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Building an Effective Compliance Program

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Overview

- What Is a Compliance Program?
 - From Guidance to Requirement
 - New Regulations – 42 C.F.R. Section 483.85
 - Proposed Rule, Final Rule, Revised Rule
- What are the Benefits of a Compliance Program?
- Seven Core Elements
- Specific Risk Areas and Other Concerns

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What Is a Compliance Program?

What Is a Compliance Program?

- A compliance program is a **series of internal controls and measures** to ensure that a health care facility and its employees are following federal, state and local laws governing the federally funded health care programs.
- An effective compliance program should **assist a nursing facility in its efforts to identify operational areas that present potential liability risks** under several Federal fraud and abuse statutes and regulations

Compliance Programs – History

- March 2000 – Office of Inspector General (“OIG”) Compliance Guidance for Nursing Facilities – March 2000
 - Fundamentals of establishing an effective compliance program
- September 2008 – OIG Supplemental Guidance for Nursing Facilities
- March 2010 – Affordable Care Act
 - Mandated programs by March 2013
- July 2015 – Proposed Rule
- October 2016 – Final Rule
- November 2017 – Implementation Date
- **November 2019 – Enforcement Date**

Compliance Programs – History

- Patient Protection and Affordable Care Act (“PPACA”)
 - Mandates compliance and ethics programs for a wide range of providers, suppliers, and facilities as a condition of enrollment in Medicare, Medicaid, and Children’s Health Insurance Program.
 - The mandate is divided between skilled nursing facilities (“SNFs”) and all other providers and suppliers.

Compliance Programs – History

- Section 6401(a)(7)(A)-(C) – Provisions Applicable to Providers and Suppliers
 - Establishment of Core Elements: The core elements for compliance programs for providers and suppliers shall be established by the Secretary HHS (“Secretary”) in consultation with the Inspector General.
 - Timeline: The Secretary shall determine the timeline for the establishment of the core elements, and the date of implementation of provider/supplier compliance programs.

Compliance Programs – History

- Section 6102(a) & (b) – Provisions Applicable to SNFs
- Timeline:
 - Secretary, working jointly with the Inspector General, shall promulgate regulations for an effective compliance and ethics program by March 23, 2012
 - SNFs then have one year to implement a program that meets the published criteria
 - New compliance requirements imposed on SNFs will likely be similar to requirements ultimately imposed on other providers

Compliance Programs – History

- Section 6102(a) & (b) – Provisions Applicable to SNFs
- Requirements for Compliance and Ethics Programs
 - Reasonably designed, implemented, and enforced so that they will be effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care; and
 - Includes at least the following required components:
 - Reasonably Capable Standards and Procedures
 - Oversight and Enforcement

Compliance Programs – History

- Section 6102(a) & (b) – Provisions Applicable to SNFs
 - Proper Delegation
 - Communication
 - Compliance
 - Disciplinary Mechanisms
 - Modification
 - Reassessment

Compliance Programs – History

- 42 C.F.R. Section 483.85
 - Components
 - (1) Standards/policies; (2) High-level personnel; (3) Sufficient resources/authority; (4) Due care; (5) Effective communication; (6) Monitoring/auditing; (7) Enforcement; (8) Responding/reporting
 - Organizations with five or more facilities
 - Mandatory Annual Training
 - Compliance officer – Must report to operating organization's governing body and not be subordinate to GC, CFO or COO
 - Compliance liaisons at each facility
 - Annual reviews – All operating organizations must assess effectiveness on an annual basis

Compliance Programs – History

- 42 C.F.R. Section 483.85
 - **Compliance and ethics program** – a program of the operating organization that has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care
 - **High-Level Personnel** – individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization
 - **Operating Organization** – the individual(s) or entity that operates a facility

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What Are the Benefits of a Compliance Program?

Benefits of a Compliance Program

- Demonstrating a facility's commitment to honest and responsible conduct and its good faith effort to comply with applicable statutes, regulations, and other requirements and may significantly reduce the risk of unlawful conduct and corresponding sanctions
- Improving a facility's reputation for integrity and quality, increasing its market competitiveness and reputation in the community
- Enhancing resident satisfaction and safety through the delivery of improved quality of care
- Increasing the likelihood of preventing unlawful and unethical behavior or identifying and correcting such behavior at an early stage
- Encouraging employees and others to report potential problems

Benefits of a Compliance Program

- Self-Disclosure Protocol
 - <https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>
- When a provider has a compliance program and self-reports a compliance issue, the OIG (and others) take such programs into account in determining whether to impose penalties, including fines and corporate integrity agreements

Benefits of a Compliance Program

- Ethical culture
 - A nursing facility's leadership should foster an organizational culture that values the prevention, detection, and resolution of quality of care and compliance problems

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Elements of an Effective Compliance Program

Elements of a Compliance Program

- (1) Implementing written policies and procedures and standards of conduct
- (2) Designating a “High-level personnel” with responsibility to oversee compliance
- (3) Conducting effective training and education
- (4) Developing effective lines of communication
- (5) Enforcing standards through well-publicized disciplinary guidelines
- (6) Conducting internal monitoring and auditing
- (7) Responding promptly to detected offenses and developing corrective action

Elements of a Compliance Program

(1) Implementing written policies and procedures and standards of conduct

- Suggested policies and procedures
 - Purpose of Compliance Program
 - Code of Conduct
 - Due Care in Hiring and Contracting
 - Communication of Program to Employees and Contractors
 - Compliance Program Roles
 - Questions and Suspected Violations
 - Monitoring
 - Response to Detected Offenses

Elements of a Compliance Program

(2) Designating a “High-level personnel” with responsibility to oversee compliance

- Compliance Officer
- Compliance Liaison
- Compliance Committee
- Other key program roles:
 - Officers and Board of Directors
 - Employees
 - Independent Contractors
 - Physicians

Elements of a Compliance Program

(3) Conducting effective training and education

- Communication of the Compliance Program to employees and contractors
- Orientation program for new employees
- List of positions for which specific compliance training is mandatory along with records of attendance
- Training for newly hired physicians on documentation standards
- Annual training program regarding compliance
- Acknowledgment of Code of Conduct and Compliance Program Guidelines

Elements of a Compliance Program

(4) Developing effective lines of communication

- Access to Compliance Offer
- Provide information on how to make anonymous reports
- ***No retribution or retaliation***
- Prompt response from management
- Documentation and filing of questions and reported potential violations
- Inquiries to government payers when deemed appropriate

Elements of a Compliance Program

(5) Enforcing standards through well-publicized disciplinary guidelines

- Equal and consistent application
- Manager and supervisor accountability
- Positive reinforcement
- Discipline and recognition
- Intent v. neglect – range of sanctions

Elements of a Compliance Program

(6) Conducting internal monitoring and auditing

- Under the supervision of the Compliance Officer
- Annual plan of monitoring activities (e.g., will review the OIG's yearly work plan and identify risk areas)
- Annual report to the CEO and the Board
- Review of effectiveness of communication of the Compliance Program, adherence to established training standards, consistent application of disciplinary guidelines, etc.

Elements of a Compliance Program

(7) Responding promptly to detected offenses and developing corrective action

- HR and Compliance Officer must establish disciplinary actions
- Self-Reporting of wrongdoing or mistakes is required, and will generally be considered as a mitigating factor
- Prompt return of wrongful payments
- Amendment of procedures, when appropriate, to prevent further violations

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Specific Areas of Risk and Other Concerns

Specific Areas of Risk

- Quality of care and resident's rights
 - Collaboration with QA Committee
 - “At a minimum,” analyze deficiencies and citations
 - Comprehensive care planning
 - Staffing levels
 - Transfer/Discharge practices
 - Abuse reporting

Specific Areas of Risk

- Due care in hiring employees and contracting with independent agents
- Employee screening – including appropriate screening for excluded individuals
 - No Federal health care program payment may be made for items or services furnished by an excluded individual or entity
 - Screen all owners, directors, officers, employees, and contractors (temporary staffing)
 - OIG's List of Excluded Individuals **AND** Medi-Cal's Suspended and Ineligible Provider List
 - Background Checks
 - Certification
 - Annual Review

Specific Areas of Risk

- Billing and cost reporting
 - Billing for therapy services
 - Implementation of Patient-Driven Payment Model (“PDPM”) on October 1, 2019
 - Will “carryover” some compliance issues from the RUGs system and produce new challenges
 - Changes in therapy utilization will be contrasted from practices under the RUGs system
 - Claims of over-utilization may shift to under-utilization
 - False or inaccurate cost reports

Specific Areas of Risk

- Creation and retention of records
 - Medical records: care planning and charting
 - Financial records: supporting claims billed and costs incurred
 - Compliance records: demonstrating compliance efforts and activities

Specific Areas of Risk

- Physician self-referrals
 - Under the federal physician self-referral prohibition, commonly known as the “Stark law,” a physician who has a direct or indirect financial relationship, which includes both ownership and compensation arrangements, with a provider of certain types of services (“designated health services”) may not make referrals to that provider for the provision of such services for Medicare patients unless an exception is available under the Stark law or its regulations.

Specific Areas of Risk

- Federal Anti-Kickback Statute
 - E.g., free goods and services, marketing arrangements, financial arrangements with physicians and other sources of referrals
 - Prohibition against remuneration (in any form, whether direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care program business

Specific Areas of Risk

- Federal Anti-Kickback Statute
 - E.g., free goods and services, marketing arrangements, financial arrangements with physicians and other sources of referrals, discounts, swapping
 - Prohibition against remuneration (in any form, whether direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care program business

Other Concerns

- State and federal surveys regarding Compliance Program
 - Consistent enforcement?
 - Guidance to surveyors?

- Privileged communications
 - Demonstrating compliance efforts v. sharing privileged work product
 - Attorney-Client? Quality Assurance?

Resources*

- March 2000 – Office of Inspector General (“OIG”) Compliance Guidance for Nursing Facilities – March 2000
 - Available at: <https://oig.hhs.gov/authorities/docs/cpgnf.pdf>
- September 2008 – OIG Supplemental Guidance for Nursing Facilities
 - Available at: https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf
- July 2015 – Proposed Rule
 - Available at: <https://www.federalregister.gov/documents/2015/07/16/2015-17207/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>
- October 2016 – Final Rule
 - Available at: <https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>
- July 2017 Amendments to Final Rule
 - Available at: <https://www.govinfo.gov/content/pkg/FR-2017-07-13/pdf/2017-14646.pdf>

*All links were last accessed on August 29, 2019

Thank You

Questions?

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