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CMS Revamps Medicare Managed Care Compliance Program Guidelines



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The Centers for Medicare & Medicaid Services recently released final Compliance Program Guidelines (Final Guidelines) for Medicare Advantage (MA) organizations and Prescription Drug Plan Sponsors (collectively, Sponsors).

CMS issued these guidelines as Chapter 9 of the *Medicare Prescription Drug Benefit Manual* (PDBM) and Chapter 21 of the *Medicare Managed Care Manual* (MMCM), but the content of both chapters is identical and applies equally to the MA and Part D programs.

CMS issued Draft Compliance Program Guidelines (Proposed Guidelines) on Feb. 8 and said 68 entities submitted comments, representing a broad spectrum of stakeholders, including Sponsors, consumer advocacy groups, pharmacy associations, and health plan associations.

Apparently in response to commenters, CMS made significant changes between the Proposed and Final Guidelines.

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Takeaways

The Final Guidelines emphasize the building blocks of a ''culture of compliance,'' although CMS does not use this term. A culture of compliance typically is characterized by involvement of senior management, integration of compliance in education and training, enterprise risk management, and reinforcement by incentive systems.

The Final Guidelines stress such structural attributes of an effective compliance program, rather than the more specific, prescriptive standards under the previous version of Chapter 9.

The Final Guidelines also key on *prevention* of fraud, waste, and abuse (FWA), in contrast to the emphasis on *detection* of FWA under the prior version of Chapter 9 (which had not been updated since 2006).

Furthermore, as a matter of tone, it is notable that CMS has replaced the term ''FWA'' with ''compliance'' in many places throughout the Final Guidelines, which likely reflects CMS's view that a compliance program should be holistic and not narrowly focused on specific issues that generate overpayment liability. CMS's compliance enforcement activities in recent years appear to

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show that protecting beneficiaries is as high, or higher, than protecting the Medicare trust funds.[1]

Indeed, most CMS sanctions have been based on beneficiary protection concerns, such as failure to provide required beneficiary notices, Part D formulary access issues (including rejection of formulary drugs as nonformulary, failure to provide access to drugs in the six ''protected classes,'' and inappropriate use of step therapy and prior authorization), failure to collect premiums timely, and marketing violations by agents and brokers.

Although the Final Guidelines in many ways give Sponsors more flexibility as to how to structure their compliance programs, CMS's new approach should not be viewed as lowering expectations. As CMS has shown in recent audit results and decisions to impose sanctions and terminate contracts, MA and Part D compliance is a top agency priority.

While many of the details of a compliance program are left to Sponsors, CMS appears to expect senior-level oversight of a rigorous compliance program that ensures ongoing compliance with all MA and Part D program requirements, instead of a whack-a-mole approach that responds to particular FWA issues as they are identified.

Some of the important changes in the Final Guidelines are discussed below.

Involvement of Senior Leadership

CMS expects significantly more involvement of senior leadership in the development and oversight of a Sponsor's compliance program than under the prior Chapter 9, but CMS has backed down from some of the more rigid requirements it had proposed.

The governing body—which CMS defines in the Final Guidelines as ''that group of individuals at the highest level of governance of the sponsor, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees'' but not including ''C-level management''—was an afterthought in the prior Chapter 9.

The Final Guidelines include a new, extensive section in which CMS states that the governing body ''must exercise reasonable oversight with respect to the implementation and effectiveness of the sponsor's compliance program'' and bulleted lists of required oversight obligations, recommended oversight activities, and best practices for the governing body to collect and review ''measurable evidence that the compliance program is detecting and correcting Medicare program noncompliance on a timely basis.''

However, CMS chose not to adopt a proposed requirement that the Sponsor's governing body develop, review, and approve compliance policies and procedures (P&Ps). Under the Final Guidelines, participation in development, review, and approval of P&Ps is optional—although CMS did finalize a proposal that a Sponsor's full board should review and approve the Standards of Conduct.

With respect to the CEO, its key role under the Final Guidelines appears to be empowering the Sponsor's Compliance Officer. CMS states that the CEO and senior management should ensure that the Compliance Officer is integrated into the organization and ''is given the credibility, authority and resources necessary to operate a robust and effective compliance program.''

Furthermore, the CEO must receive periodic reports from the Compliance Officer of risk areas facing the organization, strategies being implemented to address them, and results of those strategies, and the CEO must also be advised of all governmental compliance enforcement activity. The Final Guidelines also require Sponsors to provide compliance training to their CEO's.

Importantly, CMS clarified that a Sponsor's Compliance Officer does not need to have a solid-line reporting relationship with the CEO; a dotted-line relationship is permissible. In the Proposed Guidelines, CMS stated that ''[t]he Sponsor must designate a Compliance Officer and Compliance Committee who report directly to and are accountable to the organization's chief executive or other senior management.''

The Final Guidelines stress such structural attributes of an effective compliance program, rather than the more specific, prescriptive standards under the previous version of Chapter 9.

It was not entirely clear whether CMS intended to require that a Compliance Officer have a direct-line reporting relationship with the CEO, so that, for example, the CEO would be directly responsible for hiring, firing, and determining compensation for the Compliance Officer. The applicable regulations clearly do not require such a direct-line reporting relationship. However, CMS auditors have indicated to Sponsors that CMS expects to see direct-line reporting and CMS officials have made similar statements in public remarks, which has muddied the waters.

In the Final Guidelines, CMS clarified that ''[t]he direct reporting relationship between the compliance officer and the senior-most leadership refers to the direct reporting of information, not necessarily to a supervisory reporting relationship. This can be accomplished through a dotted line or matrix reporting.''

The bottom line seems to be that, although a Compliance Officer is permitted to have a dotted-line reporting relationship with a Sponsor's CEO, CMS would prefer to see direct-line reporting.

First Tier, Downstream, and Related Entities

CMS continues to struggle to articulate clear boundaries as to the types of entities that qualify as FDRs. The Final Guidelines state that Medicare FDR requirements apply to entities ''to whom the sponsor has delegated administrative or health care service functions relating to the sponsor's Medicare Parts C and D contracts.''

This language is similar to the current definition of ''first tier entity'' under the MA and Part D regulations.

[1] Risk Adjustment Data Validation (RADV) audits are a notable exception to this observation. RADV audits are a reminder that, even if the focus of CMS is elsewhere, the government will aggressively pursue overpayments if the potential dollars at stake are high enough. MA and Part D Recovery Audit Contractors similarly may bring a renewed focus on overpayment liability.

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However, CMS retreated from proposed language that would have treated as FDRs only those entities to which the Sponsor had delegated ''core functions'' (although CMS did not describe what qualified as a ''core function'').

CMS gives one example of a relationship that would not be subject to the FDR requirements—a contract between a Sponsor and a real estate broker in connection with the rental of office space. On the other hand, CMS provides a non-exclusive list of 15 broad functions that would create an FDR relationship.

It is certain that CMS expects Sponsors to treat as an FDR any entity that has direct involvement in the administration of the MA or Part D benefit, but it remains unclear at what point an entity's tie to Medicare program administration would become so tenuous that the FDR requirements would not apply.

In a positive development for Sponsors and FDRs, CMS seems to have recognized that it is challenging for an FDR that contracts with multiple Sponsors to comply with the unique Standards of Conduct, P&Ps, and training of each Sponsor. CMS did not finalize a proposed requirement that FDRs use each Sponsor's Standards of Conduct and P&Ps.

Under the Final Guidelines, FDRs may use comparable Standards of Conduct and P&Ps, provided that they meet CMS requirements. Furthermore, pharmacies will now be able to either develop their own training materials or use a Sponsor's, as CMS eliminated its long-standing prohibition on pharmacy-developed training materials.

Enterprise Risk Management

CMS appears to have embraced the ''six sigma'' approach to enterprise risk management. In the Final Guidelines, CMS included a list of ''indicators of an effective compliance program,'' which include ''[u]se of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance with key Medicare Parts C and D operations such as enrollment, appeals and grievances, prescription drug benefit administration.''

CMS indicates that a Sponsor's Governing Body should review ''dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.'' CMS also cites the use of dashboards and scorecards as effective tools to identify potential compliance concerns with FDRs.

Self-Reporting

CMS clarified that self-reporting of FWA is voluntary. In the Proposed Guidelines, CMS restated the current regulatory requirement that ''[s]elf-reporting of FWA and Medicare program noncompliance is voluntary,'' yet, later in the same section, indicated that ''[i]f after conducting a reasonable inquiry, the Sponsor (e.g., the Medicare Compliance Officer or [Special Investigations Unit] determines that potential fraud or misconduct related to the Parts C or D programs has occurred, the conduct *must be* referred to the [National Benefit Integrity Medicare Drug Integrity Contractor] promptly.'' (Emphasis added.) CMS revised ''must be'' to ''should be'' in the Final Guidelines, removing the conflict between the manual and the regulation.

Other Noteworthy New Policies

- *Excluded Individuals.* Although old Chapter Chapter 9 briefly addressed excluded providers, the Final Guidelines provide additional detail regarding Sponsor obligations to ensure that they do not employ the services of excluded individuals. Sponsors must now: 1) check the exclusion lists monthly to ensure that none of its employees or FDRs are, or become, excluded; 2) have processes in place, and require their FDRs to have processes in place, to identify, deny, and prevent payment for claims from excluded providers at point-of-sale; and 3) implement policies requiring all new and existing permanent and temporary employees, governing body members, FDRs, and FDR employees to disclose any exclusion.
- *Special Investigations Unit (SIU).* The Final Guidelines require Sponsors to create an SIU capability, if not a distinct SIU. Old Chapter 9 suggested that Sponsors establish an SIU, but it was optional. Under the Final Guidelines, ''[d]epending upon the size of and resources available within the organization, sponsors must either establish a specific SIU or ensure that responsibilities generally conducted by an SIU are conducted by the compliance department.''
- *Deletion of Part-D-Specific Vulnerabilities.* The Final Guidelines are much shorter than the prior version of Chapter 9, largely because CMS deleted lengthy lists of specific FWA vulnerabilities under Part D. For example, CMS has deleted the old Chapter 9 list of specific ''schemes that could be perpetrated'' in cases involving crossover claims between Parts B and D. This is consistent with CMS's theme of expecting compliance with all MA and Part D requirements, rather than focusing on overpayment schemes.
- *Compliance as a Factor in Performance Reviews.* CMS indicates that ''Sponsors may consider including compliance as a measure on an individual's annual performance review.'' This seems to be further evidence that CMS is encouraging structures and processes that promote compliance from all employees, regardless of whether an employee is housed in a Sponsor's compliance department.