DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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FACT SHEET

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CMS Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse

Prescription drug abuse is a serious and growing problem nationwide. Unfortunately, the Medicare Part D prescription drug program (Part D) is not immune from the abuses associated with this nationwide epidemic. The Centers for Medicare & Medicaid Services (CMS) takes this problem seriously and is taking steps to protect Medicare beneficiaries and the Medicare Trust fund from the harm and damaging effects associated with prescription drug abuse.

CMS' fraud and abuse strategy for Part D is data driven and focuses on the validation and analysis of Part D claims data (Prescription Drug Event, or PDE, data) that CMS receives from Part D sponsors. We are leveraging CMS' access to all PDE data and using it to guide our anti-fraud efforts and share the results of our analysis with Part D plan sponsors, law enforcement agencies and pharmacy and physician licensing boards, as appropriate, so this information can assist our joint efforts to combat fraud and abuse. A centerpiece of this strategy that focuses on protecting beneficiaries is the identification of Part D enrollees who have potential opioid or acetaminophen overutilization issues that indicate the need to implement appropriate controls on these drugs for the identified beneficiaries. In addition, data analysis is employed to identify prescribers and pharmacies that may warrant further action to curb fraudulent or abusive activities. With the proposed rule issued January 6, 2014, CMS seeks to provide the agency with new tools to employ when problematic prescribers and pharmacies are identified. The key provisions of the proposed rule are discussed below, as are the ongoing CMS actions to combat fraud and abuse.

Fraud and Abuse Provisions in the CY 2015 Policy & Technical Changes to the Medicare Advantage and Prescription Drug Program Proposed Rule

Require that Prescribers of Part D Drugs Enroll in Medicare: Section 6405 of the Affordable Care Act requires that physicians and non-physician practitioners who order durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) or certify home health care must be enrolled in Medicare. The statute also permits the Secretary to extend these Medicare enrollment

requirements to physicians and non-physician practitioners who order or certify all other categories of items or services in Medicare, including covered Part D drugs. CMS is proposing to require that physicians and non-physician practitioners who write prescriptions for covered Part D drugs must be enrolled in Medicare for their prescriptions to be covered under Part D.

Impact of Proposal: Requiring prescribers to enroll in Medicare would help CMS ensure that Part D drugs are only prescribed by qualified individuals.

Permit Revocation of Medicare Enrollment for Abusive Prescribing Practices and Patterns: CMS is proposing to add authority to revoke a physician's or eligible professional's Medicare enrollment if:

- CMS determines that he or she has a pattern or practice of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements; or

- His or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

- The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

Impact of Proposal: Providing CMS the authority to revoke such prescribers' Medicare enrollment and would help protect beneficiaries and the Medicare Trust Fund from fraud, waste and abuse.

Provide Direct Access to Part D Sponsors' Downstream Entities: The proposed provision would provide CMS, its antifraud contractors, and other oversight agencies the ability to request and collect information directly from pharmacy benefit managers, pharmacies and other entities that contract or subcontract with Part D Sponsors to administer the Medicare prescription drug benefit.

Impact of Proposal: The provision would streamline CMS' and its anti-fraud contractors' investigative processes. Currently, it can take a long time for CMS' contractors who are often assisting law enforcement to obtain important documents like invoices and prescriptions directly from pharmacies, because they must work through the Part D plan sponsor to obtain this information. This proposal is designed to provide more timely access to records, including for investigations of Part D fraud and abuse, and responds to recommendations from the Department of Health and Human Services (HHS) Office of Inspector General.

Improve Payment Accuracy: The proposed regulation also would implement the Affordable Care Act requirement that MA plans and Part D sponsors report and return identified Medicare overpayments.

Impact of Proposal: The provision would codify and clarify rules regarding when Part D and MA plan sponsors must report and return overpayments.

Results of Ongoing CMS Actions Against Part D Fraud and Abuse

Reduction in the number of Medicare beneficiaries receiving coverage for prescription drugs that threaten their health and safety. The Medicare Part D Overutilization Monitoring System (OMS) was fully implemented on July 31, 2013, to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of prescribed medications.

CMS provides quarterly reports to sponsors on beneficiaries with potential opioid or acetaminophen overutilization issues identified through analyses of PDE data and through beneficiaries referred by the CMS Center for Program Integrity (CPI). Sponsors are required to respond to CMS within 30 days on the status of the review for each beneficiary case. The principle performance metric for OMS is the number and percentage of acetaminophen and opioid overutilizers. An initial comparison with 2011 PDE data pre-dating the implementation of OMS shows there has already been a substantial reduction in the number of acetaminophen and opioid overutilizers in Medicare Part D.

OMS July 31 Report Summary Compared to 2011 Analysis

PART D OMS SUMMARY	CY 2011[1]			CY 2013 through June[1]		
	Count (1/1/2011 to 12/31/2011)	% of Part D Population	% of Product Utilizers	Count (1/1/2013 to 6/30/2013)	% of Part D Population	% of Product Utilizers
All Part D Enrollees	31,485,287			36,742,129		
Total APAP Utilizers	9,450,190	30.01%		7,382,443	20.09%	
Beneficiaries with Potential APAP Issues	150,760	0.48%	1.60%	31,245	0.09%	0.42%
Total Opioid Utilizers	8,783,979	27.90%		9,056,058	24.65%	
Beneficiaries with Potential Opioid Issues	22,222	0.07%	0.25%	4,351	0.01%	0.05%
Beneficiaries with CPI Referrals[2]	N/A			13		

[1] The OMS July 2013 reports included analysis of PDE data with dates of service from January 1, 2013 to June 30, 2013, and received by June 30, 2013. The CY 2011 analysis used PDE with dates of service from January 1, 2011 to December 31, 2011, and received by June 2, 2012.

[2] Beneficiaries with CPI referrals were not subject to Part D oversight until mid-2012. CPI referral cases may originate several years prior to being sent to Part D for follow-up with plan sponsors.

Increased Law Enforcement and other referrals resulting from proactive data analysis: To date, for FY 2013, CMS has made 60 referrals to law enforcement based on proactive analysis and initiated 182 proactive investigations that are open and being developed for referral to law enforcement. The provisions of the proposed rule would provide CMS the additional ability to take administrative action when a pattern or practice of abusive prescribing is identified through data analysis and confirmed through subsequent investigation.

Accurate Prescriber Identifiers Used to Confirm Prescribing Authority: Through rulemaking finalized in 2012,[1] CMS required Part D sponsors to submit Prescription Drug Events (PDEs—Part D claims data) with active and valid individual prescriber National Provider Identifiers (NPIs) beginning January 1, 2013. CMS began to apply edits to any PDE without an active and valid individual NPI on May 6, 2013. Of the 2013 PDEs submitted through the end of June, only about 0.02 percent (approximately 148,000 of the 611.3 million PDEs) were rejected by CMS either because the prescriber identifier reported was not an NPI or the NPI submitted by the provider was inactive or invalid. CMS will continue to monitor sponsor performance regarding the use of valid and active NPIs.

CMS examined the taxonomy codes[2] for 2013 PDEs, which are self-reported by the providers to identify their specialty in the National Plan and Provider Enumeration System (NPPES). Of the 2013 PDEs (submitted through July 1, 2013) with a valid NPI, only about 0.5 percent were for drugs prescribed by providers with a taxonomy code that would be inappropriate for a prescriber (such as, adult companion). Based on a review of the PDEs reporting these apparently inappropriate taxonomy codes, CMS determined that about 10.6 percent were for controlled substances. We further determined that, for all but 16.5 percent of these PDEs for controlled substances, the prescriber in fact did have a valid DEA number. Thus, despite the inappropriate taxonomy code, the vast majority of these prescribers were found to be authorized to prescribe. CMS is conducting ongoing analysis to identify other possible sources of these errors, such as incorrect selection of an NPI when the prescriber has multiple identifiers.

[1] 77 FR 54664: http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf
[1] http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html

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