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The Drive To Quality: Are You On The Bus or Under It?

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I. **Introduction\(^1\)**

In November 2012, OIG published a report with the sobering title, "*Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars in 2009.*"\(^2\) According to OIG’s report, twenty-five per cent of all claims submitted by SNFs were erroneous, resulting in $1.5 billion in inappropriate payments. The majority of erroneous claims dealt with upcoding, according to OIG. Additionally, skilled nursing facilities misreported information on the Minimum Data Set (MDS) forms on 47% of the claims submitted.\(^3\) These misrepresentations implicate billing and quality of care concerns since the MDS serves multiple functions including resident care needs assessment, care delivery and reimbursement.

Among OIG’s recommendations to the Centers for Medicare and Medicaid Services (CMS) are that CMS focus increased attention to the accuracy of the MDS forms and change the method for determining how much therapy is needed. OIG also recommends that CMS reconsider how it pays for therapy in skilled nursing facilities. Moreover, OIG’s 2013 Work Plan underscores the need for effective compliance and ethics programs, which become mandatory for skilled nursing facilities by March 23, 2013.

As has been the case for years, health care providers and their counsel have been familiar with compliance programs. Indeed, the OIG has published compliance guidance for various sectors of the health care industry since the 1990s. Of particular significance are the changes required by the 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. 111-1520), collectively referred to as the Affordable Care Act or ACA. It is the intent of this handout to highlight only a limited portion of the extensive legal requirements that relate to health care providers. The focus of this handout is on skilled nursing facilities (SNF) since the law requires that SNFs have an “effective” compliance and ethics program by March 23, 2013.

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\(^2\) *Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars in 2009, OEI-02-09-00200 (November 2012).*

\(^3\) The “MDS” is the Minimum Data Set which is a standardized tool nursing facilities use to assess each beneficiary. The information contained on the MDS is used to classify nursing home residents into resource utilization groups (RUGs). The RUGs determine the amount Medicare reimburses the facility.
Although the focus will be on SNFs, the general underlying approaches and principles concerning compliance and ethics programs are applicable across the spectrum of health care providers. When designing or redesigning a compliance program, providers should realize that no one size fits all. Additionally, as demonstrated below, compliance and ethics programs need to be dynamic and responsive to an organization’s changing needs rather than static programs lacking both flexibility and adaptability, as necessary.

II. Mandatory Compliance Programs for Nursing Facilities

Section 6102(b)(1) of the ACA requires that by March 23, 2013, nursing facilities must “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.” In order to understand what constitutes an “effective” compliance and ethics program, it is instructive to view Section 6102’s required “components” of a compliance program. Those components require nursing facilities to do the following:

- establish compliance standards and procedures that employees and agents must adhere to “that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations”;

- designate “high-level personnel” who have “the responsibility to oversee compliance” and who also have “sufficient resources and authority to assure” compliance;

- the organization must use due care “not to delegate substantial discretionary authority to individuals the organization knew, or should have known...had a propensity to engage in criminal, civil, and administrative violations”;

- the standards and procedures must be communicated effectively to “all employees and other agents” by means such as training programs or disseminating publications with clear explanations of requirements;

- the entity must employ “reasonable steps to achieve compliance” such as utilizing monitoring and auditing systems reasonably designed to detect violations;
the entity must consistently enforce, through appropriate disciplinary mechanisms, the compliance standards;

following an offense, the organization must take all “reasonable steps to respond appropriately” after the offense has been detected in order to prevent further similar offenses;

the organization must periodically reassess its compliance program in order to identify any necessary changes reflective of changes within the organization and its facilities.

The required components listed above are essentially the same as the OIG compliance program guidance and Chapter 8 of the United States Sentencing Commission’s 2012 Federal Sentencing Guidelines. Merely having a compliance program incorporating those “required components” without more is insufficient. The compliance program, in order to be effective, must be implemented, monitored and modified as needed. For example, according to the USSC Federal Sentencing Guidelines, “An organization’s failure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.” Id. at 498. Moreover, the Federal Sentencing Guidelines referred to above state that both “the size of the organization and similar misconduct” are factors which will be considered. Id.

III. Compliance Planning for Nursing Facilities

A. Prior OIG Guidance

The concept of compliance programs for SNFs is not new. The OIG published its Compliance Program Guidance for Nursing Facilities (CPG) more than a decade ago. As it suggested for compliance programs in other sectors, such as hospitals, home health agencies, clinical laboratories, third-party medical billing companies, durable medical equipment, prosthetics, orthotics and supply industry, as well as hospices and Medicare Advantage organizations, in March 2000, OIG recommended nursing facilities adopt seven core elements in their compliance program. OIG stated in its 2000 CPG that “at a minimum, a comprehensive compliance program should include the [ ] seven elements.” Id. at 14291.

6 At the time of OIG’s publication in the Federal Register, the term “Medicare+Choice” was used to describe what is now known as Medicare Advantage programs.
On September 30, 2008, OIG published its Supplemental Compliance Program Guidance for Nursing Facilities. Like its predecessor for SNFs, the supplemental guidance offered “voluntary guidelines to assist nursing facilities in identifying significant risk areas in evaluating and, as necessary, refining ongoing compliance efforts.” One of the reasons OIG published its supplemental guidance is because of the “significant changes in the way nursing facilities deliver, and receive reimbursement for health care services... and increased concerns about quality of care in nursing facilities, which continues to be a high priority of OIG.” Notably, OIG’s supplemental guidance was not intended to supplant its earlier CPG. Rather, its 2000 CPG as well as its 2008 supplemental guidance, taken together, “offer a set of guidelines that nursing facilities should consider when developing and implementing a new compliance program or evaluating an existing program.”

B. Guidance from the Centers for Medicare and Medicaid Services (CMS)

1. Regulations for SNFs Were Required By March 23, 2012

Pursuant to the ACA, CMS was required to promulgate regulations regarding compliance and ethics programs for nursing facilities by March 23, 2012. See e.g., 42 U.S.C. 1320a-7j(b)(2). As of this writing, CMS has yet to publish such regulations. However, on February 2, 2011, CMS stated that “we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future.” The fact that CMS has not yet promulgated its compliance and ethics regulations, as required, will not excuse a nursing facility from having an effective compliance and ethics program by March 23, 2013.

2. CMS Compliance Guidance in Other Program Areas

It is illustrative to view CMS’ regulatory mandates for compliance programs in other areas. In so doing, nursing facilities will have a reasonable idea of what they can expect when CMS publishes its nursing facility compliance program guidance. For example, CMS published a Final Rule related to the Medicare Advantage and Medicare

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8 Id. at 56833.
9 Id.
10 Id.
11 The date of this writing is January 19, 2013, at which point CMS had not promulgated regulations regarding compliance and ethics programs for nursing facilities.
Prescription Drug Benefit Programs on April 15, 2010. In its final rule, CMS required that Medicare Advantage organizations as well as Medicare Prescription Drug Benefit (Part D) plan sponsors have an “effective” compliance plan.

The applicable regulations regarding compliance programs for both Medicare Advantage organizations and Medicare Part D plan sponsors are identical. See e.g., 42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi), respectively. The effective date for those mandatory compliance programs was January 1, 2011. The seven “core requirements” articulated in the regulations for Medicare Advantage organizations and Medicare Part D plan sponsors provides useful guidance and a hint of what CMS is likely to include in its compliance program regulations.

IV. 2013 OIG Work Plan

The 2013 Work Plan summarizes new and ongoing reviews and activities that OIG plans to pursue. Regarding nursing facilities, OIG has noted eight areas where it will focus attention. Five of those areas are carry-overs from previous years while there are three new initiatives. This paper focuses only on the new initiatives which are briefly described below.

A. New Initiatives in OIG 2013 Work Plan

1. State Agency Verification of Deficiencies

OIG has stated that it intends to review whether State survey agencies verify plans of correction for those nursing facilities that were determined to have deficiencies. When a survey team determines deficiencies, it sends an official Statement of Deficiencies (CMS Form 2567) to the facility. The facility must submit an acceptable Plan of Correction within 10 calendar days of receiving the Statement of Deficiencies. See 42 C.F.R. § 488.402(d) and CMS State Operations Manual, § 7300.3. Following receipt of a

75 Fed. Reg. 19678 (April 15, 2010)

Id. at 19687-19691.

The five carry-over areas consist of reviews of: 1) adverse events involving Medicare beneficiaries receiving post-acute care in SNFs and inpatient rehabilitation facilities (IRF); 2) quality of care issues and the extent to which the Resident Assessment Instrument (RAI) is used to develop appropriate care plans; 3) “poorly performing nursing homes” and the extent to which the State and CMS use enforcement mechanisms to improve performance; 4) the extent to which nursing home residents are hospitalized where the underlying condition was either manageable or preventable; and 5) questionable billing patterns for Medicare Part B services provided to nursing home residents. See 2013 Work Plan, available at: https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf. Last accessed on January 19, 2013.
facility’s Plan of Correction, the State agency must determine whether the facility regained “substantial compliance” with the applicable regulation that was the basis of the deficiency.

Depending on a number of factors, including the scope and severity of the deficiency, the State survey agency verifies correction of a deficiency (i.e., a return to substantial compliance) with either a revisit or a “paper review” of the Plan of Correction. According to OIG, at least one State survey agency did not always verify that nursing facilities corrected deficiencies as required by the Federal regulations. While OIG’s attention in this regard will be focused largely on the State survey agency, facilities should always ensure that their Plans of Correction are realistic, accurate and have an appropriate target date by which it plans to be in compliance with a previously cited deficiency. Importantly, a plan of correction is a promise to the government to correct the deficiency and allows for continued funding by government payers. A provider that knowingly submits a plan of correction to the government that it does not intend to implement subjects the organization to liability under the Federal False Claims Act.

2. Use of Atypical Antipsychotropic Drugs

With this new initiative, OIG will examine the usage of atypical antipsychotic medications in nursing facilities. It will focus on the percentage of residents receiving antipsychotic medications as well as the specific drugs prescribed. Of particular interest is the regulatory requirement at 42 C.F.R. § 483.25(l)(i). The regulation requires facilities to ensure that residents are free from “unnecessary drugs.” CMS defines “unnecessary drugs” as follows:

An unnecessary drug is any drug when used: (i) in excessive dose (including duplicate therapy); or (ii) for excessive duration; or (iii) without adequate monitoring; or (iv) without adequate indications for its use; or (v) in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or (vi) any combination of the reasons above.

CMS publishes specific information about every skilled nursing facility on its Nursing Home Compare website. Under the Quality Measures category for facilities, CMS posts the percentage of residents at each facility receiving antipsychotic medications. One category is titled, “Percent of short-stay residents who newly received an antipsychotic medication. **Lower** percentages are better.” (Emphasis in original). The other related category is “Percent of long-stay residents who received an antipsychotic medication. **Lower** percentages are better.” (Emphasis in original.) As of this writing, the average per cent of short-stay residents who newly received an antipsychotic...
medication in Pennsylvania facilities is 2.8%, while the national average is 2.9%. The average percentage for long-stay residents in Pennsylvania who receive antipsychotic medications is 22.1%, while the national average is 23.4%. Nursing facilities should compare their percentages to the average percentage for their respective state and nationally in order to gauge their level of antipsychotic usage.

Facilities having a large resident population with Alzheimer’s disease, dementia or other cognitive impairments may legitimately have a higher percentage of antipsychotic medication usage than a facility where the need is not as great. Still, every reasonable attempt should be made to: 1) either eliminate or reduce the dose of antipsychotic medications, or 2) justify the continued use (both the specific drug and dose) by adequate documentation.

In July 2012, OIG released a report, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs. In its recent report dealing with antipsychotic medication usage, OIG determined that 99% of the records they reviewed failed to comply with one or more Federal requirements. Additionally, CMS has expressed a goal of reducing antipsychotic medications by 15% by the end of 2012. Nursing facilities should expect that State agency surveyors, CMS and OIG will be closely scrutinizing the use of antipsychotic medications in 2013.

An extreme case of inappropriate use of antipsychotic medications recently made headlines. On January 9, 2013, California Attorney General Kamala D. Harris issued a press release in which she described why a former Director of Nursing (DON) at a skilled nursing facility was sentenced to three years in state prison based on her plea of “no contest” to a felony count of elder abuse with an added allegation that the abuse contributed to the death of a resident.

According to the Attorney General’s office and official documents, the former DON ordered psychotropic medications for 23 nursing home residents which the former medical director approved after they had been administered. The former medical director failed to examine the residents to determine if the psychotropic medications

16 Department of Health and Human Services, Office of the Inspector General, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs, OEI-07-08-00151 (July 2012).

were even clinically warranted. The former DON “ordered” the psychotropic medications for the 23 residents “not for therapeutic reasons, but instead to control and quiet them for the convenience of staff,” according to the Attorney General’s office. When at least one of those residents refused the medications, he was forcibly held down and injected with the psychotropic medication.

One of the criminal counts against the former DON was “assault with a deadly weapon, to wit, Risperdal, a psychotropic medicine.” The former pharmacist and CEO who were charged with the felony of conspiracy to commit an act injurious to public health, both pled no contest. The former CEO not only hired the DON, she was alleged to have allowed the forcible “convenience drugging” to continue after she knew about its existence. The physician and the CEO received sentences of 300 hours of volunteer services.

The type of case described above is highly unusual and fortunately rare. However, in May 2011, OIG released a report, Medicare Atypical Antipsychotic Drugs Claims for Elderly Nursing Home Residents, in which it noted that in 22% of the atypical antipsychotic claims it reviewed, the medications “were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes.” 18 The extent of inappropriate psychotropic drug use is underscored by a recent letter from the American Medical Directors Association (AMDA) to nursing facility medical directors. In its June 18, 2012 correspondence, AMDA asks the medical directors of facilities “to join with AMDA and CMS, in the nationwide effort to reduce the unnecessary use of antipsychotic agents by refocusing the interdisciplinary team on a better understanding of the root cause of dementia related behaviors.”19

Facilities can expect to see increased focus on resident assessments and care plans, with modification as needed, for those residents receiving antipsychotic medications. Additionally, CMS has expressed a goal of reducing antipsychotic medications by 15% by the end of 2012. Nursing facilities should expect that State agency surveyors, CMS and OIG will be closely scrutinizing the use of antipsychotic medications in 2013. Towards that end, and in keeping with providing quality care, facilities should ensure that their initial resident comprehensive assessment, subsequent assessments and care planning are properly performed and implemented.

Another recommendation for providers to consider is to avail themselves of the many tools and educational programs available for free that assist facilities in reducing and eliminating the use of psychotropic medications. For example, AMDA as well as organizations such as the American Health Care Association and programs such as Advancing Excellence in America’s Nursing Homes, offer useful techniques, sample policies and clinical practice guidelines aimed at reducing antipsychotic medication usage.

A skilled nursing home provider that does not perform a review of its psychoactive medication usage and ensure that psychoactive medication prescribing practices are incorporated into its quality assurance activities will find itself under the bus when it comes to surveys and perhaps subjected to government enforcement activities.

3. **Oversight of the Minimum Data Set (MDS)**

The third new initiative announced in the 2013 OIG Work Plan deals with how accurately CMS and the States oversee the appropriateness and completeness of Minimum Data Set (MDS) facilities submit. The MDS data that nursing facilities must submit for each resident on admission and at specified intervals (e.g., Significant Change MDS) is used for, among other things, determining reimbursement.

As noted above, in its November 2012 report, “Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars in 2009,” OIG identified that nursing facilities misreported MDS data on 47% of the claims submitted to Medicare. Clearly, facilities can expect a heightened level of scrutiny for the MDS forms they submit.

Again, the intersection between MDS accuracy and quality care is clear. Poor assessments of new residents performed by nurses who lack experience and/or training raise significant compliance concerns and warrant review by the Compliance Officer as part of compliance initiatives.

V. **Quality Assurance and Privilege**

1. **Overview of Statutory and Regulatory Requirements**

The issue of quality assurance documents and privilege in the context of nursing home surveys frequently arises. Attorneys in various states advise their nursing home clients with what they believe the law requires. Perhaps, the area with the most
confusion deals with a facility’s incident reports. Adding to the confusion is the fact that some State survey agencies will demand to see incident reports as well as quality assurance documents and other states leave it to the facility to decide whether to disclose incident reports or not. Until last year, there was no case law on point. However, the U.S. Court of Appeals for the Third Circuit decided the issue in a case it designated as precedential on August 14, 2012.

There are two separate but related issues that come into play in this context. Nursing facilities are required to have a quality assessment and assurance committee (QA) comprised of the director of nursing, a physician and at least 3 other members. 42 C.F.R. § 483.75(o). According to the regulation, each nursing facility must “develop and implement appropriate plans of action to correct identified deficiencies.” Id. In order to determine whether a facility is complying with the requirement, surveyors will interview QA committee members and may, at their discretion, ask to see QA documents.

Both the statute and the implementing regulations note that “A State or the Secretary may not require disclosure of the records of such committee except in so far [sic] as such disclosure is related to the compliance of such committee.” Id., see also 42 U.S.C. § 1396r(b)(1)(B). It is clear that there are restrictions on disclosure of QA committee records and facilities and surveyors generally understand that principle. However, facilities have sometimes claimed a “QA privilege” for incident reports, arguing among other things, that the incident reports are QA material and therefore a facility is not required to disclose its incident reports to surveys. That is a losing argument, at least in the Third Circuit.

2. Relevant Case Law

On August 14, 2012, the U.S. Court of Appeals for the Third Circuit ordered that its February 2, 2011 decision in the case of the Jewish Home of Eastern PA v. Centers for Medicare and Medicaid Services, HHS, be designated as precedential.20 Significantly, this is the first time any federal court has dealt with the issue of whether a SNF’s incident reports are shielded by a quality assurance privilege in the context of federally mandated surveys.

There is no paucity of cases involving discovery of incident reports and claims of privilege by hospitals, SNFs and other health care providers. However, no federal court has previously addressed the issue of whether the Federal Nursing Home Reform Act,

also known as “OBRA ’87,” creates a privilege that shields incident reports from
discovery by surveyors conducting a survey on behalf of CMS. 42 U.S.C. § 1396r(b)(1)(B)

The case began as an appeal before an Administrative Law Judge (ALJ) of the
Health and Human Services’ Departmental Appeals Board. In order to participate in the
Medicare program, skilled nursing facilities such as the Jewish Home of Eastern
Pennsylvania (JHEP) must be in substantial compliance with federal requirements. CMS
enters into agreements with each state to have surveyors from a state agency, typically a
state department of health, conduct unannounced surveys to determine whether a SNF
is in substantial compliance with program requirements.

On two separate surveys, surveyors found that JHEP was not in substantial
compliance. Specifically, it violated eight federal regulations as determined on one
survey and twelve additional regulations, determined on another survey. Consequently,
CMS imposed two CMPs totaling $29,950. Although JHEP appealed the imposition of
the CMPs, it neither challenged the underlying basis for the CMP nor asserted that it
was in compliance with federal program requirements. Rather, it claimed that CMS’
determination of noncompliance was invalid because it was based on “privileged”
quality assurance records that should not have been given to the surveyors. Specifically,
JHEP claimed that the surveyors relied on information contained in the facility’s incident
reports as a basis for the deficiency citations. Prior to the trial, it filed a motion to
suppress the quality assurance documents, which the ALJ denied.

The government argued that there is no privilege that allows a SNF (or other
Medicare provider) to refuse to provide incident reports to federal or state surveyors
conducting a survey for purposes of participation in the Medicare program. To the
contrary, HHS argued that 42 C.F.R. § 483.13(c) requires SNFs to investigate and report
all allegations of resident mistreatment, neglect or abuse and misappropriation of
resident property to State survey agencies. The incident reports at issue contained the
same information that the regulations require SNFs to report to State survey agencies.

Immediately prior to the trial, JHEP stipulated that it was not in substantial
compliance with the federal regulations that served as a basis for the two CMPs. It also
renewed its objection to admitting the incident reports into evidence. The ALJ refused
to exclude the incident reports, finding that they were not generated by the Quality
Assurance Committee and after post-trial briefing, upheld the two CMPs in their
entirety.

JHEP appealed the ALJ’s decision to the Departmental Appeals Board (Board) and
again argued, among other things, that its incident reports were quality assurance
documents and therefore protected from disclosure by the “quality assurance privilege” found at 42 U.S.C. § 1396r(b)(1)(B). The Board observed that neither the Social Security Act (Act) nor the applicable regulations employs the term “privilege” and affirmed the ALJ’s finding.

The Board agreed with CMS and noted, “it would be strange indeed if the very documentation which a facility is required to generate for a [regulatory compliance] purpose were also shielded from those very regulators whenever it has been reviewed by a QA Committee or whenever an individual whose responsibilities include conducting or documenting such investigations also serves on a QA Committee.” Id.

The Board refused to accept the claim that incident reports (also called “event reports” and “occurrence reports”) are bona fide quality assurance documents which are subject to disclosure restrictions under the Act and implementing regulation at 42 C.F.R. § 483.75(o). To the contrary, the Board held that although incident reports might end up before a QA committee, it could find “no basis to treat such raw factual material as itself the product of the QA Committee process.” Id. The incident reports are analogous to patient care records, such as nursing notes and progress reports, reasoned the Board.

On appeal to the Third Circuit, the JHEP again asserted that the Act and the regulation shield incident reports from discovery based on the quality assurance privilege. The Third Circuit noted that 42 U.S.C. § 1396r(b)(1)(B) requires a nursing home to have a quality assessment and assurance committee that meets at least quarterly and develops and implements appropriate plans of action to correct identified quality deficiencies. The Court noted that the relevant section of the Act states, in part:

A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph. Id.

Accepting HHS’ position, the Court held that the incident reports at issue were “contemporaneous, routinely-generated incident reports that were part of the residents’ medical records and were not minutes, internal papers, or conclusions generated by the Quality Assurance Committee.” JHEP filed a petition for certiorari, which the Supreme Court denied.

Much confusion has existed among both the provider community and even the government regarding the discoverability of incident reports in the context of Medicare-related surveys. Skilled nursing facilities need to understand the import of the Third Circuit’s decision. Simply put, an incident report, which is merely a factual document
contemporaneously generated at the time of an accident or incident, will not enjoy any privilege from discovery in the context of Medicare-required surveys.

Merely because a document such as an incident report may up before a QA committee does not transform its essential character into a QA document that can be shielded from discovery. On the other hand, bona fide QA documents such as the deliberations, internal working papers and minutes of a QA committee are protected by statute from being used by surveyors as a basis to cite a deficiency. In the wake of the Third Circuit’s precedential decision in the Jewish Home case above, facilities should carefully consider how they can best protect those documents that are bona fide QA documents.

3. Déjà vu, All Over Again?

CMS imposed a third CMP on the Jewish Home of Eastern Pennsylvania of $600 per day effective from November 2, 2007 through January 17, 2008, based on ongoing noncompliance with federal participation requirements. The JHEP appealed the CMP and argued that the regulation at 42 C.F.R. § 483.75(o) precludes the Secretary from relying on privileged quality assurance documents. As before, it conceded that it was not in compliance with program requirements.

Rather than asserting it was in compliance, it objected to CMS introducing its Plan of Correction into evidence, again asserting a quality assurance privilege. The ALJ upheld the CMP and found that no privilege existed for the Plan of Correction which was not even prepared for the facility’s QA committee. The ALJ observed that the Plan of Correction is a necessary document that SNFs must submit to State survey agencies within 10 days of being cited for a deficiency.


VI. Quality Assurance and Performance Improvement (QAPI)

Section 6102(c) of the ACA directs the Secretary of HHS to provide technical assistance and promulgate regulations for each nursing facility regarding the implementation of a Quality Assurance and Performance Improvement (QAPI) system.
It is unclear when CMS will actually promulgate the QAPI regulations though CMS has stated that it intends to make QAPI material publically available on its QAPI website.\textsuperscript{21}

Essentially, QAPI builds on systems that nursing facilities already have in place. Specifically, QAPI is a combination of Quality Assurance and Performance Improvement. Quality assurance, discussed in detail above, is typically concerned with assuring that the care provided meets a certain minimum level. By its nature, quality assurance is retrospective and reactive. For example, if a nursing facility had a problem with residents sustaining injuries from otherwise “avoidable” falls, it would be incumbent on the facility’s QA committee to explore the root causes of that problem. It would be a regulatory violation if the falls were avoidable and the facility did not take adequate measures to prevent the falls. See e.g., 42 C.F.R. § 483.25.

On the other hand, Performance Improvement, sometime referred to as Quality Improvement, tends to be proactive and ongoing. The goal of Performance Improvement is the prevention of undesirable outcomes by attempting to foresee what might happen and taking appropriate actions to eliminate or mitigate those risks.

CMS has identified five strategic elements that it considers “basic building blocks to effective QAPI.” Those elements are: 1) design and scope; 2) governance and leadership; 3) feedback, data systems and monitoring; 4) performance improvement projects; and 5) systematic analysis and systemic action.\textsuperscript{22} In complying with ACA’s mandate and in an effort to assist facilities, CMS has posted a wealth of QAPI-related information on its QAPI website. Nursing facilities will be required to have an acceptable QAPI plan within one year from the date the regulations are promulgated. Similar to the mandatory compliance and ethics programs, it would be prudent to develop a QAPI program sooner rather than later. This is true not just because of the need for regulatory compliance but for the broader goal of ensuring quality care to all residents.

VII. Conclusion

Compliance and ethics programs are now mandatory for nursing facilities. Ideally, providers have been reviewing and modifying their compliance and ethics

\textsuperscript{21} The CMS QAPI website can be found at: http://go.cms.gov/Nhqapi. Last accessed on March 29, 2013.

programs long before now. Among the salient issues concerning compliance programs is the fact that no one size fits all facilities and as mentioned above, in order to be effective, a compliance plan needs to be dynamic and able to be modified as needed. It is critically important that compliance initiatives include quality of care matters as part of an effective compliance program.

Providers also need to focus on areas such as reducing inappropriate antipsychotic medication use and making sure that its MDS (initial and subsequent) data is accurate and supportable. As noted, the OIG will be examining whether State survey agencies are appropriately verifying Plans of Correction. Consequently, facilities can expect their respective State survey agencies to pay more attention to their Plans of Correction and dates of alleged compliance.

Although QAPI programs will not be required until one year after CMS promulgates its QAPI regulations, proactive providers should be developing their QAPI programs now, if they have not already begun to do so. QAPI programs, like compliance and ethics programs, serve to diminish the potential for civil, criminal and administrative violations while enhancing the quality of resident care.