

Developing a Patient-Centered Nursing Home Compliance Program That Is 3E (Effective, Efficient, and Economical)

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As discussed in the last issue,¹ in less than one year (November 2019) all nursing facilities participating in the Medicare and Medicaid programs will be required to develop and implement a Compliance and Ethics Program. The challenge for nursing facilities is to establish a program that is appropriately focused on ensuring compliance with all applicable laws and regulations, as well as:

- Health and safety of patients;
- Quality of care;
- Accuracy and completeness of documentation; and
- Integrity of bills and claims for payment submitted to federal health care programs (*e.g.*, Medicare and Medicaid), other third-party payers, and patients.

Moreover, in light of the many requirements imposed on long-term care (LTC) facilities under the revised conditions of participation (COPs) for Medicare and Medicaid,² how can the obligation to implement and maintain a Compliance and Ethics Program be accomplished in a “3E” (*i.e.*, effective, efficient, and economical) manner? The solution lies in aligning and integrating the mandated Compliance and Ethics Program with other key COP requirements related to:

- Resident rights³;
- Patient “freedom from abuse, neglect, exploitation”⁴;
- Quality of life⁵;
- Quality of care⁶;
- Quality Assurance and Performance Improvement⁷; and
- Training.⁸

Through a centralized, comprehensive, and coordinated process for addressing these regulatory mandates, a nursing facility can develop its Compliance and Ethics Program in a 3E manner.

BACKGROUND

The Patient Protection and Affordable Care Act (ACA) included “Accountability Requirements for Skilled Nursing Facilities and Nursing Facilities.” Section 6102 of the ACA requires that a nursing facility participating in the Medicare or Medicaid program establish and maintain:

a compliance and ethics program... that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations... and in promoting quality of care.⁹

The ACA “required components” of a nursing facility Compliance and Ethics Program are:

- Establishing “compliance standards and procedures” for employees and others;
- Designating “high-level personnel... [with] overall responsibility to oversee compliance with such standards and procedures and [providing] sufficient resources and authority to assure such compliance;”
- Exercising “due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through exercise of due diligence, had a propensity to engage in...violations;”
- Communicating effectively to employees and others the applicable standards and procedures through training programs and dissemination of information;
- Implementing auditing and monitoring systems;
- Establishing and publicizing a “reporting system” whereby employees and others can report potential violations “without fear of retribution;”
- Taking reasonable steps to respond to detected offenses and repetition, as well as any necessary remedial steps; and
- Undertaking periodic “reassessment of [the] compliance program.”¹⁰

In a final rule published on October 4, 2016, the Centers for Medicare & Medicaid Services (CMS) amplified upon and codified these requirements at 42 CFR § 483.85. Upon issuance of the final regulation, CMS advised:

We do recognize that there would be varying levels of resources available to smaller and larger organizations. Although the requirements for compliance and ethics programs finalized in this rule go to all operating organizations, with additional requirements for those with five or more facilities, we would expect all operating organizations would...use the facility assessment they developed...in developing and operating their programs. For example, the operating organization must provide, among other things, sufficient resources to reasonably assure compliance with the program’s standards, policies, and procedures. ... In addition, operating organizations must also take steps to effectively communicate the standards, policies, and procedures of its program to its entire staff, individuals providing services under contractual arrangements, and volunteers, consistent with their expected roles. ...This can be accomplished by mandatory training, orientation programs, or disseminating information that explains in a practical manner what is required under the operating organization’s program. Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably assure compliance with the requirements...¹¹

CMS has emphasized that it is critical that a nursing facility’s Compliance and Ethics Program be *effective*.

For any operating organization's compliance and ethics program to be effective, it is crucial that all of the organization's staff, including those who are providing services under contract, and volunteers, consistent with their roles, need to understand the standards, policies, and procedures for that program. If these individuals do not understand the program's requirements and their responsibilities under that program, they will not be able to comply appropriately and that will severely reduce, or perhaps eliminate the effectiveness of the program. ... We believe that each operating organization needs to have flexibility to determine the best way for each of them to comply with these requirements and this final rule provides them that flexibility to determine what kind of dissemination of information or training they need to provide. In addition, it is the training or dissemination of information that is crucial. For example, the operating organization could choose to arrange with [a] contractor to have the contractor provide the required training or dissemination of information for the compliance and ethics program...¹²

HOW TO ESTABLISH A "3E" COMPLIANCE AND ETHICS PROGRAM

To establish its Compliance and Ethics Program in an *effective, efficient, and economical* manner, a nursing facility needs to establish a centralized, comprehensive, and coordinated internal program for addressing key compliance and integrity-related functions, as specified in the new CMS COPs for nursing facilities. This entails using the facility assessment process to develop a focused plan for implementing its Compliance and Ethics Program along with other COP requirements relating to

patient rights, safety of patients, quality of care/life, and training.

Such a coordinated approach to address the integrity of the services provided by a nursing facility can be facilitated through designation of an office and/or individual within the facility with overall responsibility for ensuring adherence to the mandated principles, as set forth in the CMS COPs for nursing facilities. By implementing these related mandates in a coordinated manner, a nursing facility will be able to address key COP requirements that are related to maintaining an *effective* Compliance and Ethics Program.

COP REQUIREMENTS RELATED TO INTEGRITY OF SERVICES PROVIDED TO PATIENTS

In issuing its "Reform of the Requirements for Long-Term Care Facilities" in October 2016, CMS advised:

These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.¹³

In determining how to implement the mandate for a Compliance and Ethics Program, it is important to recognize and understand the related integrity and quality of care requirements set forth in the revised COPs. These include the following.

Resident Rights

CMS has revised and expanded the Resident Rights requirements specified for nursing facilities. Among other things a nursing facility is obligated to ensure the following:

- A resident has a right to “a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility;”
 - A resident may exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility;
 - A resident has the right to designate a representative to exercise his or her rights;
 - A resident has the right to be informed of, and participate in, his or her treatment;
 - A resident has the right to voice grievances to the facility or other agency without discrimination or reprisal and without fear of discrimination or reprisal;
 - The facility will make information on how to file a grievance or complaint available to a resident;
 - The facility will establish a grievance policy to ensure the prompt resolution of all grievances regarding resident rights. The policy is to identify a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through to their conclusion, leading any necessary investigation, issuing grievance decisions, and coordinating with federal and state agencies as necessary; and
 - A facility will undertake prompt efforts to review and resolve resident grievances.¹⁴
- A facility cannot employ or engage an individual who has been convicted of a crime related to “abuse, neglect, exploitation, misappropriation of property, or mistreatment,” or had a state disciplinary action taken against his or her professional license relating to such conduct; and
 - A facility must report crimes that may have occurred in a federally-funded LTC facility and establish implementing policies and procedures.¹⁵

Quality of Life

CMS has specified that “each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being, consistent with the resident’s comprehensive assessment and plan of care.”¹⁶

Quality of Care

CMS has mandated that “the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive, person-centered care plan, and the residents’ choices.”¹⁷

Quality Assurance and Performance Improvement (QAPI)¹⁸

Each LTC facility is obligated “to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.” The program is to include “a Quality Assessment and Assurance Committee comprised of professionals within a facility” and reporting to the facility’s governing body or designated person.

Training Requirements

“A facility must develop, implement, and maintain an effective training program” for all new and existing staff, contractors, and volunteers, and address issues including:

Freedom from Abuse, Neglect, and Exploitation

CMS has stated that a “resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation.” Among other things, a nursing facility is obligated to ensure the following:

- A facility must “not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;”
- A facility must investigate any alleged violations involving abuse, neglect, exploitation or mistreatment, and report as necessary to appropriate authorities;

- Resident rights and facility responsibilities;
- Abuse, neglect, and exploitation;
- Quality assurance and performance improvement;
- Infection control; and
- Compliance and ethics.¹⁹

RECOMMENDED ACTIONS FOR NURSING FACILITIES

- As part of the mandated “Facility Assessment,”²⁰ and on an annual basis thereafter, determine what resources are needed to develop and implement the Compliance and Ethics Program.
 - Designate an individual and/or office that will direct the Compliance and Ethics Program and also review/address other integrity issues related to resident rights, complaints about abuse/neglect, and quality of care concerns.
 - Develop and adopt policies and procedures for implementing the compliance program, as well as addressing other integrity issues such as the reporting, investigating, and resolving of complaints and grievances that are raised.
 - Ensure (in collaboration with the Human Resources Department) that comprehensive credentialing and sanctions screening is conducted prior to employing or engaging anyone to work in the facility, and monthly reviews thereafter.
 - Develop various ways of communicating information to patients, families, employees, and others about integrity issues, such as the compliance and ethics program, resident rights, quality of care, as well as how and to whom concerns, complaints, and grievances should be directed. This might include posters throughout the facility, information in Patient Admission packets, and employee badges.
 - Coordinate the development and presentation of training regarding the Compliance and Ethics Program, with other facility-wide training programs, as required by the new COPs for nursing facilities, and maintain documentation regarding receipt of training.
 - Establish a Hotline whereby any complaint, concern, or grievance can be raised on a confidential basis to be reviewed, investigated, and resolved by the designated compliance officer or department, along with a tracking system for recording, monitoring reviews, reporting on findings, and taking any necessary remedial steps.
 - Develop a process for investigating complaints, grievances, and other concerns that are raised, including the recording and tracking from receipt to resolution, and any remedial steps taken.
 - Undertake in conjunction with the QAPI Committee an annual risk assessment, and identification of high risk areas, along with development of “controls” and subsequent auditing/monitoring by designated staff or outside auditors/reviewers.
 - Develop and implement an audit work plan addressing the high-risk areas identified, consistent with the facility’s needs and resources.
 - Undertake an annual review of the operations and resources of the Compliance and Ethics Program, as well as its effectiveness.
- By having one individual or department responsible for the nursing facility Compliance and Ethics Program, as well as other integrity, patient rights, quality of care, and training requirements imposed by the COPs, an organization can establish such a program in a 3E (effective, efficient, and economical) manner. It is recommended that nursing facilities start (or refine) the process and organizational structure/implementation now.

Endnotes

1. “The Deadline is Fast Approaching for Meeting the Legal Mandate for an Effective Nursing Home Compliance Program.” JHCC – September-October 2018.
2. 81 *Fed. Reg.* 68688 (October 4, 2016).
3. 42 CFR § 483.10.
4. 42 CFR § 483.12.

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5. 42 CFR § 483.24.
6. 42 CFR § 483.25.
7. 42 CFR § 483.75.
8. 42 CFR § 483.95.
9. 42 USC 1320a-7j(b)(3).
10. 42 USC 1320a-7(b)(4).
11. 81 *Fed Reg.* 68814-15 (October 4, 2016).
12. *Id.*
13. 81 *Fed. Reg.* 68688 (October 4, 2016).
14. 42 CFR § 483.10.
15. 42 CFR § 483.12.
16. 42 CFR § 483.24.
17. 42 CFR § 483.25.
18. 42 CFR § 483.75.
19. 42 CFR § 483.95.
20. 42 CFR § 483.70(e).

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