DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE / CENTER FOR PROGRAM INTEGRITY

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TO: All Medicare Part D Plan Sponsors

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SUBJECT: Part D Sponsors' Response to CMS-Issued Fraud Alerts

Periodically, CMS issues alerts to Part D sponsors concerning fraud schemes identified by law enforcement officials. Typically these notices describe activities involving pharmacies practicing drug diversion or prescribers participating in illegal remuneration schemes (e.g., prescribers receiving payment as an inducement or reward for writing prescriptions). CMS issues these notices so that contracting organizations can take appropriate steps to ensure that Medicare payments are not made for fraudulent claims for prescription drugs. Sponsors have asked how they should respond to the fraud alerts; in particular how they should treat claims from the providers identified in the alert. CMS provides the following guidance on the appropriate steps organizations should take in response to these alerts.

Part D sponsors are obligated, per 42 C.F.R. § 423.504(b)(4)(vi), to adopt and implement an effective compliance program which includes measures designed to prevent, detect, and correct fraud, waste, and abuse. CMS also provides sponsors guidance on fraud, waste, and abuse issues in Chapter 9 of the Medicare Prescription Drug Benefit Manual (PDBM).

The fraud alerts usually describe alleged fraudulent schemes for which the identified parties have not yet been found legally responsible. CMS advises that sponsors may take action (including denying or reversing claims) in instances where the sponsor's own analysis of its claims activity (prompted by its receipt of a CMS-issued fraud alert) indicates that fraud may be occurring. Sponsors' decisions to deny or reverse claims should be made on a claim-specific basis. That is, sponsors should not react to a fraud notice by simply denying or reversing all claims from a particular prescriber or pharmacy when the information in the alert and the sponsor's own analysis indicates that the identified parties may be associated with legitimate as well as fraudulent claims.

To help ensure that sponsors pay no further fraudulent claims, upon receiving the alert, sponsors should review the contractual arrangements they may have with the identified pharmacies or prescribers. For example, it would be appropriate for sponsors to consider terminating their contracts with the identified pharmacies or prescribers if law enforcement agencies have issued indictments against particular pharmacies or prescribers and the terms of the sponsor's contract with these pharmacies or prescribers authorize contract termination in such an instance.

CMS also intends that sponsors will use the information in the alerts to augment the fraud monitoring processes they must establish to meet Part D program requirements. Sponsors can use the fraud alert information to target the efforts of their fraud detection process and the drug utilization review that they are required to conduct pursuant to 42 C.F.R. §423.153(b)(2). As noted in Section 50 of Chapter 9 of the PDBM, sponsors should have the system capability to establish edits on a given provider and use that edit to automatically deny or suspend payment for a script written by that specific provider or filled at a given pharmacy. Sponsors should also utilize data analysis to identify trends and develop more focused audits. Again, the information in the alert allows sponsors to focus their data analysis tools on the claims submitted by the identified providers. The alert itself is not sufficient grounds for a sponsor to take action without its own supporting analysis of specific claims and the confirmation of fraud using the sponsor's established protocols.

Part D sponsors are also obligated to review their past paid claims from these parties based on the fraud alert information. The regulations at 42 C.F.R. § 423.505(k)(3) require Part D sponsors to certify the accuracy of the claims data it submits to CMS. With the issuance of a fraud alert, CMS has put sponsors on notice that they should review claims involving the identified providers. To meet the "best knowledge, information, and belief" standard of the certification, sponsors should make their best efforts to identify claims that may have been part of the alleged fraud scheme and remove them from their sets of prescription drug event (PDE) data submissions.

Finally, all paid claims have an impact on the true out of pocket (TrOOP) and cumulative drug spend used to calculate each beneficiary's progression through the Part D benefit and into those phases (e.g., catastrophic) during which Medicare assumes greater responsibility for drug costs. To ensure that Medicare and the sponsors are not indirectly paying for fraudulent claims, sponsors must reverse the affected claims with their pharmacies and reduce their members' TrOOP and drug spend amounts accordingly.

If you have any questions about the information in this memorandum, please contact Scott Nelson at scott.nelson2@cms.hhs.gov.