American Hospital Association™
Advancing Health in America

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November 4, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) **writes to express significant frustration and concern with the Centers for Medicare & Medicaid Services' (CMS) delay in releasing critical sub-regulatory guidance in a timely and clear manner**. Providing high-quality care to patients is the highest priority for our hospitals and health systems.

As you are well aware, the Conditions of Participation (CoPs) set forth broad requirements that hospitals must meet in order to participate in the Medicare program. Failure to comply with the CoPs results in potential termination from the program, a consequence that would severely jeopardize the operational sustainability of most hospitals. We agree that these requirements are necessary; and given the utmost importance of patient safety and the gravity of CoP noncompliance, meeting all CoP requirements is an integral piece of both long-term and day-to-day decision-making processes for our members. However, to properly interpret and understand how the CoPs interact with the specific circumstances of all hospitals and health systems, our members rely on interpretive guidance to fill in the gaps, provide clarification and offer direction. CMS's continued failure to provide this critical guidance has severely hampered our members.

Two recent examples – ligature risk and hospital co-location – illustrate both the immediate and long-term impact of CMS's failure to publish guidance. As discussed in more detail below, the lack of meaningful clarity on these two issues has resulted in confusion, missed opportunities to improve patient access and care, unnecessary expenses, and an unpredictable forecast for how the agency intends to proceed.

Ligature Risk. Treating patients who pose a threat to themselves or others is a vital but challenging task for hospitals and medical staff. These patients require that a specific set of policies are in place to ensure not only the specific patient's safety, but also the safety of other patients, family members and staff. As such, hospitals need to have policies in place to, at the very least, mitigate, and, if possible, eliminate the threat and risk of harm. While hospitals fully understand the precautions necessary to treat these patients, they currently lack the guidance necessary to ensure that their policies and infrastructure comply with the Medicare CoPs.

Hospitals have requested interpretative guidance on this issue for some time, and AHA staff have had numerous conversations with CMS on the issue dating back to 2017, including a letter sent in October 2018 urging action on ligature risk. While CMS released draft guidance for comment in April 2019, it has failed to follow through and publish final guidance. This is concerning, as hospitals need to know what additional training or surveillance protocols need to be put in place, and they need to know how the policies will impact engineering and facility-specific infrastructure decisions. The agency's lack of follow-up is not only problematic but dangerous. Finally, as ambiguity around ligature risk standards remain, a lack of clarity and the agency's recent silence on the issue have left open the opportunity for a difference in surveyor opinion during the surveyor process, something our members already are experiencing, and an issue that likely will worsen as the policies remain unresolved.

Hospital Co-location. As is the case with ligature risk guidance, our members continue to wait for CMS to release final guidance pertaining to hospital co-location. Over the course of several years, AHA staff have raised the issue of co-location with CMS. Specifically, AHA first requested clarification in 2015, followed by a letter to the agency on the issue. Draft guidance finally was released in May 2019.

The ability for hospitals and other health care facilities to co-locate and share space represents an important step in streamlining services and expanding access to care in various capacities across the country. When possible, hospitals are eager to explore partnerships with other hospitals and health care facilities in order to provide better, more coordinated care to patients. For example, in urban and suburban areas, two hospitals, such as an adult general acute care hospital and a children's hospital or a psychiatric hospital, may be co-located to improve efficiency and access for patients. In rural areas, hospitals may lease space to visiting specialists from out of town several days per month.

The option to enter into these types of agreements is especially vital for small and rural hospitals, which do not have physicians on staff at all times and rely on visiting physicians to provide care that would otherwise require patients to travel long distances to visit the nearest hospital for that specific care. However, without clear language establishing the option to co-locate, as well as a regulatory framework for compliance, those hospitals, and ultimately patients, that stand to benefit from co-locating cannot and will not do so for fear of noncompliance with the Medicare CoPs. This not only

affects the immediate provision of certain services, but it has long-term impacts on how hospitals budget, renovate or invest in new construction in the future.

We urge the agency to release final guidance for both ligature risk and co-location. However, these represent only two specific issues facing our members. There is no doubt that delays in critical interpretative guidance from the agency on other issues, now, and in the future, will present difficulty and stagnation for hospitals seeking to do the right thing.

We appreciate the intent of the President's recent executive order outlining when the use of agency guidance is appropriate, but believe guidance still plays an important role in the health care field. Our members rely on CMS to meet its obligation to communicate expectations for hospitals and health systems. As a result, CMS must either decide, under the requirements of the executive order, to begin issuing long-awaited interpretive guidance or develop alternative approaches to keep hospitals and health systems informed and updated on Medicare CoP compliance.

In the absence of guidance, we urge CMS to consider the following recommendations focused on stakeholder engagement and information-sharing:

- Host a quarterly call with stakeholders to provide updates and answer questions;
- Issue a statement setting forth CMS's interpretive guidance plan in light of the Executive Order; and
- Transition to an annual, predictable set of dates for the release of CoP-related notices of proposed rulemaking and final rulemaking.

Thank you for your attention to this matter, and we look forward to your response. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director of policy, at mhowell@aha.org or (202) 626-2317.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development