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

DATE: December 13, 2011

TO: All Prescription Drug Plan and Medicare Advantage-Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

SUBJECT: Clarification of Medicare Part D Policies with Respect to Overutilization

A recent report from the U.S. Government Accountability Office found evidence of significant "doctor shopping" in Part D, with 170,000 beneficiaries receiving prescription drugs prescribed by five or more medical practitioners for frequently abused classes of drugs. The purpose of this memorandum is to clarify Medicare Part D policy with respect to sponsors' efforts to prevent overutilization of Medicare Part D drugs, particularly painkillers such as opioids. In our HPMS memo, "Improving Drug Utilization Review Controls in Part D," dated September 28, 2011 ("HPMS Overutilization Memo"), we solicited comments from Part D sponsors and other interested stakeholders on how the Medicare Part D program can more successfully exert control over payment for inappropriate overutilization of drugs. While we review comments received, we want to clarify for sponsors that they have several existing tools they can and should employ to meet the requirement to establish drug utilization management programs and quality assurance measures and systems to monitor and control for both under- and over-utilization [42 CFR §423.153]. We urge sponsors to use these tools, as well as follow CMS instructions on how report cases of suspected illicit activity.

PROMPT PAY REGULATIONS

We have heard concerns that prompt pay requirements have been interpreted to inadvertently require sponsors to "pay and chase" claims for drug claims they believe to be fraudulent, rather than preventing the payment before it happens. We clarify that compliance with the clean claims regulations [42 CFR §423.520] does not prevent sponsors from establishing required drug utilization management programs and quality assurance measures and systems to address overutilization. Per §423.520(b), a clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section. When a sponsor suspects fraud with respect to a particular claim, including indications of fraud involving numerous prescribers or numerous pharmacies, the claim would not be clean because it would require substantiating documentation or constitute a special circumstance requiring special treatment, such as requiring more identifying information about the prescriber, the pharmacy, or more information about the beneficiary.

Per §423.520(c), if a Part D sponsor determines that a submitted claim is not a clean claim, it is required to notify the submitting pharmacy that the claim has been determined not to be clean, specify all the defects or improprieties rendering the claim not a clean claim, and list all additional information necessary for the sponsor to properly process and pay the claim. This notification must be provided within 10 days after an electronic claim is received and within 15 days after a non-electronic claim is received. Thus, so long as sponsors provide these notifications in good faith, there is nothing in the prompt pay regulations that prevents sponsors from meeting the requirements of Social Security Act § 1860D-4(c) by implementing effective programs to control fraud, waste and abuse.

REPORTING FRAUDULENT ACTIVITY AND DRUG-SEEKING BEHAVIOR

The reporting of potential fraud to CMS and/or its designee is an important mechanism for protecting Medicare beneficiaries from harm and the Medicare Trust Fund from fraud, waste and abuse. We remind Sponsors that they should notify the MEDICs of potential fraud, waste or abuse in accordance with the guidelines described in section 50.2.8.2 of the Prescription Drug Benefit manual. CMS believes that Sponsors should self-report potential fraud discovered at the plan level, and also report potential fraud that is discovered at the first tier entity, downstream entity, or related entity levels. Sponsors are also encouraged to consider reporting the conduct to government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol), or the Department of Justice. [see http://www.oig.hhs.gov/fraud/docs/complianceguidance/dispress.pdf].

In order to reduce prescription drug abuse among beneficiaries in Part D, CMS will consider Part D plan reporting requirements of fraud and abuse and drug-seeking behavior in future rulemaking.

PRIOR AUTHORIZATION, RETROSPECTIVE REVIEW AND PROTECTED CLASS DRUGS

Prior authorization requirements are a common utilization management tool employed by Part D sponsors to ensure appropriate coverage under the Medicare Part D program. Such requirements must be consistent with the FDA approved label when applying prior authorization to assess beneficiaries' eligibility for coverage and must be submitted to CMS for approval as a component of the sponsor's formulary. Thus, sponsors may submit reasonable prior authorization requirements for approval for drugs, such as opioids, that are susceptible to abuse and diversion.

While Part D sponsors cannot implement prior authorizations for protected class drugs, they can conduct retrospective reviews on all drugs, including protected class drugs. For instance, if a pattern of overutilization of opioids is determined through beneficiary-level retrospective review, sponsors can require documentation to determine medical necessity and may deny payment for subsequent claims if insufficient evidence is obtained to substantiate Part D coverage eligibility. Even for drugs where utilization management tools such as prior authorization are generally not employed in widely used best practice formulary models, Part D sponsors may conduct appropriate consultations with physicians regarding treatment options and outcomes. Such

interventions with prescribers would be part of retrospective reviews in cases involving multiple prescribers of the same drug that may be associated with doctor shopping.

LESS THAN 30 DAY PRESCRIBING

Although the Medicare Part D program has no authority over prescribers, we point out that Part D sponsors can encourage prescribers to prescribe in less than 30 days supplies, as appropriate. For instance, as part of their interactions with prescribers, such as through drug utilization management programs and quality assurance measures and systems, Part D sponsors may promote less than 30 day prescribing of drugs that are more susceptible to abuse or diversion, especially opioids. We note that we have proposed to require plan sponsors to establish and apply daily cost-sharing rates in certain instances in our recently published proposed rule (76 FR 63018 (October 11, 2011)) to align incentives for less than 30 day prescribing.

CMS reminds Part D sponsors that we will be monitoring the use of all these tools to ensure that they are appropriately implemented. Sponsors that establish inappropriate controls will be issued compliance notices.

Any questions regarding this memo may be directed to Lisa Thorpe at Lisa.Thorpe@ cms.hhs.gov.