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SUBJECT: WHITE PAPER ON THE SURVEY PROCESS

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Introduction

Some 130,000 pages of federal regulations govern nursing facilities in the United States, more than the accumulated regulations for the nuclear power industry. Each attempt to clarify, expand, or amend these statutes seems to intensify the debate on how to best bring quality care to those who spend part or the balance of their lives, in a long term care facility. The vast majority of the long term care population are frail elders. The divine spark within us may be that humans are the only species that will sustain those who can no longer provide for themselves. While all agree sustenance is essential, few can agree on the best path—or regulatory model—to ensure that residents receive appropriate and adequate long term care (LTC).

The nation has attempted to assure safe, effective care by creating an oversight process for LTC. The current regulatory path emerged from a study in the mid-1980s by the National Academy of Sciences Institute of Medicine (IOM) Committee on Nursing Home Regulation. Following a two-year study of nursing home performance and existing nursing home regulation, this IOM Committee made recommendations to Congress and the Administration on how to improve the regulatory process and the quality of care received by residents.¹ In response to the IOM's recommendations, Congress enacted the nursing home reform provisions contained within the Omnibus Reconciliation Act of 1987 (OBRA 87) and HCFA [now known as the Centers for Medicare and Medicaid Services (CMS)] subsequently issued implementing regulations and guidance for the survey process.

Under OBRA 87 (codified at 42 CFR part 483) the federal government requires each nursing facility that receives Medicare or Medicaid funds to meet minimum standards for care. States are authorized to conduct on-site surveys in nursing homes to ensure provider compliance with those standards. To promote national consistency, CMS has published

¹ Hawes C. (October 26, 1995). Testimony to the United States Senate. *Hearing on Special Nursing Home Quality Care Standards*.

surveyor guidelines to assist surveyors and facilities in interpreting F-TAGs (requirements) and to help surveyors conduct surveys. The *State Operations Manual (SOM)* contains the procedures for conducting the survey. The *SOM* includes specific instructions about gathering and interpreting information collected before and during the survey, drafting and presenting the statement of deficiencies to facilities, drawing conclusions about the scope and severity of the facility's alleged non-compliance, determining penalties for noncompliance, and other issues such as various levels of appeal. All state survey agencies must use the procedures and tasks in the *SOM* to conduct the survey. Each state may have additional survey regulations and requirements, which may complement but not contradict the *SOM*.

The regulations governing nursing home practices and performance require facilities to provide services to try to achieve "the highest practicable physical, medical and psychological well-being" of every resident. The medical regimen must be consistent with the staff's assessment of the resident (performed according to a uniform instrument known as the Minimum Data Set) and related to the interdisciplinary care plan. Facilities must demonstrate that any declines in a resident's physical, mental, or psychological well-being are unavoidable; that is, resulted from an individual's underlying conditions and problems, not from faulty or deficient facility practices. These requirements are intended to focus more on a facility's actual performance in meeting residents' needs in a safe and healthful environment than on "paper compliance" or the mere *capacity* or potential to provide such care.

Why the Involvement of PALTmed: A Nursing Facility Medical Director and Attending Physician Organization?

PALTmed's concerns on behalf of medical directors and attending physicians arise from its focus on resident care and from regulations and guidelines charging the medical director with oversight of the clinical care of nursing home residents. While PALTmed accepts the principle that the care of frail elders in long-term care facilities needs oversight, PALTmed also believes the survey process can and must be improved.

PALTmed promotes a resident-based perspective of care that includes the resident as well as the family/responsible person. Any approach to evaluating the care that is delivered in LTC facilities should emphasize primarily its relevance to individual residents.

A nursing facility's medical director carries an ethical responsibility for the health and safety of the facility's staff and residents. Additionally, federal regulations (F-TAG 501, Presence of Medical Director) state that medical directors, retained by the facility, are responsible for implementing resident care policies and coordinating medical care in the facility. OBRA does not clarify specific duties and responsibilities of the medical director. Following the law's implementing regulations, PALTmed voluntarily published

guidelines for the role of the medical director in House of Delegates Resolution A91 *The Role and Responsibilities of the Medical Director in the Nursing Home*².

Both directly and indirectly, the regulatory process influences medical decision-making. Surveyor statements and actions, real or perceived, may result in withholding of appropriate care or provision of inappropriate care. Medical directors can help ensure that regulatory requirements are consistent with evidence-based clinical information. The medical director can help surveyors understand when medically appropriate care is rendered, despite the occurrence of negative outcomes.

Concerns Regarding the Effectiveness of the Current Survey

Oversight of nursing facility care is necessary. However, more than a decade of surveying and enforcement efforts has demonstrated some significant flaws in the system. PALTmed believes that these survey and enforcement problems must be acknowledged and addressed to allow the nation to fulfill its promise of dignified care and sustenance for frail elders and others living in the LTC continuum.

PALTmed believes that the following key issues inhibit maximum effectiveness of the nursing home regulatory process:

1. The vast diversity of U.S. nursing facilities (e.g., size, locale, type, acuity level, and ethnicity) makes evaluation challenging.
2. Surveys are not conducted consistently across and within states.
3. There are inherent difficulties measuring quality. There is a potential for counterproductive disincentives if measurements are used that do not adequately adjust for case mix relative risk.
4. There is excessive reliance on the presumption that individual poor outcomes are evidence of poor care. Investigations often appear to be limited to identifying F-TAGs to cite, rather than to see if appropriate systems of care were in place.
5. Providers perceive that the survey process is too punitive, too rigid, promotes the practice of “regulatory medicine,” and inhibits creativity. This environment may increase the burn out rate and turn over of staff.
6. The process fails to utilize the extensive amount of information compiled via the survey and certification process as the basis for quality improvement approaches to help facilities identify and correct care and systems problems.
7. Many specific requirements for the care of frail elders are created without adequate evidence-based studies to support them. There should be more focus on developing appropriate measures of care and quality to decrease the role of subjective assessments in the process.
8. Documentation has taken precedence over care in an effort to meet compliance expectation.

² American Medical Directors Association (1991). *The Role and Responsibilities of the Medical Director in the Nursing Home*. Available <http://www.amda.com>.

PALTmed Vision for the Ideal Survey Process

PALTmed's broad goal is to optimize resident care in LTC facilities. Care improvement comes primarily from the practitioners and providers who give the care, but the regulations and survey process are a major influence on their performance. Reforming the survey and certification process based on the principles outlined in this paper will be crucial to improving resident care and outcomes. Good care for LTC residents should emanate from a partnership between medical directors, attending physicians, facilities, the regulatory and survey agencies, and others. PALTmed values the concept of the collaborative approach to care in this context as well as in the nursing facility.

Regulations cover many non-clinical items, such as environmental issues. While PALTmed recognizes their importance, it will focus on those requirements directly related to clinical resident care. A cardinal belief of this organization is that a successful survey process should be able to identify and promote appropriate, consistent, care. That is the real basis for any facility's clinical and financial strength.

PALTmed believes that the following principles are essential to reform the survey process so that it will meet the needs of residents while holding care providers responsible to deliver consistent, quality care:

1. The survey should be "resident-centered"; that is, it should exist to improve the life and care of the LTC population. It should analyze care based on residents' needs more than on general regulatory expectations for all individuals with a given condition or problem.
2. Surveys should use process indicators to measure whether a facility has appropriate systems in place to deliver care as well as how these systems and processes are applied to care for individual residents.
3. The survey process should utilize an analysis of aggregate, risk-adjusted data of the LTC population to determine how well care is delivered. A single adverse outcome is not sufficient evidence of poor care, but may be a reason to investigate further whether proper care systems existed and were applied. For example, the interdisciplinary care team can work toward specific indicators of care and the reduction of falls, but cannot prevent all falls.
4. The survey process should move away from the concept of "compliance" versus "non-compliance" and toward a rating system that measures how well care processes are applied to resident needs.
5. Surveys must be based on realistic regulatory expectations. Zero tolerance for process deficits is not a feasible goal, and the notion that any negative outcomes related to process deficits is a potential deficiency is not realistic. It must also be understood that negative outcomes are not necessarily related to a process failure, given a population that is institutionalized *because* they are declining.
6. The survey process must be objective and consistent among facilities and throughout the states. Survey agencies must assure that the survey process can adapt and change as changes occur in the field of LTC. Surveyors are too

often forced to decide subjectively whether a facility or the care delivered is “compliant” based on incomplete instructions and individual interpretations. A more appropriate survey approach should allow surveyors to evaluate specific results in the context of a facility’s overall efforts to act appropriately. Consistency in performing surveys requires accountability. Surveyors should be accountable to the state agencies, and the state to CMS, to perform surveys consistently throughout the country.

7. The survey process should not be adversarial, but rather an educational tool whose purpose is to improve resident quality of care and quality of life. It should strive to dispel the perception that it focuses on paper compliance rather than care. Since there is nothing in the law that states that surveyors should be prohibited from providing appropriate feedback, assistance and education in addition to oversight, surveyors should be able to (a) determine if systems of care exist and are applied; (b) identify system problems and failures and, (c) help inform facilities of appropriate protocols, practices, and management approaches that may assist in improving these care systems and processes.^{3,4}
8. The survey should use evidence-based criteria for investigating clinical issues. Where there is no compelling evidence to support specific requirements, the survey should allow facilities and physicians greater latitude in providing resident care.
9. The nature and extent of medical record documentation necessary to confirm performance and compliance by the facility should be resolved.
10. The “Scope and Severity” grid needs revision. Scope and severity should be based upon well-defined, objective, and consistent criteria. The use of terms such as “harm”, “potential harm” and “immediate jeopardy” are without agreed upon practical definitions. This is crucial, since the position of even a single citation on the scope and severity grid may determine the severity of a sanction and may even determine whether a facility is terminated from the Medicare/Medicaid program, the consequences of which may potentially affect the patient’s mental and physical well being, if they must be moved to another facility. The extent of danger to a resident must be measured in a realistic and practical manner with clearly defined terms and definitions. Minor infractions should be dealt with accordingly. They should not be given the same weight as major ones. The terms “avoidable” and “unavoidable” must be clarified or eliminated since there is no agreement on their application. How they are interpreted determines whether a citation is even assessed. As currently drafted, it appears that the same “rules of evidence” to determine compliance do not apply evenly throughout the *SOM*.
11. Any attempt to link the number of citations or accumulated civil monetary penalties to define a “successful” survey should be discouraged.

³ New York Association of Homes and Services for the Aging (2001). *Bad Medicine*. Available: <http://www.nyahsa.org>.

⁴ Michigan Department of Consumer and Industry Services (2001). *Clarification of Terms Used in Long Term Care Enforcement*.

12. Facilities and care givers should be provided with a professional, fair and unbiased dispute resolution and appeals process, conducted by an independent third party neither related to nor financed by the regulatory and survey agency and specifically qualified to make informed decisions based on the current geriatric and long term care body of knowledge.
13. Remedies should focus on improving resident care. A remedy involving loss of CNA training should be assessed only when the survey process demonstrates a facility's inability to appropriately provide such training. Fines assessed should be returned to direct resident care rather than applied to state/federal programs. There should be no incentive for surveyors to fund government oversight by way of facility civil monetary penalties.

Role of the Nursing Facility Medical Director

PALTmed believes the facility medical director should play a strong role in the survey process and can be a driving force in quality care for the residents⁵ by assisting in the development of the systems of care necessary for survey success. In House of Delegates Resolution L02 *The Role of the Medical Director in the Survey Process*, PALTmed recommends that the medical director be involved in the survey process by both understanding the survey itself and the elements of care that influence survey results. Promoting responsive or “smart” regulatory methods, providing education to and working on technical projects with surveyors, and working with CMS to improve survey methods may engender a cooperative, professional survey climate that involves medical directors as useful and necessary resources. PALTmed further urges the adoption of more explicit or even mandatory roles for medical directors in the survey process.

Recommendations

PALTmed desires a more professional and collegial relationship between the medical director and the survey team. There is a real opportunity to diminish the adversarial atmosphere surrounding the survey process. To do so requires an alteration in the regulatory environment of the survey process, which is necessary to promote quality treatment of the nation's LTC residents.

Three models of regulatory approach toward survey processes have been postulated⁶.

- **Deterrence Regulatory Model.** In this model, regulators view the industry as amoral, willing to bend rules and hide problems if they can get away with it and profit. The use of frequent inspections, sanction and penalties, coupled with rigorous and uniform regulation will deter unwanted behavior. The approach

⁵ American Medical Directors Association (unpublished). *The Role of the Medical Director in the Survey Process*.

⁶ Walshe K (2001). “Regulating U.S. Nursing Homes: Are We Learning From Experience”, *Health Affairs* 20 (6) 128-142.

- tends to be formal, legalistic, punitive and sanction-oriented. This type of management style was rejected by business 20 years ago.
- Compliance Regulatory Model. In contrast, “compliance” regulators see the industry as basically well intended and likely to comply if able. They tend to view the current system as hostile, burdensome and hindering quality improvement. A more formal, supportive and developmental approach is advocated, with sanctions being a measure of last resort.
 - Responsive or “Smart” Regulatory Model. This model combines features of both previous models. The underlying principle is that regulatory approaches should be adapted in response to the behavior of the individual organization. Cooperation and development is directed towards facilities that have shown a high level of regulatory compliance. Rigorous, frequent, corrective and/or punitive action is directed towards poorer performing facilities. A combination of the two extremes is possible depending on the performance and abilities of the home.

PALTmed believes the Regulatory or “Smart” Model most closely encompasses the ideals we envision. It will be the framework within which further portions of the PALTmed vision can be established.

An enhanced role for the medical director is essential to maximize the potential of the survey. PALTmed will reach out to all stakeholders in the survey process to seek optimum resident care outcomes, again embracing the power of the LTC interdisciplinary team. As a basic tenet, it would be suggested that the survey team at least interview the Medical Director before the completion of a final report. If the medical director role is significant enough to be mandated by law, the medical director should be expected to also play a role in the survey process.

Further research to determine evidence-based outcomes is essential for the LTC population. PALTmed welcomes and supports LTC-specific research done by the PALTmed Foundation and other reputable groups. PALTmed will work with other organizations to identify and develop evidence-based and risk-adjusted process and outcome quality measures.

PALTmed will create work groups to address specific areas of the survey process, possibly including, but not limited to the following issues:

- Scope and Severity determination,
- Principles of the “Perfect Survey”,
- Dispute resolution and remedies,
- Specific changes to address within the *SOM*, and
- Identification of evidence-based indicators that offer promise to measure quality care.

PALTmed is committed to the health and well-being of the residents of LTC facilities. Reform of the survey process is a key ingredient to this goal. PALTmed is willing to work with all stakeholders to fulfill the promise of the survey and certification system.

RESULTS: Passed. Work Group on the Survey Process to develop strategic plan.