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A Glimpse of the Future of Compliance Oversight by CMS: Part D Plans Case Study

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CMS Experience with Part D Program Likely to Spill Over into Provider Community

The "day of reckoning" for Part D plans and their compliance programs has arrived. The Centers for Medicare & Medicaid Services (CMS) has begun oversight audits of their programs after a very rough start. What they are learning and how they go about ensuring these plans are complying with mandated standards is important to hospitals because once CMS moves to implement mandated compliance standards in response to health care reform, it likely will take its experience with the Part D program and apply it to the provider community.

By way of background, it is important to note that the provider community led by the hospital sector has been extremely active in the development, implementation, and advancement of their "voluntary" compliance program. By contrast, prescription drug plan (PDP) sponsors have been "mandated" by law and regulation to adopt and implement an effective compliance program and have been slow to do so.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[1] established the Medicare Part D outpatient prescription drug benefit, which included the requirement for PDPs to establish a program that includes being able to prevent, detect, and correct noncompliance with CMS' program requirements. (Chapter 9 of CMS' Prescription Drug Benefit Manual outlines the elements.)[2] In short, an effective compliance program was viewed by Congress as a critical part of ensuring PDPs protect the integrity of Medicare funds by preventing fraud, waste, and abuse.

The magnitude of expenditures and impact of this benefit on beneficiaries, from both health and financial perspectives, have made it a priority for compliance pro-

grams as a guard against fraud and abuse. Since 2005, federal regulations[3] have required PDPs to have compliance plans in place. Despite the requirements and emphasis placed on protecting the Part D benefit, few PDPs have met CMS' requirements for addressing fraud detection, correction, and prevention by developing an effective compliance program. Although CMS is responsible for oversight and implementation of safeguards to protect the integrity of the Part D benefit, it has moved slowly in providing oversight and enforcement of those required compliance provisions.

The Office of Inspector General (OIG) repeatedly has raised concerns about the noncompliance of PDPs and reported that while PDP sponsors have some form of compliance plan, none had fully addressed the compliance program requirements.[4] In a second evaluation of the issue, the OIG[5] stated that CMS oversight of PDP sponsors has been lacking and recommended CMS conduct routine audits of PDP sponsors' compliance programs to ensure that they meet all applicable federal requirements.

The U.S. General Accountability Office (GAO) also has noted a failure of PDP compliance in a March 3, 2010[6] report that blasted CMS for not conducting the necessary oversight audits as it had published in its 2005 Part D Oversight Strategy. GAO reported that "CMS officials told GAO the agency had completed desk audits (reviews of requested documents) in 2008 and 2009 and was beginning to implement an expanded oversight strategy."

On April 15, 2010, CMS issued a final rule[7] in an effort to increase its oversight efforts and to ensure that sponsors have effective compliance programs in place. As part of the conditions necessary to contract as a Part D plan sponsor, any entity seeking to contract as a Part D plan sponsor must have administrative and management arrangements in place.[8] The CMS strategy has been to use Medicare drug integrity contractors (MEDICs) to assist in this oversight audit work.

The Part D safeguard activity that was to be conducted by MEDICs was delayed until this last year when they performed compliance audits of 28 plans. As a result of this heightened oversight, there is considerable activity on the part of PDPs to bring their compliance programs up to speed, including many of the familiar elements of a hospital compliance program such as development and implementation of written compliance guidance; designation of a compliance officer; providing effective compliance training; implementation of effective lines of communication; enforcement of standards; auditing and monitoring high risk area; establishing procedures for prompt response to and report of compliance issues, et cetera.

There is significance of all these Part D compliance issues for hospitals. First, the PDP compliance programs are mandated. As noted at the outset of this article, under health care reform, CMS in consultation with the OIG will be providing similar "mandated" compliance guidance to the provider sectors. Meeting these requirements will be a condition of participation.

CMS has been learning about how to provide oversight of a compliance program from its experience with the Part D plans. Hospitals should monitor closely how CMS is going about this process because they can expect that once CMS has fully grasped how to effectively hold organizations accountable under Part D compliance requirements, CMS likely will employ the same strategy for the new mandated compliance program requirements for hospitals. It will be interesting to see what the results are from this first round of compliance audits and where it will take CMS in the upcoming year as this audit process continues.

Endnotes:

1. Public Law 108-173.
2. CMS, "Prescription Drug Benefit Manual," ch. 9—Part D Program to Control Fraud, Waste and Abuse (April 25, 2006). Available online at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.
3. 42 CFR §23.504(b)(4)(vi).

4. Prescription Drug Plan Sponsors' Compliance Plans, December 2006, OEI-03-06-00100.
5. Oversight of Prescription Drug Plan Sponsors' Compliance Plans, October 2008, OEI-03-08-00230.
6. Medicare Part D, CMS Oversight of Part D Sponsor's Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion, GAO-10-481T, March 3, 2010.
7. 75 Fed. Reg. 19678 (April 15, 2010).
8. 42 CFR §423.504(b)(4)(vi).

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