

CMS Compliance Plan:

An executive's guide to limiting risk during CMS audits

The compliance plan is a vital tool that helps plans remain on good terms with the Centers for Medicare & Medicaid Services (CMS), limits their risk exposure during CMS audits and delivers quality and service to plan members. Mandated by law, comprehensive compliance programs can help organizations meet and maintain “best in practice” standards that prevent, detect, and correct both noncompliance with CMS requirements and fraud, waste, and abuse. Because penalties for noncompliance are severe and long-lasting, it is vital that plan executives fully engage in the compliance plan process.

Introduction

For Medicare Advantage (Part C) Plans and Prescription Drug (Part D) Plans, there is no question that the stakes for establishing, implementing, monitoring, and improving compliance programs have never been higher. Immediate termination, suspension of enrollment, suspension of marketing, and civil money penalties that can exceed \$500,000 are the potential enforcement consequences that national, regional, and local plans are facing for violations, according to sanction letters issued by CMS.

“No plan can afford to not retain or enroll members, get hit with heavy fines, or be suspended or terminated from the program,” according to Robin Magwood, associate director, government program management and strategy, OptumInsight. Further, the negative publicity surrounding noncompliance activities can damage plans’ reputations and future business prospects, she remarked, adding that being subject to an enforcement action has lingering effects that may last for months after penalties or fines have been levied. “One MA plan could not market for eight months, which clearly affects its business long after that eight-month period ends,” Magwood said.

With consequences this severe, compliance officers and other high-level executives at MA organizations and stand-alone prescription drug plans are working diligently to ensure that they meet the mandatory compliance program requirements. The Affordable Care Act Sections 6401/6102 expanded mandatory compliance programs to the rest of the Medicare program (FFS providers/suppliers) and to the Medicaid (providers/suppliers, nursing facilities/skilled nursing facilities) and CHIP programs. These changes became effective Jan. 1, 2011.

Plans may have—or think they have—satisfactory compliance programs in place, but these programs typically are not adequate under the provisions of the mandatory requirements, which spell out very specific actions that plans must take to achieve compliance. Plan executives must work in tandem with their compliance officers to make certain that compliance programs are indeed effective, from the top down and from the bottom up.

To best facilitate this process, plan executives need to clearly understand the core requirements for compliance programs, know the potential risks and sometimes severe penalties associated with noncompliance, and learn how to proactively improve their plans’ compliance process to yield favorable CMS audit and overall performance results.

Plan executives also must be aware that successful compliance programs contribute greatly to an organization's profile with the agency, which is seeking to improve protections for Medicare beneficiaries. Each year CMS conducts an analysis of an organization's prior year performance and has used non-compliance letters, along with other indicators, to deny applications for initial contracts and service area expansions on the basis of noncompliant past performance. Further, a sanction letter requires an organization to implement immediate corrective measures to address the deficient practices, activities that can drain company resources.

Indeed, without executive support, compliance programs may falter. CMS reports at least four key audit deficiencies in 2010 that were directly related to a lack of involvement from the company's "C-suite" personnel (see "Compliance Program Deficiencies Provide Roadmap for Progress" sidebar).

New core requirements, changing compliance paradigm

Under initial regulations, published April 15, 2010, and amended by a Sept. 1, 2011, final rule¹ governing the Medicare Advantage (MA) program (Part C), prescription drug benefit, plans "must" adopt and implement an effective compliance "program," which "must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste and abuse."²

According to the regulations, plans "must, at a minimum," include seven core element requirements listed in the regulation.³ These seven core elements are:

1. Written policies, procedures and standards of conduct
2. Designation of a compliance officer and a compliance committee that report directly to the plan CEO or senior management
3. Establishment, implementation, and provision of effective training and education
4. Effective lines of communication, ensuring confidentiality between compliance officer/compliance committee and employees, managers, directors, etc.
5. Well-established disciplinary standards through the implementation of procedures which encourage good faith participation by all affected individuals
6. Establishment, implementation and an effective system for routine monitoring and identification of compliance risks
7. Establishment and implementation of procedures and systems for prompt response to compliance issues as they are raised.

¹ 79 FR 54600 (Sept. 1, 2011).

² 42 CFR §422.503.

³ Medicare Advantage Manual, Part D

Compliance program deficiencies provide roadmap for progress

Understanding which compliance program deficiencies are most common can help plan leadership focus its compliance program assessment and improvement efforts. In 2010, the Centers for Medicare & Medicaid Services (CMS) found the following key deficiencies during compliance program audits:

- Lack of sufficient "C-suite"/board level involvement, awareness, oversight, and support of compliance functions
- Compliance officer has indirect or infrequent reporting relationship to the CEO or board
- Compliance officer has direct reporting relationship to legal counsel or performs dual roles that might lead to conflicts of interest
- Lack of senior management involvement in and review and enforcement of standards of conduct and compliance and fraud/waste/abuse policies and procedures
- Failure to ensure receipt of comprehensive, up-to-date policies and procedures and standards of conduct and/or to implement mechanisms for ensuring adherence to them
- Lack of awareness of confidential, anonymous reporting mechanisms
- Compliance and/or fraud, waste, and abuse training not up to date and targeted to individual job duties/risks and not tracked and/or measured to determine whether training is received in a timely manner and is effective
- Lack of organizational compliance and fraud, waste, and abuse risk assessments
- Major functions are delegated to outside entities (e.g., pharmacy benefit managers) without exercising proper monitoring, oversight, and auditing to ensure compliance and detect fraud/waste/abuse
- Failure to implement systems for tracking and ensuring prompt response to detected noncompliance and fraud, waste, and abuse
- Application of compliance models or processes (e.g., commercial business compliance models) that do not meet Medicare requirements
- Failure to implement and oversee OIG provider exclusion and GSA debarment lists processes to screen out providers/suppliers
- Lack of specific mechanisms targeted to fraud, waste, and abuse, such as auditing in high-fraud geographic areas
- Failure to report fraud/waste/abuse to CMS Medicare Drug Integrity Contractor (MEDIC)⁴

⁴ Tranchida, Brenda; Bechtel, Marianne; CMS Program Compliance and Oversight Group, "CMS Mandatory Compliance Plans: What You Need to Know!" presented Feb. 11, 2011, at American Health Lawyers Association Medicare Advantage and Part D Affinity Group Brown Bag Webinar.

These new CMS requirements and broader enforcement authority should put plan executives on notice that there has been a paradigm shift in how compliance is tracked and detected at the agency. "Additionally, the establishment of the new Center of Program Integrity in April 2010 is yet another demonstration that CMS' focus on compliance and FWA in all of its programs to include Medicaid is here to stay," according to Magwood.

"CMS has quickly become very savvy, utilizing data-driven approaches to conduct on-site audits. CMS is using multi-disciplined audit teams—including fraud experts and those trained in developing sophisticated algorithms for data mining—to identify plan vulnerabilities," according to Magwood, who has roughly 20 years of health care experience at CMS.

Significantly, plan senior management may not fully recognize that "the agency has transitioned from routine, retrospective policies and procedures auditing to real-time, data-focused issue identification and follow-through to operations," she added. Any plan that does not have a comprehensive compliance plan up and running "should be very concerned, because compliance programs are not optional," she said.

Magwood also noted that the "member experience" has been given considerable importance. "Plans want to make certain that their beneficiaries are getting the kind of experience they should be getting," she said. "If plans create and nurture that positive member experience with an appropriately crafted and executed compliance program, they also are more likely to realize the added bonus of higher quality star ratings," she said.

Those plans that fail to act to address and enhance compliance program effectiveness could be blindsided by harsh penalties. Importantly, business leaders are held accountable for compliance results. As evidenced in recent sanction letters, one PDP was cited for a "numerous and repeated marketing violations...together with the lack of an effective compliance program to prevent, detect and respond to compliance deficiencies." Intermediate sanctions—suspension of enrollment and marketing—were imposed.

In another recent sanction letter, a large national MA plan was fined \$171,240 for failure to issue accurate annual notices of change and evidence of coverage, a violation that in CMS' view demonstrated that the plan was "carrying out its contract in a manner 'inconsistent with the effective and efficient implementation of this part.'"

One MA-PD plan was fined \$586,800 in 2010 after a CMS audit focused on billing practices, formulary administration, compliance plan, and appeals and grievances processes found that the plan failed to bill enrollees for monthly premiums, thus causing enrollees to unknowingly incur large balances due for those unpaid premiums; the plan also failed "to meet other compliance requirements in addition to the initial failure to bill premium."

Magwood explained that once a plan is "on the CMS radar," it may be subject to increased scrutiny in the future, so having a compliance program in place that includes thorough standards of conduct, effective internal monitoring of vendor delegations and a pro-forma view of agent/broker practices, amongst other key compliance features, "will go a long way toward either precluding audits altogether or having uneventful audits."

Bottom line, she cautioned plans and plan leadership to recognize that a compliance program "is not simply a paper document created once and stuck in a drawer—it has to be implemented effectively and followed each and every day."

For example, a plan may have the appropriate member materials displayed on its website but it may not have checked to ensure that the materials are properly linked and displayed—an action that will be taken by a CMS auditor during a plan audit. A plan also may have a toll-free number for member questions and complaints, but might never use "secret shoppers" to help it examine customer service call center performance. Investing in simple services such as this can ensure program effectiveness and save organizations from losing thousands or potentially even millions of dollars due to imposed suspension of marketing or other operational disruptions.

Preparing for compliance program and audit success

Because plans usually are not informed of an upcoming audit until five days prior, and because ensuing regulatory requests from CMS require near-immediate responses, the time to prepare for audits "is right now," Magwood advised. OptumInsight™ can help plan executives and compliance officers establish and provide ongoing testing and validation of their compliance programs in an efficient and cost-effective manner.

"An external party brings cross-industry, best-practice insight and can leverage functional experts and provide third-party objectivity," she explained. Specifically, OptumInsight can help plan executives handle or avoid penalties, fines and negative publicity with the following compliance offerings:

- **Regulatory Management Services**—Audit preparation, corrective action plans, corporate integrity agreements, focused reviews of operational areas
- **Annual Compliance Services**—Mock audits, open enrollment compliance testing, provider network access review
- **Ongoing Monitoring and Quarterly Compliance Services**—Compliance/operations integrated dashboard development, member experience testing, vendor delegation review and remediation plan, policy updates, compliance function impact
- **New Program Development**—Application development, readiness review preparation, governance structure, compliance committee set-up

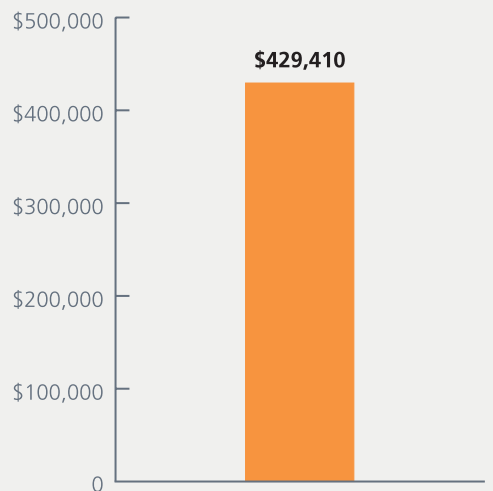
OptumInsight's compliance expertise is unmatched because it includes seasoned team members experienced in both Medicare and Medicaid programs and operations (on both the CMS and plan sides), those who have practical knowledge of skilled nursing facilities, special needs plans and coordinated care facilities, and those with finance, claims, FWA, and auditing skill sets.

OptumInsight also offers a comprehensive, one-stop shop with sophisticated IT capabilities and resources that provide plan clients with the expertise and technology to move their organizations forward in the existing compliance environment.

In OptumInsight's view, investing in a plan's compliance program is an investment in the company's future. "Ignoring or running from compliance is a no-win situation," Magwood said. "Instead, embrace compliance as a natural extension of leadership and governance duties, because at the end of the day, plans will be getting evaluated, and the results of a compliance program audit can either make you or break you."

Civil money penalties add up

Although the costs of program termination, marketing suspension, and enrollment suspension are noteworthy and long-lasting, they are difficult to calculate in hard numbers. However, civil money penalties imposed during the past year are easier to measure—and are not insignificant.



Civil money penalties imposed by the Centers for Medicare & Medicaid Services for program violations (August 2010–August 2011)

Signs that a compliance plan needs work

According to the Centers for Medicare & Medicaid Services, the following scenarios suggest that a plan has not maximized its compliance program:

- The plan's compliance officer does not report to the board or CEO
- The plan does not have a compliance committee
- Employees are afraid to report compliance program problems to their supervisors
- There is no mechanism for anonymous reporting of compliance program issues
- Allegations are not appropriately investigated
- Reported incidents are corrected, but overall systems are not fixed⁵

⁵ Tranchida, Brenda; Bechtle, Marianne; CMS Program Compliance and Oversight Group, "CMS Mandatory Compliance Plans: What You Need to Know!" presented Feb. 11, 2011, at American Health Lawyers Association Medicare Advantage and Part D Affinity Group Brown Bag Webinar.

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