WHAT WERE THEY THINKING?

Creating Better Compliance with a Look Behind the CMS Language

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- Compliance is complicated. The New Requirements present new and different challenges.
- Today we are at a distinct disadvantage as we still lack the Guidelines.
- Also, the revised survey process.
- Defending staff and care processes in a system which appears to be retreating from outcomes to process is scary.
- Surveyors are less prepared and more clinically challenged with the emerging acuity and co-morbidities presented by our patient population; to say nothing of the complexity of the new CoP.
The facility management decision; whether to practice:

to the survey

OR

the purpose and intent on the new Requirements

This decision is neither easy or simple

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Medicare and Medicaid Programs; Reform of Requirements for Long Term Care Facilities

Final Rule
This presentation cannot touch every aspect of change affected by the new Requirements of Participation. I am attempting to review the highlights and risk points as I currently see them. The missing guidelines are a major component of our efforts to maintain and sustain substantial compliance in an increasingly enforcement, not quality, focused system.

Since the current requirements were developed, significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed and become more diverse and clinically complex. Over the last two to three decades, extensive, evidenced-based research has been conducted and has enhanced our knowledge about patient safety, health outcomes, individual choice, and quality assurance and performance improvement.

We are requiring that each patient receive and the facility provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, consistent with the patient’s comprehensive assessment and plan of care.
Based on the comprehensive assessment of a patient, we are requiring facilities to ensure that patients receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the patient’s choices.

We are adding a competency requirement for determining the sufficiency of nursing staff, based on a facility assessment, which includes but is not limited to the number of patients, patient acuity, range of diagnoses, and the content of individual care plans.

We require facilities to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its patients competently during day-to-day operations and emergencies.
We are requiring all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.

PG 12

We are requiring the operating organization for each facility to have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations.

PG 12/13

Consistent with the HHS focus on reducing unnecessary hospitalizations, this final rule strengthens the minimum health and safety standards for LTC facilities in hopes of contributing to a reduction in unnecessary hospital admissions of LTC patients.

PG 17
HHS is also working to reduce the incidence of healthcare associated infections (HAIs) across providers.

Given the growing numbers of individuals receiving care in LTC settings and the presence of more complex medical care, these individuals are at an increased risk for HAIs. To advance these initiatives, this final rule implements revisions that we believe will provide more opportunity to achieve broad based improvement and contribute to reduced healthcare costs, while allowing for targeted interventions specific to each LTC facility.

Trauma survivors, including veterans, survivors of large-scale natural and human-caused disasters, Holocaust survivors and survivors of abuse, are among those who may be patients of long-term care facilities. For these individuals, the utilization of trauma-informed approaches is an essential part of person-centered care.

The statute restricts some positions and tasks to physicians... the care of every patient be provided under the supervision of a physician. Where appropriate and permissible by statute, we have allowed for flexibility in who may perform certain tasks or services within their respective scope of practice.
We recognize that standards of care are constantly evolving and have therefore tried to create meaningful, yet appropriate flexible requirements.

These requirements are meant to ensure safe, professional, patient-centered care in all Medicare- and Medicaid-participating LTC facilities, while leaving room for facilities to improve and excel.

It is not our intention to reduce staff time spent performing direct patient care;

Our requirements, including QAPI, Compliance and Ethics, and Infection Control as well as requirements for policies and procedures, are intended to protect the health and safety of patients, prevent harm and support quality of life for patients.

Reimbursement rules are outside the scope of this rule making, and Medicaid reimbursement rates are determined by the states, with limited involvement by CMS. We do not participate in disbursement of public funding. We encourage commenters to address Medicaid reimbursement and public aid concerns to relevant state agencies and departments.
We believe that “abuse” requires a willful act, while “neglect” does not.

Abuse enabled through the use of technology would include the use of social media, as well as the use of cameras or the internet.

The definition (adverse events) encompasses events that harm the patient, that are a result of substandard treatment, inadequate monitoring and failure or delay of necessary care.

As written, the definition does not exclude anticipated events, but rather states “adverse events” are “usually unanticipated”.
Generally speaking, the authority of an individual vested with decision-making power under state law would exceed that of an individual without formal legal recognition.

...a patient who was adjudged incompetent under the laws of a state would retain the right to exercise those rights not addressed by a court order, that the patient representative can only exercise the rights that devolve to them as a result of the court order, that the patient’s wishes and preferences should continue to be considered, and that the patient should continue to be involved in the care planning process to the extent practicable, as the patient is at the center of the care team.

...a new section at 483.10(c)(8) to specify that these rights cannot be construed as a right to receive medical care that is not medically necessary or inappropriate.
This reorganization, to the extent that the regulatory language is unchanged, does not reflect any intent by CMS to change prior interpretations of regulatory language. Rather our intent, as stated in the preamble to the proposed rule, is to improve the logical order, readability, and clarity of the regulations.

If facility staff believe that a patient representative was making decisions or taking actions that are not in the best interest of the patient, the facility would have to comply with any state reporting requirements that might apply.

(Resident or family group) ... provision does not require a facility to implement every recommendation of a resident or family group, but that the facility should be able to provide the rationale for their response.
Individuals have access to surveys of the facility conducted by federal or state surveyors and any plan of correction in effect with respect to the facility for the preceding 3 years. We note that this provision does not require a specific format, but consistent with 483.10(g)(10)(i), it must be in a form and manner accessible to and understandable by the patient.

The facility must protect and facilitate a patient’s right to communicate with individuals and entities both inside and external to the facility, including reasonable access to the internet, to the extent it is available to the facility.

Person-centered care was one over-arching principle of our proposal. In addition, we believe that principles of quality of life and quality of care are also over-arching principles that apply to all the requirements for long-term care facilities.
We believe we have taken a comprehensive view of the role of patient representative and the right of patients to choose whomever they want to assist them in making healthcare and other decisions both while the patient retains decision-making capacity and in the event a patient should not have or would lose after admission this capacity.

The term is not intended to create a new role...

Nothing... requires that a patient appoint or have a patient representative.

Our intent is to ensure that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian...

Facilities are expected to be aware of when a guardianship is limited and not automatically defer all decisions to the guardian.

We understand there is a potential for abuse in the relationship between a patient and his or her patient representative, such as a guardian, and want to ensure that facilities recognize their role in identifying and reporting such concerns in accordance with applicable state law.
Equal Access to Quality Care

This provision is not intended to require every facility have every possible capability and unlimited capacity. However, a facility cannot choose, deliberately or inadvertently, to provide higher quality care to some patients over other patients in the facility based on diagnosis, severity of condition or payment source.

Facilities are expected, as required by our provisions for a facility assessment, to know their own capacities and capabilities when making admission decisions.

Once an individual is a patient of the facility, the facility is obligated to provide equal access to quality care.

If a patient condition changes such that a facility does not have the ability and is unable make accommodations to provide the care that a patient requires, that is an acceptable reason for discharge or transfer.
However, the facility will have to include in its documentation the specific patient needs that it cannot meet, the facility attempts to meet the patient needs, and the service(s) available at the receiving facility that will meet the patient’s needs.

We believe that the comprehensive care plan should serve as an important tool for delivering patient-centered care and encourage facilities to explore ways to allow patients, families, and other representatives to access the care plan on a routine basis as appropriate, for instance, using technology solutions that enable real-time access to authorized users and dynamic updating by members of the care team.

...we regard the terms “medical record” and “clinical record” as synonymous.
Care necessary to prevent an adverse event or outcome should not be delayed just to obtain a signature on a care plan. However, we expect that patients will be involved, to the extent possible and as desired by the patient in care planning.

...Patient has the right to sign the care plan after significant changes.

A patient may not be able to identify a specific person they want included in the care planning process, or a specific individual may be unable to participate, but that should not prevent the patient from including a role, such as an individual to provide spiritual, nutritional or behavioral health input.

Our proposals support the guidance issued by HHS for implementing person-centered planning and self-direction in home and community-based services programs. We agree that the principles in that guidance regarding dignity and self-direction apply equally to individuals who reside in a nursing facility.
We agree that the use of personal possessions must comply with fire safety.

We expanded the individuals who must be provided immediate access to the patient to include the patient’s representative as well as any representative of the protection and advocacy systems... and any representatives of the agency responsible for the protection and advocacy systems for individuals with a mental disorder established under the Protection and Advocacy for Mentally ill.

...We believe [visitation] that "reasonable restrictions" as well as "reasonable access" should only be limited based on clinical or safety concerns.
... Safety restrictions that may be imposed by facilities. These restrictions protect the security of all the facility's patients, and include requirements such as keeping the facility locked at night; visitors making prior arrangements for late night access, denying access or providing and supervised access to a visitor if that individual has been found to be abusing, exploiting, or coercing a patient; denying access to visitors who are inebriated and disruptive.

PG 112

... We agree that clinical restrictions [visitation] in order to prevent the spread of communicable disease is appropriate.

PG 112

... the right of family members to participate in a family group is a result of and subordinate to the patient's right in this instance. We can envision circumstances where a patient would not want and it would not be appropriate to allow a family member, such as an estranged spouse or an abusive relative, to participate in a family group as a result of a patient's presence in a facility.

PG 113
We decline to give “friends” or “other persons” interested in the welfare of the patient or patients a right to participate independently of an invitation from the (family) group, as this additional participation should be determined by the group rather than imposed upon it.

PG 114

We require that facilities must respond to a grievance voiced by a patient or family group with a response and corresponding rationale. We expect that such response would generally be a written response, but might also take another form.

PG 114

NOT REQUIRED

... Provide the family group access to a bulletin board or other public notice space for their exclusive use to communicate with the facility communities.

PG 115
the patient has the right to share a room with his or her roommate of choice when practicable . . . and both patients consent to the arrangement.

included the phrase “when practicable”, as we realize that such arrangements may not always be possible, or may require some delay in order to accommodate.

Involuntary transfers should not be undertaken solely for the convenience of staff. However, there are circumstances, generally involving safety, where advance notice and preparation may not be appropriate. . . . When one roommate is diagnosed with a communicable disease or when the move is necessary for the safety of either patient in a room, even if one of the roommates disagrees.

Some patients may not realistically be able to participate in activities outside the facility. However many may be able to do so, particularly with family or other assistance and planning. The facility has a responsibility to promote and facilitate patient self-determination, rather than act as a hindrance or barrier. At the same time we recognize that there may be safety and security concerns with unfettered access to outside spaces and in and out of the facility. . . . competing interests must be balanced.
... Patients should not be required to accept services from providers to which they object, or entities that impose unreasonable charges on the patient’s personal funds.

We do not propose to require facilities to expand their internet access.

A patient’s “support person” does not necessarily have to be the patient’s representative who is legally responsible for making medical decisions on the patient’s behalf. A support person could be a family member, friend, or other individual who is there to support the patient during the course of the stay.
... Review of admission contracts may be a part of our facility surveys.

... long-term care facilities are likely to serve multiple populations. Throughout this rule CMS has tried to maintain an appropriate balance reflecting the multiple populations.

... these populations deserve high quality care in a safe, clean, comfortable and homelike environment. We agree no single right outweighs another right and sometimes this requires balance; ... that provides safe treatment.

The purpose of requiring the facility to have a grievance official is to ensure that there is an individual who has both the responsibility and authority for ensuring through direct action or coordination with others, that grievances are appropriately managed and resolved. This person would be a resource for patients, staff and oversight entities.

It is not our expectation that every facility hire a new, full time individual to preform this function, but, instead that every facility have a designated individual to serve this function, consistent with the needs of the facility.
Evidence demonstrating the results of all grievances for a period on no less than 3 years provides a record of this work and can serve as a valuable information resource for facilities. However, we do not agree it is necessary to explicitly require all investigation documentation be retained for 3 years. Furthermore, such evidence may be maintained electronically, rather than utilizing physical storage space.

We did not address the use of alarms in the proposed rule. We would expect the use of a position alarm to be addressed in the patient’s care plan. If an alarm is used as a restraint, it is subject to our provisions relating to restraints. We understand some alarms may have a limited use for diagnostic purposes and a useful role in the assessment process, as staff are learning about an individual. . . . . there is a clear distinction between position change alarms and door alarms.

We are not, at this time, requiring criminal background checks on volunteers, but would expect facilities to exercise reasonable care consistent with the volunteers’ expected roles and not knowingly engage volunteers who have been found guilty of abuse, neglect, exploitation, misappropriation or property, or mistreatment by a court of law.
. . . prohibit facilities from employing certain individuals who have a disciplinary action in effect against a professional license. We believe that this provides facilities some flexibility to exercise discretion with regard to previous disciplinary actions.

. . . a facility is not expected to query 50 states for information on each licensed individual. We expect the facility to check with the state in which the facility is located and care is delivered and potentially bordering states or other states that the individual is known to have been licensed in, based on the individual’s resume or other employment information available to the facility.

If a facility determined that action by a court of law against an employee are such that they indicate that the individual is unsuited to work in a LTC facility, or “unsuit for service”, (for example, felony conviction of child abuse, sexual assault, or assault with a deadly weapon), we would expect the facility to report that individual to the nurse aide registry (if a nurse aide) or to the state licensing authorities (if a licensed staff member).
. . . provision does not make the facility automatically liable for every loss of personal property, nor preclude the facility from having policies that establish when the facility is liable. Rather, we would protect the patient from facilities inappropriately avoiding liability by failing to take reasonable care in protecting personal property.

PG 173

. . . non-payment applies if the patient does not submit the necessary paperwork for third party payment or after the third party payor denies the claim and the patient refuses to pay for his or her stay.

PG 174

. . . a facility must, as it does in other ways, physically assist a patient in obtaining access to services, and, importantly, cannot act as a barrier to a patient exercising a right.

PG 179
At the time a facility determines that a patient cannot be readmitted to the facility, the patient is effectively discharged from the facility.

... We require facilities, at the time they determine a patient cannot return to the facility, to comply with the requirements... as they pertain to discharge.

We agree that information such as a patient's life history may not be readily available; however we believe that facilities have an obligation to make their best attempts to obtain this information because the information could prove to be valuable to the patient's care.

We received insight and recommendations from the OIG (OEI-02-09-00201), internal workgroups, and stakeholders regarding the lack of patient's involvement in the care planning process.

The regulation as a whole focuses on the additional quality attributes mentioned by commenters: safety, effectiveness, efficiency, timeliness and equitability.
The purpose of the baseline care plan is to serve as an interim care plan within the initial period of residency to avoid poor quality care and reduce the risk of hospital readmission as a result of missing information.

We do not require that any of the members of the IDT participate in person. Facilities have the flexibility to determine how to hold IDT meetings whether in person or by conference call. The facility may determine participation by the nursing assistant or any member, may be best met through email participation or written notes.

... assisted nutrition and hydration, and, like all treatments, patients have the right to accept or refuse. Accepting a patient's refusal, or deferring their documented preferences, does not absolve a facility of its responsibilities to provide adequate nutrition or permit the facility not to meet a patient's nutritional needs. It does recognize that a competent patient has the right to make choices about assisted nutrition and hydration and that there are circumstances where failure to maintain acceptable parameters or nutritional status are not a reflection of failure(s) of care.
We agree that the response to a fall or incident should be episode specific, that a new intervention may not always be necessary, and that frequently a root cause analysis will be necessary.

A culture of safety and worker safety are important issues.

... our statutory authority is limited to regulations that protect the health and safety of patients; we hope that our rules also protect the safety and well-being of staff and employees, but such results cannot be the basis for our authority.

... a competency-based staffing approach that requires the facility to evaluate its population and its resources... including the number and acuity of the patients, the range of services, and base staffing plans and assignments on these assessments.

... the facility ensure that licensed nurses have the competencies and skill sets necessary to care for patients' needs as identified through patient assessments, and as described in each patient’s individual plan of care.
Non-permanent caregivers are expected to meet competency, knowledge and skill requirements to the same extent as permanent personnel.

Patient safety requires resources that are sufficient to prevent an inappropriately high rate of untoward events that could be avoided with adequate staffing levels. For such a standard to be reasonable, it must at least be based on the number of patients in the LTC facility and address NA’s, who provide most of the care to LTC facility patients.

Further, the facility assessment is conducted at the facility level and it must be used in making staffing decisions, precluding staffing decisions from being made solely at a corporate level based on fiscal considerations and without taking facility- and patient-specific factors into consideration.
Careful oversight by nursing staff serving patients is a core fiduciary responsibility of LTC facilities and the direct responsibility of the Administrator and the Director of Nursing (DoN). This responsibility must be understood to extend to the adequacy of training and the operational deployment of nursing staff at all times, including night and weekend shifts, and during holidays—regardless of the business structure of the facility, and independent of any policies promulgated by individuals or entities that may be operationally and/or financially connected to a given LTC facility.

REQUIRED READING

Nursing Services- pg 255-279

... behavioral health issues have a medical and biological component and that healthcare, including the healthcare in LTC facilities, requires a holistic approach. We have finalized this section not to elevate the treatment of mental disorders and emotional issues above physical health issues, but to ensure that assessment and treatment of behavioral health issues are viewed with the same importance as physical and receive the resources necessary to provide appropriate treatment to patients in need of behavioral health services.

PG 271-272

PG 282
No healthcare provider, including a LTC facility, can guarantee any particular result for its patients. In addition, an LTC facility can only be responsible for the care they provide and not the care the patient received prior to admission.

PG 283

... these requirements neither mandate specific techniques or care nor do they require facilities to forego the use of any medically acceptable drugs or techniques.

We disagree that these finalized requirements have an anti-medication orientation.

Non-pharmacological or behavior interventions are required in an attempt to reduce or eliminate psychotropic medications, but only if these non-pharmacological methods are not clinically contraindicated for the patient.

PG 284

These requirements do not mandate that a LTC facility admit any patient with a serious mood disorder. However, if a patient does have behavioral health issues, the facility is responsible for providing the appropriate care for the patient.

PG 288
... We believe there needs to be a holistic approach to behavioral health and that it should encompass a patient’s mental, emotional and physical well-being.

"Behavioral health encompasses a patient’s whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment on mental and substance use disorders."

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... We want to emphasize that the proposed requirements concerning psychotropic medications are not intended to have a chilling effect or in any manner discourage the prescription or use of any medication intended for the benefit of a patient who has been diagnosed [with] a specific condition that requires these medications.

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The goal or purpose of the requirements finalized in this rule is not to limit the overall amount of psychotropic drugs used by the facility or to supplant the judgment of a physician or other prescribing clinician concerning the use of psychotropic medications. ... The purpose of the requirements is to ensure that patients receive psychotropic drugs only when these medications are appropriate and intended for the patients benefit.
We are particularly concerned about the possibility that including opioid analgesics in the definition could result in negative consequences for pain management, especially since they are usually given PRN prescriptions. Therefore we have removed the drug category of “opioid analgesics” from the finalized definition of “psychotropic drug”.

The CDC guidelines provide recommendations which focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end of life care.

For many patients, psychotropic drugs are clearly appropriate to address a diagnosed disorder, necessary for their health, and prescribed for their benefit. For those patients taking psychotropic drugs, we expect that each patient would be evaluated by their attending physician to determine whether GDR and behavioral interventions for a psychotropic drug are clinically indicated.
restricting the ability of health care practitioners to prescribe medication for uses other than those that have FDA approval could violate the prohibition against interference with the practice of medicine at section 1801 of the Act.

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there are situations in which PRN prescriptions for psychotropic drugs are appropriate for patients.

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notification of the ordering physician [lab results] should align with facility policy and procedure. It is also common practice for health care settings to establish procedures for determining normal/abnormal values. Therefore, in situations that may provide an abnormal result, but do not warrant an emergency response or repeat test, facilities have the flexibility to address these situations in their policies and procedures and determine how notification should take place.
... a facility may not charge a patient for the loss of or damage to dentures when the loss or damage is the responsibility of the facility.

PG 337

These requirements are broad enough to encompass dental services provided by a dental hygienist working within their scope of practice.

PG 338

... the facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility.

PG 339
The three-day time frame is to make the referral, not to complete the dental appointment, or obtain repaired or replaced dentures.

... understand that there may be circumstances that prevent a timely referral. Extenuating circumstances could include issues such as the patient’s preferred provider’s office not being open or the need to obtain an insurance pre-authorization. Facilities would be expected to document such circumstances.

PG 340

... require that menus reflect the religious, cultural and ethnic needs of patients, as well as input from patient or patient groups.

... meals should be served at times in accordance with patient needs, preferences, requests and the plan of care.

PG 343 - 344

... facilities could procure food directly from local producers, farmers or growers, in accordance with state and local laws or regulations.

... not prohibit or prevent facilities from using produce grown in facility gardens.

... facility have a policy regarding use and storage of foods brought to patients by visitors to ensure safe and sanitary handling.

PG 345
Given the potential diversity of each facility, we continue to believe that a “one-size-fits-all” approach to food service and nutrition services serves neither the patient nor the facility. A facility should have the flexibility to determine how to best meet its patient’s needs in the area.

A patient’s request to eat outside mealtimes does not necessarily need to be documented in the plan of care, nor should a patient be able to eat outside of meal time only if it is required by the plan of care. However, where nutrition is a concern and being monitored for a specific reason(s), or where there are dietary restrictions necessitated by a patient’s medical condition(s), the provision of such snacks and meals must be consistent with the plan of care.

This requirement is not intended to require the availability of a 24-hour-a-day full service food operation, but rather accommodate patients who cannot or choose not to eat at a scheduled mealtime. This requirement does not mandate that every facility be able to provide every possible religious, cultural or ethnic diet. However, a facility should consider these factors with respect to the population it serves, as well as input from patients and patient groups.
We agree that an individual's preference for smaller portions or who are overwhelmed by large portions should have that preference or need accommodated.

... the provisions as proposed require appropriate menu development at the facility level, but also clearly allow, and in fact require, that meals meet individual needs and accommodate patient preferences.

[facility assessment] Will enable each LTC facility to thoroughly assess their patient population and the resources that are needed to provide the care they need. It will also enable the facility to determine the resources it has so that it can determine what resources it needs to competently care for its patient population. By having the facility assessment documented, it will also provide a record for staff and management in the future to understand the reasoning for decisions that were made on staffing and other resources. It will also provide a reference point for assessment when deficiencies are noted or when adverse events occur.

... specifically add respiratory therapy to the list of specialized rehabilitative services.
these requirements are necessary to ensure that the facility competently cares for its patient population by appropriately assessing its patient population and resources. The requirement includes specific elements that each facility needs to care for its patients. It provides for not only a process but also provides a valuable tool for facilities to use for planning for and improving care.

Facilities are required to use the facility assessment in determining how they need to comply with several requirements in this rule.

Concerning the surveyors, further guidance will be published or disseminated by CMS after this rule is published to provide additional information on what constitutes compliance with the requirements set forth in this final rule.

Binding Arbitration

It's in the courts
We are not adding a specific list of QAPI topics or required performance improvement projects at this time. We want to allow facilities the flexibility to determine what issues should be prioritized for their QAPI program based on the needs of the facility and its patients.

We believe that our focus on outcomes is appropriate. We . . . believe that data is a necessary element in doing so. Data is used to identify problems in process and practices and to set goals related to improving those processes and practices. It is then used to validate that a change is successful in improving that process or practice and subsequently to monitor that the change is sustained. Using data involves critical thinking; these are not mutually exclusive.

We agree that not all improvement activities are PIPs and believe that our proposed regulatory language is inclusive of these activities.

While we agree that areas in which an immediate jeopardy deficiency is cited require immediate action, we are not certain that a PIP will always be an appropriate response, and therefore have not adopted this recommendation at this time.
QAPI is intended to be one aspect of a LTC facility's operations that helps to maintain and protect the health and safety of patients in the facility. We have the obligation to ensure that the QAPI plan becomes more than a paper exercise.

It is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation.

What we require is satisfactory evidence that a facility is implementing its QAPI plan and maintaining an ongoing QAPI program. We retain the requirement that “Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanction.”
With regard to concerns about increased litigation, we reiterate that our purpose is neither to inappropriately make documents public nor to expose facilities to litigation risk.

Our obligation to conduct effective oversight is not waived in the face of litigation fears. We have attempted in these regulations to establish an appropriate balance between ensuring that QAPI can be conducted in an open, non-punitive environment and ensuring that we can provide effective oversight of requirements necessary to protect the health and safety of LTC patients.

We believe the requirements (Infection Prevention and Control Program) will contribute to the reduction in HAIs, which should result in a reduction in physical harm to patients and others, as well as a decrease in associated health care costs.

We believe that facilities need the flexibility to determine which national standard they are going to follow.
... it is estimated that there are between 1.6 and 3.8 million HAIs in LTC facilities annually (80 FR 42215). These infections result in an estimated 150,000 hospitalizations; 388,000 deaths; and healthcare costs between $673 million to 42 billion.

In addition, due to transfers between hospitals and LTC facilities, infection control in LTC facilities directly affects hospitals as well.

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[CFR Comment] ... a state survey agency will cite a facility for an adverse event when the LTC facility does not begin an antibiotic based on an asymptomatic urinalysis but the patient later develops an infection. ... This has occurred across the country over the past several years as providers have attempted to follow the SHEA criteria.

[SHEA = Society for Epidemiology of America]

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... antibiotic resistance has become a national concern and both the inappropriate and even appropriate use of antibiotics contribute to this problem.

Therefore, the facility’s IPCP, and its antibiotic stewardship program, also affects other facilities and individuals throughout the healthcare system.
“When and how isolation should be used for a patient, including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) that the type and duration of the isolation should be the least restrictive for the patient under the circumstances.”

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“...We agree that LTC facilities should have the flexibility to determine if more than one individual should be designated to be responsible for the facility's IPCP.

"[w]hile all staff should be responsible for infection prevention and control, we agree with the SHEA/APIC guidelines that establish an effective IPCP should designate IPCO for whom implementation and management of the IPCP is a major responsibility."
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.

The requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not only ensure compliance with the requirements in this final rule but also improvements in the quality of care provided to the patients.

The compliance officer must be able to communicate with the governing body without being subject to any coercion or intimidation.
... The requirement applies to the reconstructed area, so that where reconstruction involves a limited area within the building, we would not expect the entire building to upgrade to the new requirements.

PG 497

When change of ownership, the new owners have the option of accepting the existing provider agreement. In this case, the facility would not be "newly certified." However, when a new owner does not accept the existing provider agreement, the facility does require a "new certification" and these requirements would apply.

PG 500

Smoking is not addressed as a patient right.

PG 501
expanding the requirements for dementia management training to all staff will only further improve the care that is provided.

adding a provision to require that all new and existing staff, individuals providing services under contractual arrangement, and volunteers receive dementia management and abuse prevention training consistent with their roles in the facility.

There is a lot of opportunity in the new Requirements. The system is beginning the journey of recognizing the tremendous advancements nursing centers have made in quality, care delivery and acuity management.

But, a lot remains undone. The lack of appreciation of the professionalism of staff; the dedication to patient, their families and our community; and the freedom to do the job without fear of second guessing and loose interpretations is troubling.

What Were They Thinking?

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