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How an eye doctor's son sees compliance

an interview with Stephen Kiess

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by Allan D. Stegemann

The ACA and lessons from the Quality Corporate Integrity Agreements

» Leadership must be committed to compliance and Quality Assurance/Performance Improvement (QAPI) programs to ensure success.
» The compliance officer and Compliance department must be empowered by leadership and work effectively and cooperatively with clinical operations.
» "Systems" are a key component to success to ensure continuity in compliance programs, QAPI initiatives, and care delivery.
» Data must be used appropriately to optimize compliance and QAPI programs.
» Compliance and QAPI programs need to be embedded in organizational culture.

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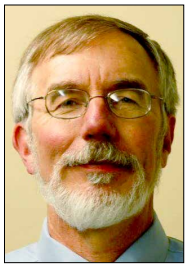
Note: At the time this article was drafted, the Centers for Medicare and Medicaid Services (CMS) had not yet promulgated effective compliance and ethics program regulations required by the ACA deadline of March 2013, but had released an advanced set of QAPI materials in February 2013, with final revisions to be completed later in the year.

Long-term care facilities, particularly nursing facilities, have arguably been the most regulated health care providers in the US health care system. Nursing facilities are subject to mandated requirements for participation in the Medicare and Medicaid programs as well as state licensure programs. As a result of recommendations from the Institutes of Medicine (IOM) and U.S. Government General Accountability Office (GAO) studies of nursing home enforcement in the 1980s, additional comprehensive federal requirements were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987. Currently, nursing facilities receive annual on-site surveys and are potentially exposed to a variety of penalties for deficient care, such as civil monetary penalties, denial of payment for new admissions, state monitoring, temporary management, and termination from the Medicare and/or Medicaid programs.


Stegemann

Enter the Affordable Care Act (ACA) in 2010.[1] The ACA brings an additional set of new requirements to nursing facilities, including:

- New transparency and disclosure reporting requirements of ownership, identities of board members, managing employees, etc.
- National and state criminal background checks for all "direct patient access" employees.
- Requirement of an effective compliance and ethics program to prevent and detect criminal, civil, and administrative violations under the ACA and to promote quality of care.
- Submission of a facility plan to meet and implement Quality Assurance/Performance

Improvement (QAPI) standards and best practices.
- Electronic submission of direct care staffing information (including agency and contract staff) in a uniform format based on payroll and other verifiable and auditable data.

Two requirements are particularly significant; the requirements for an effective compliance and ethics program and a facility plan to implement QAPI standards and best practices. Relevant sections of 6102 of the ACA that describe the compliance and QAPI programs are:

> (b) EFFECTIVE COMPLIANCE AND ETHICS PROGRAMS.—
> (1) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this section, a facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the 'operating organization' or 'organization'), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under paragraph (2).
> (2) DEVELOPMENT OF REGULATIONS.—
> (B) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program shall, in the case of an organization that operates 5 or more facilities, vary with the size of the organization, such that larger organizations should have a more formal program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements may specifically apply to the corporate level management of multi-unit nursing home chains.
> (c) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—
> (1) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this subparagraph referred to as the 'QAPI program') for facilities, including multi-unit chains of facilities. Under the QAPI program, the Secretary shall establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under paragraph (2), a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B), as applicable.

Although these two requirements will likely affect overall nursing facility management and financial operations, they are especially important because of their potential to impact the quality of care received and the quality of life experienced by nursing facility residents. A set of nursing facilities/organizations have already faced a version of these requirements; specifically, nursing facilities/organizations that have been subject to Corporate Integrity Agreements (CIAs) with the Department of Health and Human Services (DHSS) Office of Inspector General (OIG). Experience with the CIA process provides relevant insight for health care providers as ACA regulations go into effect.

The Corporate Integrity Agreement process

OIG has been providing information and guidance to health care providers since the 1990s regarding effective compliance programs. In March 2000, the OIG published *Program Guidance for Nursing Facilities* in the Federal Register and supplemented the guidelines in September 2008.[2] Significant emphasis was placed on quality of care in these compliance program guidance documents. The OIG nursing facility guidelines followed the OIG's seven elements of an effective compliance program:

1. Implementing written policies, procedures, and standards of conduct.
2. Designating a compliance officer and compliance committee.
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.

By the late 1990s, the OIG was also using another tool, the Corporate Integrity Agreement (CIA), to deal with nursing facilities that were the subject of fraud investigations and/or significant quality problems. Corporate Integrity Agreements are essentially mandated compliance programs that define the required obligations that a nursing facility must agree to meet as part of a civil settlement. In return, under the CIA the OIG agrees not to exclude the provider from participating in Medicare, Medicaid, or other federal health care programs. Most CIAs are in force for a 5-year period and address financial and/or quality issues, and the mandated elements of the CIAs can be thought of as a robust, structured model of the OIG's seven elements of an effective compliance program. CIAs drafted to address quality issues generally require nursing facilities to:

- maintain a chief compliance officer and a compliance committee for the term of the CIA;
- implement a program for performing internal quality audits and reviews;
- develop and implement written standards (including a code of conduct and policies and procedures to address the compliance program) required by the CIA and specific clinical areas, such as resident assessment, care plans, pressure ulcer care/wound care, falls, nutrition, medication use, staffing, etc.;
- implement a comprehensive, competency-based employee training program;
- provide a confidential disclosure program, including an internal review process;
- screen all persons covered under the CIA and curb the employment of ineligible persons;
- report any ongoing investigations/legal proceedings, overpayments, and reportable events;
- provide annual reports to the OIG; and
- engage an external quality monitor to conduct independent reviews of the effectiveness, reliability, and thoroughness of internal policies and procedures, systems, and processes with periodic reports of findings and recommendations to the monitored facility/organization and the OIG.

External monitor lessons

Interestingly, the CIA external quality monitors have been in a unique position to observe the intersection of compliance and QAPI programs in nursing facilities, including the challenges to successfully implement these programs under the CIA. For the past 14 years our firm, the Long Term Care Institute (LTCI), has monitored 35 nursing facility quality

CIAs, including the largest national, multi-facility nursing facility organizations, regional organizations, and single nursing facilities for the OIG, as well as state quality CIAs.

In our experience, most external monitoring engagements have a fairly predictable trajectory over the life of a CIA. Initially, the external monitor reviews structural requirements of the CIA, such as required development of policies and procedures and training of all monitored organization staff on CIA requirements and the code of conduct. Simultaneously, the external monitor begins making visits to facilities to determine, at the facility level:

- how the monitored organization's care delivery systems function;
- how the monitored organization's policies and procedures are implemented;
- how internal quality assurance/performance improvement activities are implemented and monitored; and
- how compliance functions are carried out.

For multi-facility national and regional organizations the external monitor also observes the interaction among the various levels of the organization, such as how policies and procedures are rolled-out from the corporate level through the regional/district level to the facility level, the effectiveness of communications among the various levels of the organization, and how the regional/district level conducts internal quality audits at the facility level.

In addition to on-site visits, the external monitor attends compliance committee and QAPI meetings at all levels of the organization from the outset of the monitoring process, and may initiate other monitoring activities, such as:

- calling the appropriate compliance and operational staff monthly to discuss external monitor visit findings, as well as the monitored organization's ongoing QAPI and compliance activities;
- attending internal training programs; and
- analyzing the monitored organization's internal dashboard data (e.g., benchmark data regarding specific clinical issues, resident/patient satisfaction data, internal hotline or complaint data, etc.) and external data, such as state survey findings and quality indicators/measures.

The external monitor provides periodic reports to the OIG and the monitored organization regarding the effectiveness of the monitored organization's QAPI and compliance systems, including gaps and recommendations for improvement.

Best practices

Although there is no certainty about the final implementation expectations from CMS regarding nursing facility compliance and QAPI programs, the following "takeaways" from our external monitoring experience may help nursing facility organizations implement successful compliance programs that address the new ACA requirements.

Leadership must be committed

Effective compliance programs need immediate, strong and continued commitment from key leadership including the chief executive officer. Key leadership needs to "walk the talk" by not only communicating commitment to employees through public and written statements, but by actively participating (e.g., being a committed member of the compliance or QAPI committees). Strong compliance and QAPI programs improve care, community reputation, resident census, and the "bottom line."

Empower the compliance officer

In large multi-facility organizations there may be multiple compliance staff reporting to a corporate compliance officer; however, we use the term compliance officer here to refer to the

aggregate compliance staff. Empowering the compliance officer includes four key actions:

- Giving as much independent authority as possible to the compliance officer;
- Allowing the compliance officer to independently investigate any issue to its conclusion in order to provide meaningful findings and recommendations for correction or improvement;
- Establishing a reporting structure that has the compliance officer reporting to the facility's/organization's board, or the CEO if there is no board (a reporting structure that has the compliance officer reporting to the general counsel or the chief financial officer should be discouraged); and
- Dedicating and protecting sufficient time for the compliance officer to meet responsibilities, especially if the compliance officer has other duties.

Break down the compliance and clinical operations silos

It is important that the compliance officer and clinical operations staff have a close working relationship. Often the compliance officer is viewed as an outsider who appears threatening when following-up on complaints or conducting internal audits. Likewise, compliance officers may view clinical operations staff skeptically. Both must develop mutual trust and respect for the valuable skills each brings to the facility's/organization's team. Obvious ways to enhance this cooperation are to have the compliance officer participate on the QAPI committee and key clinical operations staff participate on the compliance committee; and when appropriate, jointly conduct audits and complaint investigations.

Systems are crucial to success

Although strong, effective leadership benefits any nursing facility organization, well-designed systems are fundamental to success. Systems provide a standard roadmap to deliver appropriate care and ensure all facility operations are compliant with regulations. Effective nursing facility systems have:

- up-to-date, appropriate policies and procedures;
- competency-based training, identified staff assignments, and supervision to ensure that staff know their duties and responsibilities and appropriately carry them out;
- routine internal monitoring and auditing processes to evaluate how individual systems are working, and
- feedback to make the necessary adjustments.

The true value of systems is most apparent when significant leadership changes occur. Systems outlive leaders and can carry nursing facility operations through periods of leadership change or other significant challenges.

Embed compliance and QAPI in the culture

The requirements of CIAs were designed to change the structures and processes of nursing facilities to provide improved quality and compliance outcomes, which is identical in purpose to the new ACA requirements. This often means changing the culture of the facility/organization so that the new compliance and QAPI programs become the standard way of operating. For example, nursing facilities understandably are attuned to the time cycle and past findings of regulatory surveys. This often leads nursing facilities to prepare for the next survey during the expected "survey window" and to correct past survey problems without completing root cause analyses to ensure that problems are systematically and permanently corrected. Although somewhat useful, this emphasis on the survey should be just one part of the overall compliance and QAPI approach, which needs to include such activities as:

- routine, daily clinical/cultural rounds focused on facility residents;
- periodic reviews and audits by dedicated compliance and clinical operations staff at the facility, and more importantly, from the district/regional level in multi-facility organizations;
- formalized performance improvement projects; and
- active and engaged compliance and QAPI committees that review performance data and identify and oversee improvement plans.

Use data appropriately for compliance and QAPI activities

Nursing facilities/organizations create voluminous amounts of internal data that can be used in compliance and QAPI activities, such as:

- resident-level data derived from the Minimum Data Set (MDS) used to periodically assess all nursing facility residents;
- internal audit findings, staffing data, and complaint information from residents, family members and staff;
- internal benchmarks;
- resident satisfaction surveys; and
- external data, such as survey deficiencies, national quality measures derived from the MDS, and other national comparative data.

For individual facilities, and even for multi-facility organizations that can roll all of this information up from facilities and regions to a corporate dashboard, the analysis of this data is daunting. Nursing facilities generally become quite adept at collecting data, but have difficulty determining: (1) what data is most important; and (2) what it means in terms of current performance, not to mention identifying problems ahead. Nursing facilities/organizations need to carefully decide the most useful and reasonable data to monitor their compliance and QAPI efforts and make decisions about needed changes. Initially, simplicity is best. Start small and add additional types of data over time to provide more clarity or focus. The challenge with data is, in statistician Nate Silver's terms, to "determine the signal while eliminating the noise." Silver states: "The signal is the truth. The noise is what distracts us from the truth."[3]

Use available implementation resources

Fortunately, nursing facilities and organizations have many resources available to assist with implementation of compliance and QAPI programs under ACA. The aforementioned OIG *Program Guidance for Nursing Facilities* is likely to be a model upon which CMS will design its compliance and ethics program requirements. Likewise, the draft guidance CMS has provided on QAPI programs is quite detailed, strongly emphasizes teamwork and communication, and provides many links to useful QAPI resources. These documents are a good starting place for nursing facilities.

Conclusion

The new ACA compliance and QAPI requirements will pose new challenges for nursing facilities. Implementation may not be easy initially, but from our external monitor experience we know it can be done. If properly implemented, strong compliance programs can improve quality of care, ensure compliance with regulatory requirements, and most importantly, improve the lives of nursing facility residents.

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