Medicare Compliance Program Effectiveness Training Care1st Compliance Department

Calendar Year 2012
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• The New Regulation: New Compliance Program Requirements

• Compliance Effectiveness: What does “effectiveness” look like?
• Seven individual requirements which are most effective on an interdependent basis

• Prevents, detects, and responds to violations of law or policy

• Medicare-specific provisions which must be complied with (e.g., False Claims Act, Anti-Kickback Statute) incorporated into written policies/procedures and standards of conduct

• Demonstrates the organization’s commitment to a “culture” of compliance
Compliance Program Requirements

- Requires engagement and communication among governing body, senior executives, and employees

- Defines expectations for employees for ethical and proper behaviors when conducting the Medicare line of business

- Promotes a “proactive” vs. “reactive” approach

- Identifies risks that may have been undetected internally

- Prevents, detects, and responds to violations of law or policy
Why are the Compliance Programs Important?

- Requirement to contract with CMS

- Roadmap to prevention, early detection, and responding to non-compliance issues before they develop into larger issues
Why are the Compliance Programs Important?

• Beneficiary impact
• Financial Impact
• Operational Impact
• Regulatory Impact
• Reputational Impact
Compliance Program Audits

- On-site
  - Not just a “paper exercise” (“print, post and pray”)
  - Focused on evaluating effectiveness
     – find and fix problems – prevent, detect, and respond timely and effectively to compliance issues
- Validation, including requirements to implement programs to control and combat fraud, waste and abuse (FWA)

Guidance – Chapter 9 (Prescription Drug Manual) will be updated; uniform set of guidance for PDPs/MAOs
The Updated Regulations

  - 422 CFR 503(b)(4)(vi), 423 CFR 504(b)(4)(vi)
  - Regulation is effective June 7, 2010
  - Compliance program changes become effective with new plan year: January 1, 2011

- Most changes already contained in existing Medicare Drug Plan Manual Chapter 9 sub-regulatory guidance

- New regulation specifically requires compliance program to be “effective”—this has been in Chapter 9 since 2006

- New regulation provides more detailed regulatory requirements on each of the 7 compliance program elements; speaks specifically to “effectiveness”
Modified language in 422 CFR 503(b)((4)(vi) and 423 CFR 504(b)(4)(vi):

- “Adopt and implement”
- “An effective compliance program”
- “That includes measures to prevent, detect, and correct non-compliance with CMS program requirements”
- “As well as measures to prevent, detect, and correct fraud, waste, and abuse”
- “Must at a minimum include” the seven core element requirements listed in the regulation

[Emphasis added]
Element 1: The organization must have written policies, procedures and standards of conduct which…

- The MA and Part D Sponsor’s commitment to comply with all applicable federal and state standards
- Describe compliance expectations as embodied in standards of conduct
- Implement compliance operations
- Provide guidance to employees and others for dealing with potential compliance issues
- Identify how to communicate issues to compliance personnel
- Describe how issues are investigated and resolved
- Include policy of non-intimidation and non-retaliation for good faith participation in the compliance program


**Element 2:** Designation of a compliance officer (CO) and compliance committee (CC) “who report directly and are accountable to the organization’s chief executive or other senior management” (vs. “who are accountable to senior management”)

- CO must be an employee of the contracting entity, parent organization, or corporate affiliate
- CO may **not** be an employee of first tier, downstream or related entity
- CO/CC must periodically report directly to the governing body of organization on activities/status of program, including issues identified, investigated and resolved
- Governing body must: (1) be knowledgeable about content and operation of the compliance program; and (2) exercise reasonable oversight for implementation and effectiveness of program
Element 3:

Each C/D plan sponsor must establish, implement and provide effective training and education between the CO and organization’s employees including, “chief executive or other senior administrator” [new language], managers and “governing body members” [new language] and the organization’s first tier, downstream and related entities

- Must occur at a minimum annually and be made part of the orientation for:
  - a new employee
  - new first tier, downstream or related entities and
  - new appointment to chief executive, manager or governing body member

- First tier, downstream and related entities that have met FWA certifications through enrollment in FFS Medicare program or accreditation as a DMEPOS suppliers are deemed to have met the FWA training and education requirement
Element 4: Establishment and implementation of effective lines of communication, “ensuring confidentiality” [new language] between the Compliance officer, members of the Compliance committee, employees, managers and “governing body” [new language], and first tier, downstream and related entities:

• These lines of communication must be accessible to all
• Lines of communication allow for anonymous and confidential good faith reporting of potential compliance issues as they are identified
Element 5:
The organization must have well-publicized disciplinary standards “through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals” [new language]:

These standards must include policies that:

• Articulate expectations for reporting and assisting in resolution of compliance issues
• Identify non-compliance or unethical behavior
• Provide for timely, consistent and effective enforcement of standards when non-compliance or unethical behavior detected
Element 6:
“Establish and implement effective system for routine monitoring and identification of compliance risks” [new language]

Additional requirements:
• System includes routine internal monitoring of compliance risk areas by business units
• System includes periodic internal audits to confirm results of monitoring
• External audits of entity as appropriate, including to evaluate first tier compliance with requirements
• Evaluation of overall effectiveness of the compliance program
Element 7:
“Establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensure ongoing compliance with CMS requirements” [new language]

• If the sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely reasonable inquiry into that conduct
• Must conduct appropriate corrective actions
• And the sponsor should have procedures to voluntarily self-report potential fraud and misconduct related to the program to CMS, or its designee
Demonstrating an Effective Compliance Program
7 Elements of a Successful Compliance Program

1. Leadership (Governing Body, Compliance Officer, Compliance Committee, Organizational Culture)
2. Communications (360 degree Communications)
3. Education/Training (Frequent Training Updates)
4. Monitoring/Auditing (Internal Audits & Controls)
5. Documentation Policy/Procedures (Clearly stated & Readily available)
6. Disciplinary Guidelines (Well Publicized)
7. Enforcement (Prompt Response)
Areas for Measurement

Structure: the overall make-up of the organization

- “Culture” of compliance endorsed by leadership
- Information exchange between the Compliance
  - Officer, Senior Executives, Governing Body, and employees
- Policies & procedures
- Reporting mechanisms
- Education & training
Process: How your system works

- Ongoing risk assessments & monitoring activities
- Incorporating new regulatory and policy changes
- Response and prevention
- Enforcement and discipline
- Systemic corrections
- Accountability of operational areas to compliance department
Outcomes: Trends/Results
• Monitoring and audit results trigger a need for updated procedures and retraining employees
• Proper internal controls over delegated entities performing operational functions
• Employee engagement
• Decrease /Increase in Medicare beneficiary and PBM fraud, waste, and abuse
• Evaluate the effectiveness of your compliance plan
What Does “Effectiveness” Look Like?

- Outcomes
- Structure (Culture)
- Process
Transparency: Are you prepared to operate in a more transparent health care system?

- Does your organization have the right systems and technologies to meet new demands to collect, organize, track, retain, and report information and data accurately and completely?

- Do you have security and privacy protections in place for creating, transmitting, and storing data?

- Do you have systems in place to meet enhanced reporting and disclosure requirements applicable to your industry segment?
Quality: Are you focused on quality as a compliance issue?

• Do you clinicians understand that quality is a compliance concern and that quality of care is increasingly integral to payment?

• Do you have systems that will ensure that charting, collection and reporting of quality data and clinical documentation are accurate, complete, and sufficient to justify payment?

• Are you present during conversations and involved in decisions about quality in your organization?
• **Quality:** Are you focused on quality as a compliance issue? (Cont’d)

- Does your compliance department have the expertise to address quality-related compliance issues?
- Are your board of directors and management informed about the heightened role of quality of care under health care reform?
Accountability: Is your organization prepared for greater accountability?

• Do you have a compliance plan in place? If not, is your organization prepared to create and implement one?

• Do you know with whom your organization does business?
  • Does your organization have affiliations with excluded, suspended, or Medicare debt-owing individuals and entities?
  • Are you prepared to meet new requirements for background and licensure checks?
  • Are the persons furnishing services through your organization qualified to do so?
Accountability: Is your organization prepared for greater accountability? (Cont’d)

• Are you focused on identifying and addressing new fraud and abuse risk areas that may arise as your organization becomes involved with new payment and delivery systems (such as medical homes, accountable care organizations, bundled payments, and value-based purchasing)?

  • For example, are you thinking about risk areas such as inappropriate stinting on care, “cherry picking” patients, “lemon dropping” patients, gaming of payment windows, and misreporting of quality or performance data?

• Will you have safeguards in place to address these and other risks?

• Will compliance be part of the conversation as your organization contemplates new business and reimbursement arrangements?
Accountability: Is your organization prepared for greater accountability? (Cont’d)

• Is your organization addressing its increased compliance and quality responsibilities under health care reform?
  • Are managers, staff, and contractors aware of their responsibilities?
  • Are your training systems robust enough to support a new learning curve?

• If you represent a private insurer or employer organization preparing to participate in new public programs (e.g., participating on the exchanges or in the temporary employer retiree reinsurance program), does your organization have systems in place to ensure compliance with applicable program requirements?
Accountability: Is your organization prepared for greater accountability? (Cont’d)

• Do you have systems in place to screen for improper claims before they are filed?
  • Are you using data mining and other techniques and technologies to detect improper claims?
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