



Advancing Health in America

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September 4, 2020

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

RE: Interpretive Guidance For CMS-3401-IFC

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) urges the Centers for Medicare & Medicaid Services (CMS) to withdraw the condition of participation (CoP) that hospitals report daily COVID-19 data. However, given the significant implications of this new requirement, if the agency is intent upon moving forward with this misguided policy, **we request that CMS immediately release detailed interpretive guidance so hospitals can take the necessary steps to come into compliance.**

The COVID-19 pandemic has challenged the entirety of our nation's health care infrastructure in an unprecedented way. New hot spots continue to emerge and COVID-19 surges across the country mean that America's hospitals and health systems must be prepared to act at a moment's notice should a new wave of cases strike their respective communities. As we continue to navigate the difficult terrain of this public health emergency, certain steps must be taken to help mitigate the existing challenges. One of those steps is the availability, collection and analysis of valuable COVID-19 data. These data, like intensive care unit (ICU) bed capacity, drug and personal protective equipment (PPE) inventory and acquisition issues, can help guide the best path forward for a coordinated response. The data offer significant insight into how the federal government – collaborating with local and state governments – can best work



with our member hospitals to make critical decisions that allow efficient and effective operations on the front lines of the nation's response.

In late March 2020, the Department of Health and Human Services (HHS) initiated its request –for daily data reporting from hospitals but did not mandate these reports. Still, from the outset, the AHA and our members took this request very seriously, and responded in good faith. In fact, hospitals continued to report data when HHS made a series of sudden, significant and often confusing process changes to the federal government's COVID-19 hospital data collection. HHS already has altered the reporting process for hospitals more than a half dozen times since its inception in March; however, the field's unwavering commitment to providing HHS with the data remains strong. HHS' own data shows 94% of hospitals are reporting data to the agency.

In short, partnership – not mandates – have helped provide the federal government with the data it needs to respond to this unprecedented pandemic. The recent announcement that daily COVID-19 data reporting will now be a CoP only serves to significantly strain these partnerships between the federal government and America's hospitals.

This heavy-handed regulatory approach furthermore sends the wrong message to struggling hospitals and health systems, whose financial viability is potentially jeopardized as they struggle to meet overly burdensome regulatory requirements. Rather than insist on penalizing those hospitals in the middle of a pandemic, the federal government should consider ways in which it can offer the necessary resources and assistance to ensure proper data reporting.

This issue is further compounded by the fact that the agency failed to seek and consider stakeholder input on the potential benefits and challenges that may accompany such a rule. Instead, it published an interim final rule, which immediately became effective upon publication in the Federal Register, effectively bypassing critical procedural safeguards that are in place specifically to discourage rushing an action of this scale.

Lastly, CMS's decision to introduce a CoP has only heightened hospitals' confusion by omitting critical details about how previously established data reporting processes relate to the new CoP; how CMS will measure compliance; and what enforcement process the agency will follow.

The AHA believes the introduction of a new data reporting CoP is unnecessary, unhelpful and unfair, especially given hospitals' robust, good-faith response to date. Moreover, we are disappointed by the lack of critical detail in the interim final rule. **Given the significant implications of this new requirement, we urge CMS to release detailed interpretive guidance immediately so hospitals can take the necessary steps to come into compliance. Specifically, we ask the agency to address the many issues described in detail in the attached document.** At the very

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least, hospitals need to know who is require to report the data, how CMS will measure compliance and data completeness, and the agency's enforcement process.

Providing safe and effective high-quality care is the top priority for America's hospitals and health systems. In that effort, we remain committed to continuing to work as partners with the federal government to ensure communities across the country are best positioned to respond to the COVID-19 pandemic. However, the approach outlined by CMS fails to acknowledge the COVID-19 environment in which each of our members is operating. Increasing burdens on hospitals without substantial benefit and justification, while also failing to provide the necessary clarity for implementation and enforcement, only will result in increased confusion as providers allocate an already stretched-thin set of resources to accomplish a task that most already are performing voluntarily.

While we intend to submit detailed comments in response to the interim final rule, the issues addressed in this letter present unique circumstances requiring an immediate and comprehensive response. Please contact me if you have questions, or feel free to have a member of your team contact Akin Demehin, AHA's director of policy, at (202) 626-2326 or ademehin@aha.org, or Mark Howell, AHA's senior associate director of policy, at (202) 626-2317 or mhowell@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer