WISCONSIN HOSPITAL ASSOCIATION

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November 19, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3346–P, P.O. Box 8010, Baltimore, MD 21244–1810
P.O. Box 8010
Baltimore, MD 21244–1810

Re: CMS–3346–P, Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Proposed Rule

Dear Ms. Verma:

On behalf of our over 130 member hospitals and integrated health systems located in Wisconsin, the Wisconsin Hospital Association (WHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule that seeks to reform Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers.

In Wisconsin, our member organizations, large and small, urban and rural, provide services well beyond the four walls of a hospital, and those services are provided by physicians, advanced practice nurses, physician assistants, and other non-physician providers. Our membership includes members that operate a full continuum of care that includes not only not only hospitals, but also clinics, outpatient surgery, including ambulatory surgery centers, long term care, home health and other health care services.

Our members' embrace of coordinated care delivery models and providing care across a continuum of services inside and outside of the hospital has been a key driver in Wisconsin regularly being recognized as a top state for high quality care. With that comprehensive approach to care delivery, our members bring a perspective to regulatory burden across care settings that is often unique compared to other parts of the country. We appreciate the opportunity to comment on CMS's proposed Medicare regulatory reforms to reduce provider burden and the invitation to offer additional regulatory reforms that could reduce provider burden.

We Appreciate CMS's Attention to Reforming Medicare Regulations That Do Little to Advance Quality Care.

Regulatory burden creates additional cost on the health care system and limits the productivity of health care providers. Wisconsin, like other states, have challenges with having enough physicians to meet the demands for care of our citizens, and regulatory burden directly impacts the amount of clinical care that each physician can provide in one day. For those reasons, meaningfully reducing regulatory burden for hospitals is of significant importance to Wisconsin hospitals and health systems. We appreciate the steps that CMS has proposed to take in this proposed rule to reduce regulatory burden, but we also encourage CMS to continue seek input from the field to identify additional regulatory reforms to reduce regulatory burden on organizations, administrators, physicians, and other clinicians when such reforms do not meaningfully impact health care quality and safety.

We make several comments regarding the proposed rule below and thank CMS for the opportunity to provide input on this important topic.

<u>Retain Existing ASC Transfer Agreement Requirement</u> - We oppose CMS's proposal to remove the requirement that ambulatory surgery centers (ASCs) have a transfer agreement with a hospital, because the change will have a discernable reduction in quality care resulting from less coordinated, more variable care when a surgical patient in an ASC needs care beyond the capabilities of the ASC.

Evidence shows that well-coordinated care results in better outcomes for patients. Coordinated care is particularly important for patients in emergency situations. Attributes of well coordinated care include coordinated information sharing, standardized care protocols and plans, and limited variation in care delivery from patient to patient. As a foundation, these attributes of well-coordinated care require relationships between care providers.

As stated in CMS's summary of the proposed rule on page 47693, "A written transfer agreement and physician admitting privileges is intended to *make sure there is a relationship* between the ASC and local hospital that would serve the patient in the event of a medical emergency." (emphasis added) That relationship is important because it is foundational to well-managed, coordinated care for individuals needing emergency resources beyond the capabilities of the ASCs.

Without a written transfer agreement or physician admitting privileges in both facilities and the establishment of care relationships that those requirements ensure, ASC patients will not have assurance that their ASC has a relationship with a hospital and that the ASC and hospital have a well-managed, coordinated response should the patient need emergency resources beyond the capability of the patient's ASC. Given the increasing complexity of surgeries being performed in ASCs and that ASCs are proposing to be allowed to be performed, maintaining the requirement that an ASC have a written transfer agreement with a hospital or that its physicians have admitting privileges in both the ASC and the hospital becomes more, not less, important to ensuring coordinated, standardized care for ASC patients.

<u>Support for Alternative to Pre-Surgery H&P Requirement</u> - We support CMS's proposal to provide hospitals, ASCs and medical staffs with an alternative option to the pre-surgery comprehensive history and physical (H&P) requirement.

We agree with and appreciate CMS's intent to allow hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals could utilize a pre-surgery/pre-procedure assessment, instead of a comprehensive H&P.

Under the proposed rule, hospitals, ASCs, and their medical staffs would now have two options 1) continue to operate under the existing rule and timeframes for regarding pre-procedure H&Ps or 2) develop and adhere to procedure-specific policies for performing simplified pre-procedure assessments. We recognize that hospitals, ASCs, and their medical staffs will likely need to incur significant upfront time to develop and document procedure-specific policies under the proposed alternative, and that such upfront time may temper use of this alternative. However, we appreciate the flexibility and autonomy provided to enable providers to identify situations in which development of a simplified assessment process may result in streamlined care.

<u>Support for Clarifying the Authority of Non-Physician Practitioners to Record Progress Notes in Psychiatric Hospitals</u> – We support CMS's proposed clarification in the proposed rule that non-physician practitioners, including physician assistants, nurse practitioners, psychologists, and clinical nurse specialists, when acting in accordance with State law, their scope of practice, and hospital policy, have the authority to record progress notes in a psychiatric hospital setting.

We agree with and appreciate CMS's proposal to clarify that either non-physician practitioners or MD/DOs may record progress notes in a psychiatric hospital setting. Within their scope of practice, advanced practice clinicians such as physician assistants, nurse practitioners, and psychologists, have become important providers within psychiatric hospitals and other care settings, and are functioning in roles that previously were solely performed by physicians.

Recently, CMS has made changes recognizing the roles that advanced practice clinicians perform in hospitals and has made clarifications and changes to conditions of participation and payment reflecting the capabilities of advanced practice clinicians. However, our members continue to identify additional areas in need of clarification in the conditions of participation and payment regarding the use of advanced practice clinicians – within their scope of practice – in hospital settings. CMS's proposal regarding recording progress notes in a psychiatric hospital setting is one such example, and we appreciate CMS clarifying this issue in the proposed regulation.

Reduce Unnecessary Physician Co-Signatures by Further Addressing Inconsistent Regulations Limiting Full Use of Non-Physician Practitioner Skills - In addition to CMS's proposal to clarifying the scope of authority for non-physician practitioners in psychiatric hospital settings, we recommend several additional clarifications regarding non-physician practitioners that can reduce unnecessary physician co-signatures and help ensure these important practitioners' skills can be fully and appropriately used in hospital settings.

As noted above, our member hospitals are increasingly utilizing nurse practitioners, physician assistants, and other non-physician, advanced practice clinicians who have a scope of practice that often enable them to provide care previously only provided by physicians. We appreciate CMS's efforts in recent years to better recognize the practice authority of such advanced practice clinicians, however, our members are encountering a patchwork of updates throughout the guidance for the Conditions of Participation and Conditions of Payment that often result in our members requiring physicians to co-sign orders, notes, and other documentation even when the advanced practice clinician's scope of practice allows the practitioner to perform the service. These additional co-signatures are not only an inefficiency, but they also can significantly and unnecessarily add to the burden on physicians to individually review care, even when that care is not required to be provided as a delegated act of the physician.

Specifically, our members have also seen inconsistent guidance regarding the need for physician co-signatures and we ask CMS to consider further modifying its proposed rule to clarify several items in the Conditions of Participation for hospitals and Conditions of Payment so that physicians are not asked to co-sign orders, certifications, notes and other documentation for services provided by non-physician practitioners if such service is within the non-physician practitioners' scope of practice.

Clarify the hospital and CAH conditions of participation that a patient may be under the care of a physician or an advanced practice, non-physician practitioner.

42 CFR 482.12(c)(1) and its Interpretive Guidelines appear to contemplate that an advanced practice, non-physician practitioner may admit a patient in accordance with state law but may not recognize that such patients may be under the care of a non-physician practitioner. Like the clarification regarding progress notes in psychiatric facilities, we request that CMS consider clarifying that consistent with a practitioner's scope of practice, a patient may be under the care of either a MD/DO or a non-physician practitioner.

Clarify the PPS Hospital Conditions of Participation to permit an advanced practice, non-physician practitioner to admit a patient without a co-signature of a physician.

It appears that the CAH Conditions of Participation permit advanced practice, non-physician practitioners to admit a patient without a co-signature of a physician, but the PPS Hospital Conditions of Participation are less clear. We request that CMS consider aligning the CAH Conditions of Participation and PPS Conditions of Participation to make clear that consistent with the practitioner's scope of practice, a patient may be admitted by an advanced practice, non-physician practitioner as an act of the practitioner and not as a delegated act of a physician. Further, similar clarification is requested for admissions to swing beds and long-term care facilities. These changes would eliminate the need for an MD/DO to cosign such admission orders.

Clarify that several required certifications of care in either PPS Hospital or CAHs may be made by advanced practice, non-physician practitioners without a co-signature of an MD/DO.

Throughout the PPS Hospital and CAH Conditions of Participation and Payment, hospitals are perceiving requirements to have an MD/DO sign certifications regarding extended stays, expectations of discharge without 96 hours, and outlier cases. Like the clarification regarding progress notes in psychiatric facilities, we request that CMS consider clarifying that

consistent with a practitioner's scope of practice, such certifications that may be performed by an MD/DO may also be performed by a non-physician practitioner.

Clarify that an H&P in a CAH setting may be performed and documented by an advanced practice clinician without physician oversight or co-signature.

It appears that H&Ps may be performed and signed by an advanced practice clinician without a physician co-signature in a PPS Hospital settings, but in a CAH setting such H&P must be co-signed by an MD/DO. We request that CMS consider aligning the CAH Conditions of Participation and PPS Conditions of Participation to make clear that consistent with the practitioner's scope of practice, that an advanced practice, non-physician practitioner may perform and sign an H&P without a physician co-signature. This change would eliminate the need for an MD/DO to cosign such H&Ps in a CAH setting.

Clarify that discharge orders and summaries may be performed and documented by an advanced practice clinician without physician oversight or co-signature.

We recommend that CMS provide further clarification that advanced practice, non-physician practitioners have full authority, consistent with their scope of practice, under the PPS Hospital and CAH Conditions of Participation and Payment to make discharge orders and document and sign discharge summaries without the need for physician oversight or co-signature.

Support for Proposed Reduction in Frequency of CAH, RHC, and FQHC Self-Review – We agree with and appreciate CMS's proposal to change the frequency of requirements for Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and Federally Qualified Healthcare Centers (FQHCs) to self review several policies from an annual review to a biannual review.

Current Conditions of Participation for CAHs, RHCs, and FQHC's require each organization to annually review several policies and programs, including, as applicable for the type of provider:

- A description of services provided;
- Policies and procedures for emergency medical services;
- Guidelines for the medial management of health problems and maintenance of health care records;
- Rules for storage, handline, dispensation, ad administration of drugs and biologicals;
- Procedures for reporting adverse drug reactions and errors;
- A system for addressing infections and communicable diseases; and
- Procedures for addressing the nutritional needs of certain patients.

For the policies and programs specified in the rule, the organization would instead be required to review the policies and programs every two years rather than annually. We agree with CMS's summary of the proposed rule, that the change would reduce administrative burden without having a negative effect on patient health and safety.

Support for Proposed Changes to Swing Bed Requirements – We support each of the proposed changes to the PPS Hospital and Critical Access Hospital (CAH) Conditions of Participation governing swing beds.

We agree with CMS's summary that there are elements in the cross references between the PPS Hospital and CAH Conditions of Participation regarding swing beds and the Conditions of Participation for long-term care facilities that at best includes superfluous language that could create confusion and at worst create additional work requirements that are generally inapplicable to the types of individuals receiving services in a swing bed.

We support and appreciate CMS's proposed revisions to the PPS Hospital and CAH Conditions of Participation requirements that would:

- *Remove the cross referenced long-term care requirement to offer residents the right to choose to or refuse to perform services for the facility and prohibit a facility from requiring a resident to perform services for the facility.*

  As noted in CMS's summary, it is highly unlikely that an individual in a swing bed will perform services for the facility, thus the long term care rule is incongruous with care provided in a swing bed setting.

- *Remove the cross referenced long-term care requirement to provide an ongoing activity program.*

  As noted in CMS's summary, the required nursing care plan is based on assessing the patient's nursing care needs and supports holistic care, making the specificity of providing an long term care facility-level ongoing activity program unnecessary and burdensome for swing bed providers.

- *Remove the inapplicable cross-referenced provision that a swing bed provider with more than 120 beds employ a qualified social worker on a full time basis.*

- *Remove the cross referenced provision long term care facility requirement to provide routine and emergency dental care.*

  As noted in CMS's summary, given the typical short-term stays in a swing bed setting, providing routine dental care in such setting makes little sense, and emergency services are available 24/7 at the hospital providing the swing bed service.

<u>Support for Option to Use a System-Wide QAPI and Infection Control Program</u> - We support CMS's proposal to provide multi-hospital systems with flexibility to maintain a single, integrated Quality Assessment and Performance (QAPI) and a single, integrated infection control program for all of its members rather than requiring separate programs for each hospital.

Building upon the 2014 final rule that permitted multi-hospital systems to use a unified medical staff model under a system governing body, we agree with and appreciate CMS's intent to allow hospitals the flexibility to establish system-wide QAPI and infection control programs.

Under this proposed rule, hospitals in a multi-hospital system could either continue to retain their existing individual hospital-based QAPI and/or infection control program, or instead meet QAPI and/or infection control program requirements in the Conditions of Participation utilizing an overarching system-wide program. Particularly for systems that already have overarching system-wide coordination and direction of individual hospital QAPI and infection control programs, it is unclear what the extent of administrative savings could be achieved by shifting the compliance obligations to a system governing body. However, we appreciate the flexibility the proposed rule affords hospitals and systems to allow them to evaluate the costs and benefits of shifting the compliance obligation to a system governing body.

<u>Support for Proposed Changes to Emergency Preparedness Program Requirements</u> – We support each of the proposed emergency preparedness program changes that will reduce unnecessary regulatory burden.

Periodic Review of Emergency Preparedness Programs

Under current CMS regulation, hospitals and other providers are required to develop and to maintain or implement (1) an emergency preparedness plan, (2) emergency preparedness policies and procedures, (3) an emergency preparedness communication plan, and (4) an emergency preparedness training and testing program—all of which must be reviewed and updated at least annually. In the proposed rule, CMS proposes requiring hospitals and other providers to review and

update their emergency preparedness plan, policies and procedures, communication plan, and training and testing program at least every two years, instead of annually.

We support this proposal because the current annual requirement is unnecessarily burdensome and inflexible and does not improve patient health and safety.

Documentation of Efforts to Cooperate with Emergency Preparedness Officials

Under current CMS regulation, hospitals and other providers are required to include in their emergency preparedness plans a process for cooperating and collaborating with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. In addition, hospitals and other providers are required to document their efforts to contact such officials and to document any participation in such cooperation and collaboration. In this proposed rule, CMS proposes eliminating this documentation requirement but retaining the requirement that hospitals and other providers have a process for cooperation and collaboration with emergency preparedness officials.

WHA supports this proposal because the current documentation requirement is unnecessarily burdensome and does not improve patient health and safety.

Periodic Staff Training on Emergency Preparedness Programs

Under current CMS regulation, hospitals and other providers are required to provide initial training in emergency preparedness policies and procedures to all new and existing staff and to provide additional training at least annually. In this proposed rule, CMS does not propose changing the initial training requirement but does propose (1) requiring hospitals and other providers to provide emergency preparedness training at least every two years, instead of annually, and (2) requiring hospitals and other providers to conduct training when the hospital's or other provider's emergency preparedness policies and procedures are "significantly updated."

WHA supports the proposal to reduce the frequency of required periodic training to every two years instead of annually because the current annual requirement is unnecessarily burdensome and inflexible and does not improve patient health and safety.

Annual Emergency Preparedness Exercises

Under current CMS regulation, hospitals and other providers are required to conduct two exercises annually to test their emergency preparedness plans. One of these annual exercises must be a full-scale exercise that is community-based or facility-based. The other annual exercise must be a second full-scale exercise or a tabletop exercise. In this proposed rule, CMS does not propose changing the requirement that hospitals and other providers conduct two exercises annually, but for the annual exercise where the provider may choose between a second full-scale exercise or a tabletop exercise, CMS proposes to expand the exercise options to a second full-scale exercise, a tabletop exercise, or *a mock disaster drill*.

WHA supports this proposal to allow a mock disaster drill to satisfy one of the two annual exercise requirements because the proposal affords hospitals and other providers some additional flexibility to tailor their emergency preparedness exercises to their needs.

Thank you again for the opportunity to comment. If you have any questions, please contact Matthew Stanford at (608) 274-1820 or mstanford@wha.org.

Sincerely,

Matthew Stanford
General Counsel