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Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3260-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-3260-P, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule

Dear Mr. Slavitt:

On behalf of our 500 member non-profit and public hospitals, nursing homes, home health agencies, and other healthcare providers, the Healthcare Association of New York State (HANYs) welcomes the opportunity to comment on the Medicare Reform of Requirements for Long-Term Care Facilities proposed rule. These comprehensive proposals would significantly impact skilled nursing facilities (SNFs). We urge CMS to reconsider its overall approach in a number of areas to ensure the ongoing stability of the long-term care system and its capacity to provide care.

GENERAL COMMENTS

Scope and Impact of Proposed Mandates

HANYs agrees that many environmental changes, updates in standards of care, increases in patient acuity and care needs, and evidence-based research have occurred since CMS' current regulatory requirements were developed. As a result, long-term care has changed dramatically, including advances in the delivery of services and operational improvements.

These changes have been significant to SNFs and so too are CMS' new proposals. In fact, the proposals are so wide-ranging and far-reaching that more time is critical to understand their full implications and possible unintended consequences. HANYs welcomes CMS' extension of the public comment period to October 14.

The proposals also represent new and substantially expanded mandates for nursing facilities without any reference to additional funding to cover the added costs.

Hospital-based SNFs have traditionally operated at the lowest, even negative, margins compared to other SNFs. In addition, CMS just published the 2016.

SNF Prospective Payment System (PPS) final rule, which added requirements for SNF value-based purchasing and quality reporting programs. The unfunded mandates proposed here by CMS, coupled with relentless cost containment in recent years, threaten the ability of hospital-based SNFs to continue to provide long-term care services in their communities.

HANYS urges CMS to:

- Delay any further action on any expanded and new unfunded mandates for SNFs until future funding plans and added rate structures are approved and in place to offset the costs of implementing unfunded mandates. Specifically, HANYS urges CMS to delay action on the following new unfunded mandates and expanded proposals and to provide written clarification on each:
 - Facility Responsibilities (§ 483.11)
 - Physician Services (§ 483.30)
 - Behavioral Health Services (§ 483.40)
 - Specialized Rehabilitative Services (§ 483.65)
 - Administration (§ 483.70)
 - Training Requirements (§ 483.95)
- Apply a tiered/phase-in approach to implementation of other proposals once finalized to help ensure the stability of long-term care services. An implementation approach should specify changes and terminology updates.
- Re-examine the Regulatory Impact Analysis (RIA) and re-evaluate its results, as the financial impact analyses of some proposals do not include some operational details. For example, there are proposals where the fiscal impact has been overlooked in relation to mandatory members of the Interdisciplinary Team (IDT) or understated regarding the role of the proposed Infection Prevention and Control Officer (§ 483.80) and costs of Quality Assurance and Performance Improvement (QAPI) (§ 483.75).

SPECIFIC COMMENTS

CMS' proposals appear in *italics*.

Facility Responsibilities (§ 483.11)

Reporting Concerns about a Resident Representative

CMS proposed a new requirement [*§ 483.11(a)(5)*], that would “*clarify that if facility staff believed a resident representative was making decisions or taking actions that are not in the best interest of the resident, we would expect the facility to comply with any state reporting requirements that might apply.*”

HANYS believes it is critical that each SNF resident and patient be treated with respect and dignity. On some occasions, facility leaders and/or staff have observed others' treatment of residents as not in the best interest of the resident and have had little recourse, support, or guidance in intervening and protecting the resident from such behavior or treatment. HANYS views this CMS proposal as providing that support and guidance to providers. **HANYS supports CMS' proposed addition for a new § 483.11(a)(5).**

Resident Information about Medicare/Medicaid Coverage Changes

HANYS finds the proposal to revise § 483.10(b)(5)(i) and (ii) and 483.10(b)(6) to be burdensome, duplicative, and unnecessary. *“The revised provision would specify that the facility must inform each resident, in writing, at the time of admission to a Medicaid participating nursing facility and when the resident becomes eligible for Medicaid—(1) Of the items and services that are included in nursing facility services under the state plan and for which the resident may not be charged; (2) of those items for which the resident may be charged, and the amount of charges for those services; and (3) inform Medicaid-eligible residents when changes are made to the items and services in proposed paragraph (e)(11)(i) of this section.”* In addition, facilities would be required to *“provide notice to residents when changes are made to the items and services covered by Medicare and/or Medicaid or to the amount that the facility charges for items and services.”*

HANYS believes that this is not an appropriate role for the facility. The responsibility for informing the resident of coverage and changes to the benefit rests with the payer/insurer, whether it is a government agency or managed care organization. They are the entities that manage the services for which an individual is eligible and would know when changes occur. In addition, there are volunteers and community-based entities with appropriate expertise. Such groups include the Medicare Rights Center and long-term care ombudsmen from the Area Agencies on Aging. These groups have a community presence, are easily accessible, and are well-versed in Medicare and Medicaid coverage and cost issues.

Since nearly every SNF in New York is a dually licensed/certified Medicare/Medicaid facility, more than 600 facilities would be required to comply with this requirement for every resident admitted. However, there is no reliable and consistent mechanism that provides benefit change information to SNF providers. Nursing facilities customarily learn of coverage and benefit changes only once they have submitted claims and been denied payment for a service.

In New York, all new permanently placed nursing home residents are now required to enroll in a managed care plan to receive care. With the increased enrollment of nursing home residents into various managed care plans, it would be impossible for the nursing facility to be aware of the different benefits these plans provide.

HANYS urges CMS to remove its proposed changes to § 483.10(b)(5)(i) and (ii) for the reasons cited above.

Comprehensive Person-Centered Care Planning (§ 483.21)

Mandatory Members of the Interdisciplinary Team

Under current § 483.20(k)(2)(ii), CMS proposes to require three specific staff roles to be part of the IDT: a nurse aide with responsibility for the resident, an appropriate member of the food and nutrition services staff, and a social worker.

While HANYS agrees that a number of staff may have essential information to contribute to a person-centered care plan and the IDT process, that kind of input takes time to provide, even with the application of a number of innovative and creative technologies that CMS noted in its RIA of the new proposed § 483.21.

Time spent contributing to IDT and care planning also takes staff away from their other direct care duties and those positions must be back-filled by administration to ensure continuity of care for all residents.

In CMS' RIA, there was no recognition that it is customary for an IDT member to participate in IDT meetings for more than one resident, sometimes in the same week. This reality has the potential for increasing the estimated IDT time from CMS' estimated one hour per week to perhaps five or more hours per week, thereby potentially increasing costs substantially.

HANYS finds CMS' financial impact of IDT time is severely underestimated and is therefore a much more significant proposed unfunded mandate for SNFs.

HANYS urges CMS to not move forward with this proposal and instead conduct more fact-finding with providers directly to better determine its financial impact.

Physician Services (§ 483.30)

In-person Medical Evaluation Prior to Unscheduled Transfer to Hospital

The new proposal for § 483.30(e), requiring an in-person evaluation prior to an unscheduled transfer of a resident to a hospital, needs the same consideration and innovative thoughts as CMS' proposal for physician delegation of therapy and dietary orders.

Many facilities, especially those in rural areas, have limited in-facility access to medical practitioners. Telehealth technology offers providers and practitioners essential flexibility in the ways medical services are delivered, such as conducting assessments, diagnosing and monitoring patients' health status, and in some cases even providing treatment.

The electronic options available for practitioners to use in the delivery of medical services, without having to see the patient in-person, is varied and should be an added option supported by CMS in a new § 483.30(e).

HANYS urges CMS to expand proposal options for new § 483.30(e) to include the use of electronic telehealth technologies.

Delegation of Writing Orders to Qualified Dietary Professionals and Therapists

While HANYS commends CMS' desire to allow flexibility in this proposal, we urge CMS to make some clarifications.

First, CMS does not define a "therapist" in its proposal and, as a result, a number of questions are raised. What specific disciplines are to be included? Does CMS intend all roles with a title of "therapist" to be included or is it to be restricted to physical, occupational, and speech therapy only? Can it include respiratory therapy?

Second, it is not clear how and by whom it would be determined which professional roles would be allowed to write physician orders as proposed in § 483.30. Because the allowed roles are directly related to state-specific scopes of practice, there is some logic to having implementation of this new approach be coordinated between CMS and states. However, HANYS does not understand how that would come together nor how such a determination of "allowed professionals" would be communicated to SNF providers statewide, especially given state-by-state scope of practice differences.

In addition, CMS provides no guidance about the documentation that would satisfy a regulatory review of the delegation decision.

HANYS urges CMS to provide clarification on these points before moving forward with this proposal.

Behavioral Health Services (§ 483.40)

Lack of Regulatory Impact Analysis

HANYS is troubled by the absence of discussion about the financial impact on SNFs of this new, far-reaching proposed requirement. This new requirement has significant financial implications for SNFs as it includes adding and/or training all staff in competencies and skills for caring for residents with mental illness and cognitive impairment.

This new, significant requirement has no funding references in the proposed rule and is therefore another unfunded mandate.

Direct Care Staff Behavioral Health Services Competencies and Skills

CMS proposes a new § 483.40 with requirements "*to ensure that there are sufficient direct care staff with the appropriate competencies and skills to provide the necessary care to residents with mental illness and cognitive impairment.*" CMS continues with "*the needed competencies and skill sets include knowledge and training, including non-pharmacologic interventions, necessary to provide the care for residents with mental illnesses and psychosocial disorders.*"

HANYS requests clarification on the following questions regarding these requirements:

- What standards will be used to define “behavioral health issues”?
- What are the recent data CMS is using to identify behavioral health priorities in SNFs?
- What are “appropriate” behavioral health direct care worker competencies and skills?
- What behavioral health knowledge and training resources are available to provide nursing home staff education and skills training on a broad scale?
- How can this new requirement be differentiated from existing Preadmission Screening and Resident Review (PASARR) requirements?

While CMS names mental health conditions, adjustment disorders, and other conditions, CMS offers no Minimum Data Set or other recent data sources to help identify the scope of the different long-term care behavioral health issues in nursing homes, nor their prevalence.

CMS encouraged facilities looking for education and training resources “*to take advantage of the many tools and resources available to them for free or at low cost.*” However, CMS does not provide that information in the proposed rule. HANYS has researched and found no behavioral health paraprofessional education and training options that provide education focused on the nursing home adult resident or patient.

While grants are available from the Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services, for paraprofessional education in behavioral health, all current opportunities focus on pediatrics, adolescents, and those of a transitional age (under 25 years). There are no programs or grants offered that focus on behavioral healthcare training for long-term care workers and elderly populations, nor competencies for long-term care workers.

HANYS urges CMS to withdraw this proposal because much more foundational work and understanding are needed.

Nursing Services (§ 483.35)

Mandatory Registered Nurse (RN) Presence

In this section, CMS is seeking comments about a mandatory RN presence in SNFs. We believe that facilities must be allowed to make their own staffing plans and decisions based on the needs of their own resident populations—and these decisions must be made within the parameters of the staffing resources that are available. A fundamental issue facing many SNFs, especially in rural areas, is a basic and fundamental lack of qualified and available RNs.

Rural New York SNFs have created incentives and innovative recruitment strategies to fill vacant RN positions, but severe RN shortages continue. It is common to find that the RNs located in a region are employed by multiple SNFs in varying capacities because of the severe shortage of available RN candidates to permanently fill vacancies.

HANYS asks CMS to remain flexible on this point and not make any requirement changes.

Specialized Rehabilitative Services (§ 483.65)

Respiratory Therapy

CMS proposes a new § 483.65(a) to specifically add respiratory therapy to the list of specialized rehabilitative services, but CMS neglected to present any RIA for this new requirement.

HANYS believes that this new requirement has potentially significant financial implications for SNFs, whether the service is provided directly by a SNF or is obtained by the SNF from an outside source. In either situation, the SNF will incur significant costs.

HANYS urges CMS to postpone further action on this proposal and conduct an RIA.

§ 483.65 Relation to Preadmission Screening and Resident Review

CMS identifies confusion between what are PASARR requirements and what are the Specialized Rehabilitative Services for mental health that CMS proposes.

CMS has stated it intends to make a cross-reference to this section and §483.120 references to PASARR. For this reason, HANYS repeats our position as stated above on Behavioral Health Services (§ 483.40).

CMS should withdraw this proposal because we see much more foundational work and understanding are needed.

Administration (§ 483.70)

Governing Body Responsibilities

CMS proposes to add two new requirements in this section: a new § 483.70(d)(2)(iii) to specify that the nursing home administrator would report to and be accountable to the governing body and a new § 483.70(d)(3) to specify that “the governing body is responsible and accountable for the QAPI program.”

HANYS views the proposed § 483.70(d)(3) as defining a much more operationally prescriptive role in QAPI on a daily basis for the governing body than is appropriate or necessary. A new § 483.70(d)(2)(iii) would establish the relationship between the administrator and the governing body, stating that the administrator keep the governing body “*informed and knowledgeable . . .*” about SNF operations, including QAPI. This clearly identifies the administrator (not the governing body) as the day-to-day operational and implementation force for QAPI.

The proposed nursing home regulatory language at § 483.70(d)(3) for the governing body is not only duplicative of the administrator’s role in QAPI but is much more prescriptive than language similarly written for hospitals at 42 Code of Federal Regulations (CFR) § 482.21(e)(1). The hospital requirement states that the hospital’s governing body is responsible for ensuring an ongoing program for quality improvement that is defined, implemented, and maintained.

Moreover, on Page 42212 of the proposed rule, CMS uses that same language in discussions about QAPI that states that *“the facility’s governing body, or designated persons functioning as a governing body, ensure that the QAPI program is defined, implemented, and maintained and addresses identified priorities.”*

HANYS urges CMS to remain consistent in language defining organizational responsibilities. The administrator is responsible for daily facility operations and the governing body is responsible for having oversight of the administrator and the conduct of the administrator’s operational responsibilities including QAPI.

HANYS encourages CMS to change the language at § 483.70(d)(3) describing the governing body’s responsibility in QAPI to “ensure that the QAPI program is defined, implemented, and maintained and addresses identified priorities.”

Annual Facility Assessment

CMS proposes a new § 483.70(e), which would establish a new requirement for an annual facility-wide assessment to be conducted and documented. CMS would require that the assessment be facility- and community-based, and be reviewed and updated as necessary, but at least annually and whenever there were significant changes requiring a substantial modification to the assessment. HANYS agrees with CMS’ statement in the RIA for this proposal that states, *“conducting and documenting a facility assessment is a standard business practice.”*

In preparation of its annual budget, every SNF organization compiles and analyzes data within the context of operating the SNF, identifying care and business priorities, implementing efficiencies in all areas, and making future business plans. However, each organization pursues that activity in its own way and in a manner that best addresses its own operational and business needs and those of its governing body.

In addition, hospital-based and multi-facility systems have to add considerations into the process due to their relationships. There may be shared assets and services and other unique arrangements that are a critical part of that annual review and necessary to maintain for residents’ and patients’ continuity of care.

Such assessment processes that are effective and successful should be respected and supported and should not be encumbered by added, burdensome regulations.

It is for these reasons that HANYS urges CMS not to impose any process or documentation requirements in regard to new § 483.70(e).

Training Requirements (§ 483.95)

For those Under Contract and Volunteers

CMS proposes to add a new § 483.95 to subpart B that would set forth training requirements *“that a facility must develop, implement, and maintain an effective training program for all new*

and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles.”

HANYS asks CMS to clarify that this proposal excludes individuals providing services under a contractual arrangement and SNF volunteers who would be expected to have no direct and/or prolonged interactions with residents or patients.

Many contractors are engaged to supply services in a SNF that do not require contract workers to be in resident/patient care areas, have them engage with residents or patients, or whose work is done in areas and/or at times when residents/patients will not be present. Such contract workers could include construction workers, electricians, and outside equipment and supply vendors.

Volunteers and their duties may also exclude direct and/or prolonged interactions with residents or patients. In these circumstances, HANYS sees no need to require SNFs to provide the proposed training outlined in new § 483.95.

In situations where contracted individuals' responsibilities are to supplement facility staffing and to customarily provide direct care and/or include direct interactions with SNF residents/patients, any training requirements in § 483.95 should be a contractual obligation of the agency/employer and considered to be a “readiness to work” prerequisite for individuals to work in a SNF.

Staffing agencies that supply direct care staff to SNFs must currently ensure, through those contracts, that their personnel have the basic skills and qualifications to perform the desired duties in a SNF. So too, should these training requirements be included as part of those skills and qualifications needed to be assigned as an SNF contract direct care worker.

HANYS urges CMS to modify the new § 483.95 to clarify that SNFs are not obligated to have a training program, “for individuals providing services under a contractual arrangement nor for volunteers, if their expected roles do not require the worker to be in resident/patient care areas, engage with residents or patients, or whose work is done in areas and/or at times when residents/patients will not be present.”

HANYS appreciates the opportunity to comment on the proposed rule. If you have any questions regarding our comments, contact Debora LeBarron, Senior Director, Continuing Care, at (518) 431-7702 or at dlebarro@hanys.org.

Sincerely,



Dennis P. Whalen
President

DPW:sm