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by Brenda J. Tranchida, Esq.

CMS issues long-awaited compliance program guidance revisions

- » The new guidance incorporates 2011 regulatory changes and interpretive guidance.
- » The compliance officer's reporting role and entity's governance responsibilities are more clearly defined.
- » New requirements for oversight of first tier, downstream, and related entities; risk assessments; and use of metrics are highlighted.
- » The factors and evidence CMS will use to assess the effectiveness of a compliance program are outlined.
- » Other health care sectors that are required to have compliance programs may find this new guidance useful as well.

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> he Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), collectively known as the Affordable Care Act or ACA, significantly expanded



compliance risks for health care entities in a number of areas. In addition, Section 6401 of the ACA provides that a "provider of medical or other items or services or supplier within a particular industry sector or category" shall establish a compliance program as a condition of enrollment in Medicare,

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Medicaid, or the Children's Health Insurance Program (CHIP). The ACA further required the Secretary of Health and Human Services (HHS), in consultation with the HHS Office of Inspector General (OIG), to establish "core elements" for provider and supplier compliance programs within a particular industry or sector. In doing so, HHS has the discretion to determine both the timeline for implementation of the core elements and the requirement to have a compliance program. Section 6102 of the ACA also requires that nursing facilities have effective compliance and ethics programs in operation by March 23, 2013 (within 3 years of enactment of the ACA).

Mandatory health care compliance programs

In September 2010, the Centers for Medicare & Medicaid Services (CMS) solicited comments from industry stakeholders on how CMS should approach these new compliance program requirements. CMS included this solicitation in a proposed regulation covering a number of program integrity-related provisions of the ACA.¹ In February 2011, CMS published the final version of the regulation and stated, as it did in the proposed rule, that it intends to publish proposed regulations on the ACA mandatory compliance program provisions "at a later date."² To date, CMS has not published proposed regulations. CMS also failed to meet a specific statutory deadline (March 23, 2012) under Section 6102(b)(2) to promulgate compliance and ethics program regulations for nursing facilities. While the timing for implementation and specific requirements may be

in question, the ACA provides a clear statutory mandate for Medicare, Medicaid, and CHIP providers or suppliers and nursing facilities to have effective compliance and ethics programs.

In contrast, CMS has required Medicare Advantage (MA) managed care and prescription drug (Part D) plan entities, which provide benefits for 30 million of the nearly 50 million eligible Medicare beneficiaries, to establish compliance programs as a mandatory condition of contracting with CMS since the beginning of these programs. CMS issued substantially revised regulatory requirements applicable to these entities, effective January 1, 2011, which specifically required entities to adopt and implement an "effective" compliance program and added more detailed requirements for each of the seven basic compliance program elements (Note: This article will not detail all of these specific regulatory changes). CMS's updated regulations also clarified that an effective compliance program must include measures that prevent, detect, and correct program noncompliance and fraud, waste, and abuse.

In the last few years CMS has made these mandatory compliance programs a targeted focus of its enforcement and audit activities, including sanctioning several entities based, in part, on violations of these requirements. On February 8, 2012, CMS again turned its attention to these mandatory compliance program requirements, issuing long-awaited proposed changes to guidance exactly 6 years to the day the guidance was first issued to this industry (public comments to these proposed changes were due to CMS by March 16, 2012). In addition to offering further clarification on these requirements to MA and Part D plan entities, CMS's proposed (and ultimately final) guidance to this industry will undoubtedly shed light on the specific approaches and requirements CMS may apply to the other health care sectors (e.g., hospitals, physician practices,

nursing homes, etc.) affected by the mandates of Sections 6102 and 6401 of the ACA.

CMS proposed mandatory compliance program guidance revisions

CMS incorporated the specific language of the updated 2011 regulations into the appropriate sections of its manual guidance (Chapter 9 of the Medicare Prescription Drug Benefit Manual). Consistent with these regulatory changes, CMS also retitled the manual chapter ("Compliance Program Guidelines") to reflect an overall focus on compliance programs that effectively prevent, detect, and correct program noncompliance as well as fraud, waste, and abuse, rather than the narrower title of the current version of the chapter ("Program to Control Fraud, Waste and Abuse"). In addition, CMS clarified that once the guidance is finalized, it intends to issue a new identical chapter for MA entities (Chapter 21 of the Medicare Managed Care Manual).

CMS's updated guidance proposals also provide more specific direction concerning oversight of first tier, downstream, and related entities (FDRs) in a number of the seven compliance program elements. In addition, more broadly, the proposals state that CMS's requirements for sponsors to oversee its FDRs apply to those entities for which the sponsor has delegated "core functions" under its Medicare contracts. For these core function entities, CMS has updated its guidance language to provide that sponsors must specifically develop procedures to promote and ensure that all FDRs are in compliance with all applicable laws, rules, and regulations. A sponsor must have a risk assessment and management program, effective training and education, and effective internal controls and effective monitoring in place to exercise oversight of all of its FDRs and their associated personnel. CMS strongly recommends the use of metrics to conduct this oversight and to observe performance and operational trends.

The following summarizes the proposed changes in guidance that apply specifically to each of the seven compliance program elements.

Written policies and procedures (Element I)

CMS's proposed changes provide that the sponsor must be able to demonstrate "through written materials," a strong ethical culture and commitment to compliance with all applicable laws, regulations, and requirements. In expanding on what written materials would

be appropriate, CMS stated that typically an effective compliance program includes a resolution by the full governing body (updated annually) stating the sponsor's commitment to compliant, lawful, and ethical conduct. In the last

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few years, CMS made it a standard operating practice to obtain these kinds of governing board resolutions from entities during any enforcement and/or audit corrective action activities, prior to releasing the entity from these oversight processes.

Also, CMS states that it *expects* the entity's standards of conduct to "state the requirement that personnel in its organization and first tier, downstream and related entities (FDRs) report violations of law, regulations or program requirements to the Sponsor." In contrast, the current guidance states that the code of conduct "should encourage" reporting and includes law enforcement and CMS contractors as possible reporting sources.

This section of the updated guidance also has several new requirements, including:

- Sponsors must develop detailed policies and procedures to identify and address risks.
- Sponsors are required to be knowledgeable about Medicare requirements for each operational and administrative area that may pose a risk of Medicare noncompliance and fraud, waste, and abuse.
- Sponsors must have policies and procedures to implement each regulatory requirement of an effective compliance program.

One of the most significant changes in these proposals is the requirement that the governing body and senior management be directly involved in the development and/or review of the compliance policies *and* procedures and standards of conduct. CMS states that even if a board

committee develops/reviews these documents, they *must* be approved by the full governing body and senior management, including the "CEO and other senior officials." (The current guidance only references the code of conduct and provides that this document *should* be approved by the governing body or a committee of the governing body). CMS also states that it *strongly recommends* a standardized process for governing body review of these documents at least annually. (In contrast, the current guidance only references the code of conduct and states it should be reviewed periodically.)

Finally, CMS's proposals state that it *expects* compliance policies and procedures and standards of conduct to be distributed to employees (including to FDR employees) within 90 days of hire, annually thereafter, and whenever these documents are revised. In doing so, CMS is proposing to establish a specific 90-day deadline for initial distribution to new hires and new FDRs. CMS has strengthened the language related to this distribution requirement from "should" to "expects" and has provided clarity that sponsors will be held accountable for ensuring FDR compliance with these requirements. CMS also included new language that the sponsor must be able to demonstrate to CMS that all employees (including all FDR employees) have received these documents in a timely manner and, as a condition of employment, have read and agreed to comply with these policies, procedures, and standards. CMS also expects contracts with FDRs to include provisions that address these distribution requirements and states that a sponsor must periodically monitor and audit its own organization and its FDRs to ensure that there is documented proof that these distribution requirements are being met.

Compliance officer, Compliance committee, and high-level oversight (Element II)

CMS's 2011 regulations include new language that the compliance officer and Compliance committee must report directly to the entity's chief executive or other senior management. CMS's proposed guidance further addresses this relationship by requiring that the organization must ensure that reports from the Medicare compliance officer reach the seniormost level of the company, typically the CEO or president. Reports can flow through divisional CEOs or presidents (e.g., president of the Medicare division of the company), but should not be routed through operational management, such as the chief operations officer (COO), chief financial officer (CFO), general counsel (GC), or other executives responsible for operational areas.

CMS's proposed guidance also provides that because of the direct reporting requirement in regulations, the Medicare compliance officer's reports to the governing body must be made through the Compliance infrastructure (i.e., from the Medicare compliance officer to the corporate compliance officer; from the Medicare Compliance committee to the corporate Compliance committee). Similarly, CMS's proposed guidance also states that the compliance officer must (current guidance states "should") have express authority to report directly to the entity's senior-most leader and to the governing body at his/her discretion. Finally, while the current version of the manual includes language concerning guarding against conflicts of interest in roles performed, CMS's proposed updates explicitly provide, "there is a conflict of interest where the compliance officer is also the CFO, COO or GC."

With respect to the governing body and senior management's oversight responsibilities, the 2011 regulations require the governing body to be knowledgeable about the content and operation of the compliance program and to exercise "reasonable oversight." In turn, the proposed guidance changes highlight this important area by adding two new sections to the guidance and adding "high-level oversight" to the title of this element section. The proposals also provide at the outset that governing body and senior level engagement is critical to the meaningful and successful oversight of the entity's Medicare operations, and that the governing body is ultimately accountable for ensuring the effectiveness of the compliance program. Also, the guidance states that on a least a quarterly basis, the products of the Compliance committee, including the status of the compliance program, must be reported to the governing body or a committee of the governing body responsible for oversight of the Medicare program. Among other provisions, CMS's updated proposals state that the governing body must ensure that the Medicare compliance officer has unfettered access to the

governing body and that the scope of any delegated activities from the full governing body to a governing body committee be clearly stated in the committee's charter and reporting.

Also, in order to meet the new regulatory requirement to be knowledgeable about the content and operations of the compliance program, CMS's proposals state that the governing body must receive training and education regarding the structure and operation of the compliance program in order to enable it to fulfill its duties and exercise independent judgment over compliance issues presented. The governing body also must be specifically knowledgeable about compliance risks and strategies, must make further inquiry and take appropriate action to address compliance issues presented to it, must understand the measurements of outcome, and must be able to gauge the compliance program's effectiveness. The updated guidance also provides that the entity must ensure that CMS is able to validate, through review of governing body minutes, the level of governing body engagement in oversight of the Medicare program.

Finally, the proposed guidance additionally focuses on governance by highlighting the importance of the role of the CEO, the president, or senior management in ensuring the compliance officer is integrated into the organization and has the resources necessary to operate a robust and effective program. The proposed guidance language also explicitly provides that the CEO "must receive regular reporting of all governmental compliance enforcement activity, from notices of noncompliance to formal enforcement actions."

Effective training and education (Element III)

As noted below, many of the updates to Element III include modifying existing language from "should" to "must." In addition, CMS's proposals establish a new deadline for when general compliance training must be conducted — within 90 days of initial hire (or contracting, in the case of new FDRs). The training must be made part of orientation for new employees of both the entity and FDRs and for a newly appointed CEO, managers, or governing body members (current guidance uses the term "should").

Sponsors must require that their FDRs either conduct their own compliance training or may choose to make their training available to these entities. Sponsors are accountable for ensuring that FDR employees have training that meets CMS and regulatory requirements, and must establish mechanisms for ensuring completion of training (e.g., contracting provisions, collecting attestations, focused monitoring and auditing, etc.). CMS expects sponsors to update the general compliance training annually, if needed, and whenever requirements change. Sponsors must (current guidance uses the term "should") require that their FDRs administer their own specialized training or make the sponsor's specialized training available to FDRs where appropriate.

For specialized training, sponsors must review and revise these kinds of specialized training as needed, but at least annually. Sponsors must retain adequate records of their specialized employee training, including attendance logs, training materials, and results of any testing. Entities are responsible for maintaining records of the time, attendance, topic, and results of training (please note that although all of these areas are addressed similarly in current guidance, the current guidance uses the term "should ").

With regard to anti-fraud, waste, and abuse training, CMS's proposed guidance incorporates the specific language of antifraud, waste, and abuse training guidance that it issued in 2009, with little-to-no substantive changes. CMS's proposals add, however, that although certain individuals may be deemed to have met the requirements for this kind of training as provided by CMS, these deemed persons must still receive general Medicare compliance training and specialized compliance training in connection with their job responsibilities. Significantly, CMS's guidance proposals also add a new section that contains a requirement that sponsors must implement mechanisms to measure the effectiveness of their training, including evaluating the training to determine whether it is effective, identifying any deficiencies, and undertaking remedial actions to correct any deficiencies.

Effective lines of communications (Element IV)

CMS did not propose any significant changes to this section of the manual guidance other than to specifically

incorporate the regulatory changes (e.g., language specifically references requirements as being applicable to FDRs as well as to the entity's own organization) and, in line with these changes, to propose guidance language that clearly indicates

With respect to the governing body and senior management's oversight responsibilities, the 2011 regulations require the governing body to be knowledgeable about the content and operation of the compliance program and to exercise "reasonable oversight."

that certain provisions are now required by the use of the word "must" versus "should."

Well-publicized disciplinary standards (Element V)

Similarly, CMS did not propose any significant changes to this section of the manual guidance other than to specifically incorporate the regulatory changes and, in line with these changes, to propose guidance language that clearly indicates that certain provisions are now required by the use of the word "must" versus "should." For example, CMS's proposed guidance states that sponsors "must" prominently publicize compliance disciplinary standards to all managers and employees in their organizations and to their FDRs. Also, all employees "must" be informed that violations of standards will result in appropriate disciplinary action. Sponsors "must" be able to demonstrate to CMS that disciplinary standards are enforced in a timely, consistent, effective, and appropriate manner. Sponsors may do this by periodically reviewing and evaluating disciplinary records for fairness and consistency. Sponsors also must consistently take disciplinary action to ensure that the policy has a deterrence effect. CMS's proposals also add language that sponsors "should" include

> compliance as a measure of an employee's job performance.

Effective system for routine monitoring and auditing (Element VI) As it does in current guidance, CMS devotes a great deal of attention to this

element in its proposed updates. The proposed guidance reflects the changes to regulatory requirements in this element by now requiring that entities establish and implement an effective system for routine monitoring and identification of compliance risks. This system must include internal auditing and monitoring and external audits, as appropriate, to evaluate the entity's (and its FDRs') compliance with CMS requirements as well as the overall effectiveness of the compliance program. Many of the other changes in this element entail changing language from "should" to "must" to reflect the updated regulatory requirements. The updated guidance proposals also include a new section devoted to risk assessment. Sponsors must establish and implement policies and procedures to conduct a formal assessment of major compliance and fraud, waste, and abuse risk areas, including the use of a risk assessment tool for each operational area. A comprehensive risk assessment must be conducted at least once a year, and there must be ongoing review of potential risks. Also, any risks identified through CMS audits and oversight and the entity's own oversight mechanisms will be considered "priority risks" by CMS.

The proposals also require that entities implement an internal audit function. Although many aspects of implementation are left up to the sponsor, CMS's proposed guidance requires that sponsors must ensure that internal auditors:

- are independent,
- do not engage in self-policing,
- are knowledgeable of Medicare program requirements, and
- have access to relevant personnel, information, records, and operational areas, including operations of FDRs.

The proposed guidance also adds a requirement that sponsors develop a strategy to monitor and audit their FDRs, include in work plans the number of FDRs that will be audited each year, and define how the entities will be identified for audits. Sponsors also are required to ensure that their contracts with FDRs require record retention and provide rights of access to CMS. The proposed guidance also adds a new requirement for sponsors to perform a risk assessment to identify their highest risk FDRs from which to select a reasonable number to audit from among the highest risk groups. Sponsors also must ensure that corrective action is taken by FDRs when needed, either as a result of a sponsor monitoring or auditing, or

through audits performed by the FDRs themselves. CMS proposals also make it clear, "[a]lthough FDRs may perform their own internal auditing, the Sponsor remains obligated to perform its own auditing of FDRs."

Significantly, CMS's proposed guidance also adds a new section concerning the measurement of compliance and compliance program effectiveness. This section is not included in current guidance. More specifically, the guidance states that sponsors must evaluate the effectiveness of the compliance program at least annually and these results must be reported to senior management and the governing board. Also, sponsors must respond promptly to any identified weaknesses in the compliance program and must take appropriate corrective measures to ensure a fully effective compliance program.

The proposed manual language also incorporates guidance that was issued by CMS in 2010 concerning screening for excluded entities. The proposed language requires sponsors to review the HHS OIG exclusion and GSA debarment lists prior to any new hiring or contracting, and monthly thereafter, and to have processes in place that identify and prevent payments for claims by excluded providers. This guidance also specifically requires that sponsors ensure that FDRs develop and implement policies and procedures that require and document the review of these exclusion lists, including performing appropriate monitoring and auditing of FDRs to confirm that the FDRs comply with this requirement.

The proposed guidance also requires that sponsors have a special investigative unit (SIU). Sponsors must either establish a specific SIU or ensure that responsibilities generally conducted by an SIU are conducted by the Compliance department. SIUs are required to be accessible via phone, email, Internet, and mail, and sponsors must ensure that fraud, waste, and abuse allegations can be reported anonymously to the SIU. In addition, CMS's guidance adds fraud awareness training as an additional responsibility of the SIU.

Prompt response to compliance issues (Element VII)

The proposed guidance provides that sponsors must undertake appropriate corrective action in response to noncompliance or fraud, waste, and abuse; and these corrective actions must be designed to correct the underlying problem that led to the issue and to prevent future noncompliance. CMS added new language that states that corrective action must be tailored to address the particular issue, must include timeframes for specific achievements, and must be documented. In addition, CMS's updates require that the elements of the correction action must be documented and include ramifications (i.e., effective disciplinary measures) should the sponsor or its employees fail to implement the corrective action.

With regard to voluntary self-reporting of potential fraud or misconduct, the proposed guidance states that sponsors must conclude their own investigations of potential misconduct within a reasonable time period after the fraudulent activity is discovered (current guidance states sponsors "should initiate a reasonable inquiry immediately, but no later than two weeks from the date the potential misconduct is identified"). Also, if the sponsor concludes after conducting a reasonable inquiry that fraud or misconduct has occurred, the conduct must be referred to CMS's designated contractor "promptly" (in contrast, the current version of the guidance states, "promptly but no later than 60 days after the determination"). For significant or serious noncompliance issues (versus fraud or misconduct), CMS's proposals add language that it "expects" sponsors to report to CMS as soon as possible after the discovery.

CMS's proposed guidance also adds a new section on identifying providers who have a

history of complaints. In this section, CMS states that sponsors are expected to maintain files on providers who have been the subject of complaints, investigations, violations, and prosecutions. Sponsors must comply with requests from law enforcement, CMS, and its contractors regarding monitoring providers that have been identified by CMS as potentially abusive or fraudulent. The proposed guidance has been updated to remove (without explanation) a number of other sections that addressed particular kinds of fraud, waste, and abuse (e.g., pharmacy benefit manager (PBM) and pharmacy-related fraud, waste, and abuse).

Defining effectiveness

In addition to the above highlighted proposals that affect each of the seven required elements, CMS's proposed guidance updates provide significantly more information regarding the factors it will consider when evaluating whether an entity has an effective compliance program. As stated previously, this is particularly important because the 2011 revised regulations specifically require entities to maintain and implement an *effective* compliance program. The following are proposed revisions to specific sections (as denoted) of Chapter 9 of the Medicare Prescription Drug Benefit Manual that specifically address or define effectiveness.

In order to be effective, a sponsor's Medicare compliance program must:

- include all of the regulatory requirements;
- be tailored to each sponsor's unique organization, operations, and circumstances;
- ▶ be fully implemented; and
- be effective in preventing, detecting, and correcting Medicare program noncompliance and fraud, waste, and abuse. (Section 30)

A compliance program will *not* be effective unless entities devote "adequate resources" to the compliance program. Adequate resources (which CMS acknowledged may vary, based on a variety of factors), are defined by CMS as those that are sufficient to:

- assess the organization's risks;
- promote and enforce its standards of conduct;
- effectively train and educate its employees and FDRs;
- effectively establish lines of communication within its own organization, and with its FDRs;
- oversee FDRs' compliance;
- establish and implement an effective system for routine auditing and monitoring; and
- identify and promptly respond to risks and findings. (Sections 30, 50.2.1)

To be effective, the standards of conduct should be written in a format that is easy to read and comprehend. (Section 50.1.2) Compliance policies and standards of conduct cannot be effective if they are not distributed to employees—and read and followed by them. Because distribution of compliance policies and procedures and standards of conduct is essential to effectiveness, CMS expects sponsors to ensure that their employees and the employees of their FDRs, as a condition of employment, read, and agree to comply with all written compliance policies and procedures and standards of conduct within 90 days of the date of hire and annually thereafter. (Section 50.1.9)

To be effective, the Medicare compliance officer (MCO) should be a full-time employee and dedicated principally to the Medicare compliance program. The MCO must have training and/or experience working with Medicare Advantage or Part D programs and regulatory authorities. Further, senior leadership's empowerment and support of the MCO is critical to his/her credibility and to his/her ability to establish and operate an effective compliance program. (Section 50.2.1) Effective compliance programs "typically" include a resolution of the full governing body, stating the sponsor's commitment to compliant, lawful, and ethical conduct. This should be updated annually, because governing body membership may change. (Section 50.1.1)

An effective compliance program cannot be achieved unless the CEO or president and other senior management, as appropriate, are engaged in the compliance program. It is critical that the CEO and senior management recognize the importance of the compliance program to the organization and that the compliance officer is crucial to protecting the organization and its governing body. A critical role of the CEO or president and senior management is to ensure that the compliance officer is integrated into the organization and has the resources necessary to operate a robust and effective compliance program. (Section 50.2.4)

An effective compliance program establishes an organizational culture of compliance that emanates from the top of the corporate structure; therefore, it is critical to an effective compliance program that the governing body and senior management be directly involved in the development and/or review of the compliance policies and procedures and standards of conduct. Even if a board committee develops/reviews these documents, they must be approved by the full governing body and senior management, including the CEO and other senior officials. (Section 50.1.8)

Entities must conduct routine auditing and monitoring of their operational areas as well as the compliance program itself; effectiveness is "enhanced" by the use of performance measurements that evaluate the effectiveness of the compliance program. (Section 30)

Measurement and tracking of compliance efforts are crucial to an effective compliance program. Sponsors are expected to use dashboards, scorecards, and other self-assessment mechanisms to measure their operational compliance and the operational compliance of their FDRs. These results must be shared with senior management and the governing body. It is highly recommended that compliance performance be linked to staff, management, executive, and FDR compensation. (Section 50.6.7)

An effective program to control fraud, waste, and abuse includes policies and procedures to identify and address fraud, waste, and abuse at both the sponsor and FDR levels in the delivery of Parts C and D benefits. (Section 50.6.10)

Summary

CMS's long-awaited proposed guidance revisions provide a great deal more detail and clarity to MA and Part D Plan entities regarding their mandatory compliance program requirements. Overall, CMS's proposed changes to its compliance program guidance:

- incorporate the 2011 updated regulations and add corresponding interpretive guidance concerning these new regulatory requirements;
- provide more clarity on the reporting role of the compliance officer and Compliance committee to senior management and the governing body;
- provide additional guidance regarding the monitoring, oversight, and training of FDRs;
- highlight the importance of the accountability and governance roles played by senior

management and the governing board, and provide more specific requirements for their engagement and involvement in overseeing the compliance program;

- provide new detailed guidance for conduct-ing risk assessments;
- highlight the requirement to use metrics in evaluating the sponsor's training programs and compliance program effectiveness;
- provide specific information on what CMS expects to be provided during an audit or other evaluations of these programs to show compliance with its requirements; and
- specify what factors and evidence CMS will consider when evaluating whether a compliance program is effective.

Many of these proposed changes have no doubt been informed by CMS's enforcement and audit oversight activities and experiences in this particular health care sector over the course of the last few years. Also, as noted above, CMS's guidance updates in this sector are worth paying close attention to, because they will likely inform and influence its decision-making in promulgating regulations for mandatory compliance program requirements for the rest of the federal health care industry, as required by the new provisions of the ACA.

 ⁷⁵ Fed. Reg. 58204, September 23, 20102
76 Fed. Reg. 5862, February 2, 2011