

November 2, 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: CMS-3401-IFC

Dear Administrator 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) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Aug. 25 interim final rule on COVID-19 data reporting. These requirements are a heavy-handed regulatory approach that threatens to expel hospitals from the Medicare program if they fail to comply with frequently changing and confusing COVID-19 data collection efforts. **We urge CMS to immediately withdraw the new condition of participation (CoP) as well as eliminate the civil monetary penalty (CMP) provisions that would apply to laboratories that fail to report certain data.**

The COVID-19 pandemic continues to challenge our entire health care infrastructure in unprecedented ways. While hospitals and health systems have steadfastly cared for our patients, they also have faithfully dedicated time, attention and resources to comply with numerous data reporting requests at the local, state and national levels. The AHA and our members understand the critical importance and value of providing data – such as the number of COVID-19 positive patients, number of intensive care unit (ICU) beds available, and days available of personal protective equipment (PPE) – and take seriously our role in the data collection and submission process.

As the Department of Health and Human Services (HHS) continued to alter the reporting process and modify expectations for data submission, our members responded and adjusted their processes to fulfill new requirements. The federal government has acknowledged through public communications on multiple occasions



that 94% of hospitals were reporting the requested data prior to the release of the interim final rule. Thus, CMS' decision to threaten hospital Medicare participation is a direct rebuke of the clear willingness displayed by America's hospitals and health systems to provide all relevant data to the federal government. It threatens not only to negatively impact the collaborative work in which our members have engaged, but also needlessly jeopardizes the financial viability of hospitals across the country on which millions of Americans rely. The previous success of COVID-19 data reporting was built on partnerships not mandates; the agency should continue along this path and reject pursuing this unnecessary approach to COVID-19 data reporting. In moving forward with this interim final rule, the agency is abandoning collaboration and teamwork for a heavy-handed regulatory approach.

Adding to hospitals' frustration is the agency's decision to implement this policy through an interim final rule. Given an interim final rule becomes effective upon publication in the Federal Register, by using this avenue CMS has bypassed the traditional notice-and-comment rulemaking processes meant to inform agency decision-making, thus effectively ignoring input from key stakeholders like the AHA and our members. This process is used when there is tremendous urgency to address an issue such that it cannot wait for public input, as is required by Congress for major changes in policy. Yet, we do not understand how CMS can claim that there is an urgency for these data since, as previously stated, the vast majority of hospitals were already submitting information, and have repeatedly shown their willingness to try to accommodate the many changes in the data requested. Moreover, it took more than six weeks to release corresponding interpretive guidance. It is challenging to understand how these new requirements are of the utmost importance when the agency itself remained undecided about what data it is looking for and how hospitals are expected to comply. In short, CMS' approach from start to finish has undermined the very credibility of its argument that there is no time to waste in implementing these new requirements.

In addition to our serious concerns with the CoP provisions of this rule, the agency's decision to implement CMPs for laboratory noncompliance with reporting requirements raises red flags. Similar to hospitals, laboratories have had to wait for over six weeks for CMS to provide the kind of clarifying interpretive guidance they needed to fully understand how CMS would assess compliance and what kind of documentation they need to substantiate their compliance to on-site surveyors. Furthermore, at a time when our nation needs as much testing capacity as possible to rapidly detect COVID-19, imposing penalties on laboratories on a narrow part of what they do (i.e. data reporting) seems profoundly misguided. Laboratories need support and guidance, not penalties that threaten to deprive them of resources they need to fulfill their vital function.

Our more detailed comments follow.

HOSPITAL CONDITIONS OF PARTICIPATION FOR DATA REPORTING REQUIREMENTS

The AHA strongly opposes the use of CoPs as an enforcement mechanism for the agency's data reporting requirements and urges the agency to rescind this provision and rethink its approach with a focus on fostering partnership as opposed to implementing mandates. CoPs exist to establish standards that hospitals must meet in order to participate in the Medicare and Medicaid programs. According to CMS, "[t]hese health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries." Certainly, our members recognize the importance of standards, like infection control policy, which protect and keep safe providers and the patients whom they treat. **However, utilizing the CoPs, as the agency does here under the guise of infection control policy, is both troublesome and problematic. Such action fails to recognize the intent of the CoPs and takes lightly the extreme weight that noncompliance carries.** In fact, arguably, this action erodes and demeans the value of the CoPs and establishes a disturbing precedent of relying on CoP-level enforcement to meet any demand the agency seeks to impose upon hospitals and health systems. Of course, as evidenced by the work of our members, the value and importance of this data is undisputed, but the approach employed by the federal government lacks a substantively supportive argument to move forward.

Moving beyond the concerning use of a CoP to enforce this mandate is that the vast majority of hospitals and health systems have made every effort to satisfy the department's data reporting request. Yet, on page 54826 of the Sept. 2, 2020 Federal Register, the interim final rule states, "[w]e believe that these reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of COVID-19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide." It is important to remember that CMS need not monitor data submission because that task belongs to and remains the responsibility of HHS. CMS is merely acting as the enforcement arm once it receives notification from HHS of hospital noncompliance. **This is a concerning premise on which to base the need for the new data reporting requirements. America's hospitals and health systems already, day-in and day-out, have affirmed and reaffirmed their commitment to protecting the health and safety of all patients by caring for patients on the front lines of this pandemic, while also submitting requested data.**

This policy directly contradicts CMS' stated intent to reduce burden. Instead, these actions will increase burden and strain resource allocation to mandate a requirement that already is being met by the vast majority of hospitals. For those hospitals currently in compliance, **the new requirements undoubtedly will necessitate additional resources to ensure continued compliance and demonstrate proof of data**

submission to CMS when necessary, which has the potential to take away from patient care resources.

Finally, while the recently released interpretive guidance for hospitals provides important information pertaining to CMS' expectations, questions and concerns remain. For example, while hospitals already have begun receiving notification letters as set forth in the enforcement process, the letters do not provide the information the hospital needs to understand what data sets are missing. Ensuring that hospitals know which data are missing is critical for compliance, and we expect CMS and HHS to work together to provide that information. Further, confusion remains around when optional data sets will become mandatory and at what percent hospitals must provide data fields to be found in compliance with the requirements. **If the agency decides to move forward with these requirements, we expect it to work directly with HHS to update guidance and provide communications to the field as necessary to ensure that hospitals have all information required to meet the agency's demands.**

LABORATORY DATA REPORTING REQUIREMENTS

The AHA opposes CMS' policy of making the reporting of COVID-19 testing data a CoP for laboratories. We urge CMS to rescind this CoP, or at a minimum, to rescind the rule's provisions imposing CMPs on labs for non-compliance. Our nation's ability to respond to the COVID-19 pandemic depends upon access to timely, accurate laboratory testing for the disease. So many other public health interventions to contain and respond to COVID-19 – isolating the infected, quarantining those who have been exposed, contact tracing, deploying material and human resources to the geographic areas that need it – depend upon knowing who and how many have the disease. We agree that state and federal governments need to know the COVID-19 test results from labs to inform the broader public health response. Yet, instead of supporting labs in reporting timely, complete data to their states, CMS is choosing an approach that is not only needlessly punitive, but also confusing to labs.

As previously noted, laboratories have had to wait well over six weeks for CMS to issue clarifying interpretive guidance on how to comply with the CoPs. But the initial guidance issued on Aug. 25 indicated that CMS intended to enforce the CoP using only surveys for initial certification, recertification, or complaints, along with surveying a sample of those holding certificates of waivers. Subsequently, laboratories learned that CMS would look only for documentation that the laboratory had transmitted positive or negative test results on each patient to their state departments of health.

While we appreciate CMS limiting the scope of its enforcement activities, this approach introduces confusion with the COVID-19 result reporting mandated by the Coronavirus Aid, Relief and Economic Security (CARES) Act. Under the CARES Act, laboratories are required to report to their states not only positive and negative results, but also other much more detailed demographic data on every COVID-19 test performed. HHS issued a guidance document on June 4, 2020, which outlined these requirements and asked

laboratories to come into compliance with them by Aug. 1, 2020. The Centers for Disease Control and Prevention (CDC) augmented this guidance with more detailed technical specifications to describe how laboratories could report the data to their states. Yet, neither CDC nor HHS have indicated how the reporting requirement would be enforced. Furthermore, there has been significant confusion about which data elements are “required” for reporting, as opposed to “requested.” These distinctions are critical to know because many hospital laboratories have expressed concerns about the level of burden required to report many of the data elements. For that reason, laboratories have been eager to understand what aspects of the CARES Act reporting requirements would be enforced – and by when – to ensure they could allocate resources appropriately.

Yet, CMS has indicated subsequently that the more detailed CARES Act requirements would be outside of the scope of their enforcement activities. Unfortunately, this approach leaves laboratories no better off than they were before – they still do not know exactly how the reporting of the more detailed CARES Act reporting requirements will be enforced, and now face potential penalties from CMS for non-reporting. Furthermore, even within the much more limited scope of CMS’ enforcement, many questions remain unanswered by interpretive guidance. For example:

- Do the laboratories have to show that the test result data were successfully received by their states, or simply that the laboratory transmitted them?
- If a laboratory were to inadvertently miss the reporting of one or two patients, does that immediately put them out of compliance with the CoP?
- What process should labs follow to appeal a finding of non-compliance? Is it the same or different from that used as a part of the regular survey process?
- What level of documentation should laboratories retain to substantiate that they have reported test results?

We urge CMS to issue additional interpretive guidance as soon as possible to address these questions.

CHANGES TO QUALITY MEASUREMENT REQUIREMENTS

The AHA supports CMS’ policy of not using data from quarters one and two of 2020 to calculate performance in its hospital quality reporting and value programs. In March 2020, CMS invoked the programs’ extraordinary circumstances exception (ECE) policies to make the reporting of data optional for quarter one and quarter two 2020. We agree with CMS that using optionally submitted data may result in biased performance comparisons and result in unfair program performance calculations. This is especially true since, as the agency points out, the time of the COVID-19 public health emergency is unlikely to reflect true hospital performance.

CMS also notes that it may propose to not apply payment adjustments in program years where it determines that, as a result of measure reporting exceptions, it has insufficient

data to calculate national performance in a reliable manner. **The AHA agrees with this concept, but we also urge CMS to ensure its policies around whether to apply hospital value program payment adjustments in upcoming years are data-driven and fully transparent to hospitals and the public.** The pandemic's unprecedented impact raises many questions about whether CMS will have quality performance data that are complete and representative enough to tie hospitals' Medicare payment to their performance. For that reason, we urge CMS to ensure its reliability analyses assess whether any particular hospital types, or any geographic areas, are disadvantaged by the exclusion of data. Furthermore, the detailed results of these analyses should be made public over the next several fiscal years, regardless of whether CMS determines it has sufficient data to apply payment adjustments.

NURSING HOME PROVISIONS

Nursing homes play a critical role in providing a coordinated continuation of care for certain patients. The COVID-19 pandemic has brought to the forefront areas where nursing homes can and should improve to better manage and care for patients during a public health emergency now and in the future. Given that recognition, we understand the purpose behind the mechanisms to enforce testing requirements as established under the CARES Act, but caution CMS not to use the approach of CMPs. Rather, providing detailed guidance on how to implement these requirements successfully and offering assistance where needed likely will better prepare nursing homes for compliance as opposed to threatening financial loss. Nursing homes are vital partners for our members, and we want to be sure they have the tools, skills and resources necessary to meet the challenges we all are facing.

LIMITS ON COVID-19 TESTING

In the interim final rule, CMS establishes that Medicare now limit reimbursement to one COVID-19 diagnostic test per beneficiary. CMS' stated rationale for this decision centers around concerns about fraudulent practices related to testing, as well as concerns around patients receiving the proper care without a provider ordered test. **The AHA opposes this policy and fails to find the agency's justifications sufficient for such a drastic policy shift by the agency.**

Specifically, the agency in this rule emphasizes the importance of COVID-19 data collection and patient safety, **yet its efforts to limit testing directly contradict those very goals.** Additionally, should Medicare keep this policy in place, there is real potential for other payers to follow suit, resulting in widespread delays in access to vital testing. Practically speaking, this change will force Medicare beneficiaries to seek a provider referral for testing at any point they believe they may have been exposed to COVID-19. That approach fails to recognize the importance of taking a test and receiving results as soon as possible in order to make decisions necessary to help contain and limit the spread of the virus. **This is a short-sighted and inappropriate approach to containing and slowing the spread of the virus.** If the agency is

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concerned about fraudulent behavior, we recommend it consider a monthly limit on testing per beneficiary. **Simply put, failure to amend this policy has the potential to work against current testing efforts, ultimately contributing to additional spread of the virus.**

Please contact me if you have questions, or feel free to have a member of your team contact Akin Demehin, director of policy, at 202-626-2326 or ademehin@aha.org, or Mark Howell, senior associate director of policy, at 202-626-2317 or mhowell@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President