under the Part D program relating to the following:

1. Gender contraindications;
2. Failing to follow state pharmacy laws that prohibit the dispensing of expired drugs;
3. Failing to obtain required prior authorization for Tier 2 and Tier 4 drugs; and
4. Improper approval of claims for drugs in excess of limits permitted by the Sponsor's plan or the drug manufacturer.

The PBM argued that the Relator had failed to allege that the PBM billed the Government for the performance of DUR for the four matters described above. The court concluded that the PBM's contract with the Sponsor required the PBM to provide DUR services, in compliance with federal regulations, and that by submitting PDE data to CMS, the PBM represented that it had performed the DUR and was in compliance with federal laws and regulations. Because the PBM allegedly did not satisfy its contractual obligations in regard to the DUR, it is as if the services were never performed.

Among other things, the PBM also argued that:

- PDEs are merely data used for accounting purposes and are not "claims" or "requests for payment" contemplated by the FCA. The Court disagreed, citing the CMS Prescription Drug Manual and CMS Instructions, which indicate PDEs are claims.
- It did not violate the FCA because it looks to the Sponsor, rather than the Government, for payment and its payment is based on a fixed rate per claim processed; it is not based on the content of the PDE data. The Court disagreed with this because it found the Relator had alleged that the PBM made claims and submitted PDE data in order to cause the Government to pay out Part D funds to the Sponsor, which would ultimately flow to the PBM.

PRACTICAL TAKEAWAYS

This case, viewed alongside other recent developments in the Part D arena, including but not limited to the Office of Inspector General's ("OIG") audit of retail pharmacies' Schedule II dispensing practices and the OIG's Work Plan for Fiscal Year 2013, shows that Part D Sponsors may need to consider taking a more active role in monitoring for fraud and abuse in the Medicare Part D Program. (Click here and here for previous Hall Render articles related to Schedule II dispensing and the OIG's work plan, respectively.) Specifically, Part D Plan Sponsors may begin to increase audits of their PBMs. In turn, PBMs may put more pressure on their downstream pharmacies to ensure that PDEs are complete and accurate.

Furthermore, retail pharmacies may expect Sponsors and PBMs to increase their DUR efforts to reduce the risk that improper claims will be adjudicated and paid. Part D Sponsors and PBMs should audit and monitor claim submissions and payments for inconsistencies with Part D requirements, such as those found in this case. All entities within the Part D program should be aware of potential liability resulting from fraud and abuse in the current heightened enforcement environment.

Lastly, this case illustrates the importance for providers to promptly address issues discovered during audits. In this case, the auditor was not satisfied that the PBM was responsive to concerns raised in the audit, and the auditor became a whistleblower.

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.

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[1] *See U.S. ex rel Spay v. CVS-Caremark, Corp., 2:09-cv-04672-RB (E.D. Pa).*

[2] The PBM is one of several related organizations that are defendants in this case. The related entities serve in several nationwide roles, including Medicare Part D Sponsor, PBM and owner of retail and mail order pharmacies. In this case, it is the role of the PBM that led to the allegations by the Relator.