Federation of American Hospitals®

Charles N. Kahn III
President and CEO

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

Re: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; 85* Fed. Reg. *54,820 (Sep. 2, 2020)

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above-referenced Interim Final Rule with Comment Period (IFC) regarding Clinical Laboratory Improvement Amendments (CLIA); the Patient Protection and Affordable Care Act; and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (PHE).

The COVID-19 pandemic has placed unprecedented strain on healthcare systems, requiring them to prepare for, and respond to, surges in COVID-19 patients while also treating their non-COVID patients. The FAH and its member hospitals understand the importance of the

reporting, collection and analysis of national-level COVID-19 data, such as emergent cases and intensive care unit (ICU) capacity, to mitigate the effects of the spread and impact of COVID-19 on patients, healthcare workers, and the general public. However, the FAH believes the introduction of a new condition of participation (CoP) tied to data reporting is unnecessary and inappropriate. It undermines the successful and ongoing collaboration hospitals have had with CMS to date and unnecessarily puts patients at risk if a hospital were forced to close for being unable to submit data, especially for reasons beyond the hospitals' control, or for not reporting data elements that do not have any utility in the context of mitigating the COVID-19 PHE. ***The FAH continues to urge you not to tie hospital reporting of this data to a condition of Participation (CoP) for the reasons discussed below.***

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs to Report COVID-19 Data As Specified by the Secretary During the PHE for COVID-19

CMS currently is requiring hospitals and critical access hospitals (CAHs) to report information in accordance with a frequency, and in standardized format, specified by the Secretary during the COVID-19 PHE. The Agency points to the *COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting* (updated July 29, 2020) for the current list of data items specified. The new reporting requirements at §§482.42(e) and 485.640(d) are applicable as of the date of the publication of the IFC in the Federal Register, i.e., September 2, 2020.

Although the IFC was effective immediately upon publication on September 2, 2020, it lacked specificity and clarity, including which data elements would be required under the CoP and how frequently each would need to be reported. Interpretative guidance was not made available until October 6, 2020 and, until that time, hospitals were limited in their ability to take the necessary steps to come into compliance. Throughout the PHE, hospitals have expressed their desire to collaborate with public officials to help mitigate and address the COVID-19 pandemic, including through reporting COVID-related data elements. This process, however, has been riddled with challenges beyond the hospital's control; beginning with the shift from the Centers for Disease Control and Prevention (CDC) NHSN, a long-standing and well-understood reporting system four months into the reporting effort, errors in data processing between states and the Department of Health and Human Services (HHS), changes to data reporting elements issued with insufficient warning, and multiple changes to the submission template structures, are some of the challenges hospitals have faced.

The sudden and shifting expectations – on unrealistic timelines – coupled with a lack of clarity due to delayed guidance has resulted in hospitals not having enough information to comply with these new and inappropriate requirements. The challenges for hospitals reporting accurately and timely include but are not limited to:

- Complete and sudden change of data submission mechanisms after four months of operating on a long-standing and well-understood reporting system;
- The loss of state-based reporting to HHS, on behalf of the hospitals, as a result of states needing to recertify under the new reporting system. States that achieved certifications did so at different times, and some achieved certification and later lost it. For instance,

Florida sent out a letter indicating their certification and ability to report for hospitals on September 11, 2020, but then issued a hospital reporting update as recently as October 22, 2020 directing hospitals to report directly to HHS via TeleTracking™ citing the changes in reporting requirements as no longer beneficial for them to perform this role;

- The addition of data fields with timelines for submission that do not account for the operational implications and burden associated with collection and submission of the data;
- The lack of a clear, reliable data dictionary that would ensure consistent collection and reporting of data elements across hospitals;
- The request by HHS that hospitals report data they themselves do not collect and at frequencies that are unrealistic as illustrated in the letter below;
- The delay in release of interpretative guidance for over a month after the IFC was effective;
- Submission templates that change in format and data naming conventions with little to no warning;
- Insufficient support from CMS, HHS, and states, including access to subject matter expert contacts to answer questions on a timely basis. Although this has improved over time it is variable in how helpful a particular contact can be; and
- The absence of confirmation that the data has been received after submission.

While we continue to assert that such a compliance requirement linked to the Medicare CoP is inappropriate, we find it most troubling that the agency has not fulfilled its duty to ensure providers can comply. Consistent guidance, a clear communication strategy that provides ample and realistic reporting timeframes, and access to subject matter experts through listening sessions and office hours are needed to help ensure a successful and realistic data collection. ***While the webinars provided on this topic on October 20 and 22, 2020 are a step in the right direction, the FAH urges HHS and CMS to work with hospitals to address these issues and provide the support necessary to ensure hospitals are not unfairly penalized or set up to fail.***

<u>Complex Data Pipelines Not Under Hospital Control</u>

The way the HHS COVID-19 data submission system has been architected – and the corresponding CMS CoP requirements – hold hospitals completely at risk for penalties and solely accountable of successful reporting, making the reporting not appropriate to tie to a CoP. However, when hospitals submit data through the state, the data are required to transverse through a complicated, non-standardized data pipeline lacking central control, oversight or validation processes. In addition, hospitals do not receive any reports or validation on whether the data elements they submitted have been successfully received by HHS Protect when they submit via the state.

To date, many hospitals have been erroneously blamed for non-reporting when the data they submitted failed to either be properly sent on by the state intermediary, or improperly managed upon receipt by HHS. Upon implementation of TeleTracking™, many states were not ready to perform this role of intermediary for months. They also have different methods of managing missing data – some which involve rejecting the entire submission. All of these processes have implications for what HHS receives and when it receives it.

Tying a CoP to a data collection process with multiple and variable intermediaries and an unreliable, non-standardized and unvalidated data submission pipeline is, at best, ill advised. Multiple and uniquely complex data pipelines, with dataflow designs that vary by state, sets the stage for future pipeline management problems that are completely out of a hospital's oversight or control.

The FAH again urges CMS to rescind the CoP for hospital data reporting. At a minimum, the FAH urges HHS and CMS to work with states to align their data requirements to those of HHS and improve their reporting and to provide hospitals with timely feedback reports validating the success of their submission prior to entertaining the application of any penalties.

Timeframes Granted to Hospitals to Respond

As discussed, data reporting is not appropriate as a CoP given the short timeframes that hospitals have had to respond to data requests. Since the beginning of the data reporting process, the administration has required quick turnaround times for hospital reporting without properly considering the time hospitals need to implement changes to accommodate the reporting. Unfortunately, hospital burden has been underestimated. On July 13, after four months of reporting via the CDC NHSN portal, hospitals were informed via email that the CDC NHSN portal would be removed as an option for COVID-19 hospital reporting. Hospitals were instructed to instead submit the data elements using the TeleTracking™ portal by July 15. This change required hospitals to shift the way they were reporting data to a different mechanism with an interface, template, and functionality that substantially differed from the NHSN -- ranging from the mechanisms for data entry, update, validation and correction of data, as well as the mechanism for accessing support. Since July 15, there have been approximately six changes to the data template, some issued without advance warning and one as recently as October 19, 2020, with notification on October 17, 2020. In the latter case, a timeframe was given that allowed for an overlap in the submission of both the old template and the new template, which the FAH appreciates. In some instances, however, such as the template change of July 28, 2020, substantive changes were posted on the Release Notes page hours before the changes were implemented. These abrupt changes leave hospitals insufficient time to process and reformulate updates.

The FAH cannot overstate the importance of validating the feasibility and utility of data collection efforts as well as the importance of properly estimating lead times for shifts in data reporting requirements or reporting templates. When hospitals need to report additional data, this often requires a vendor request or an operational process change. Neither of these actions can be completed in the short timeframes that HHS often has provided to date. ***The FAH urges HHS and CMS to engage the hospital industry for feedback, prior to issuing changes in data collection efforts. These discussions should focus on the feasibility and utility of requested data collection efforts, including the burden on, and reasonable timeframes needed for, hospitals to adapt to changes in data reporting requirements. Further, the Agencies should allow hospitals ample time to prepare for these changes***.

Data Collection and Reporting Burden on Hospitals

The guidance issued in the October 6, 2020 IFC regarding *Requirements and Enforcement Process for Reporting of COVID-19 Data Elements for Hospitals and Critical Access Hospitals*, details all the required data elements for hospital reporting. The FAH appreciates CMS excepting fields 25, 28, and 32 from reporting, and in reducing the frequency of reporting for psychiatric and rehabilitation hospitals to weekly rather than daily. However, we are concerned that some of the mandatory daily-reporting data elements, which impose substantial burden, may have little utility for the mitigation of COVID-19.

Hospitals and health systems understand the value of data reporting and analysis in support of their commitment to providing safe and high-quality care to our patients and, in particular, towards the mitigation of COVID-19. However, increasing burden without a clear line of sight to the utility and benefit of the data during a time when hospitals are strained by the ongoing response to the COVID-19 pandemic is counterproductive. There is no clear indication to support the prescriptiveness of reporting daily on certain data elements that hospitals themselves do not collect at that frequency for the day-to-day operations, management, and evaluations of their systems, for instance, counts of staffing, supplies, and beds.

Beds and staff are not counted by hospitals daily. Staffing is projected ahead of time, and local determination of staffing needs per hospital is calculated weekly as a function of projections for adaptation to unexpected changes in patient volume, seasons, day of the week, and pre-determined thresholds identifying critical staffing needs. Beds are also not counted daily as they do not change so drastically day to day. With the COVID-19 surge, hospitals may implement a monthly notification process across divisions in which notifications are made to facility management when beds open or close. Implementing this requirement daily not only enormously increases burden but fails to generate utility due to the infrequent nature of the changes. Further, daily notifications and data recording of this nature creates noise by adding notifications that drown out important information. Through monthly reporting, hospitals can manage their bed counts effectively by adding and subtracting as beds open and close respectively. If hospitals can manage their operations without daily bed counts, it is not clear what utility is provided by the daily collection of this data.

If CMS insists on continuing to link the Medicare CoPs to this data collection requirement then at a minimum, the FAH requests that HHS be transparent about how it intends to use requested data elements toward the mitigation of COVID-19 when hospitals either do not collect or do not collect at the requested frequency for their own operations. In addition, the agencies should work with hospitals to determine the utility of a specific data element in light of the collection and reporting burden, particularly for elements that are collected manually or otherwise not tracked daily.

The reporting of this data has required substantial resources being redirected towards supporting activities related to the reporting. These activities include the interpretation of regulation, redesign of workflow and systems, new builds and supports of templates for electronic medical records (EMRs) as well as interfaces to extract the data, interaction with state departments of health to troubleshoot failures in successful reporting and related requirements,

and ongoing efforts to ensure correct interpretation and clarity when communication has not been timely or sufficiently clear. These activities are estimated to require an additional 120 person-hours per week in some health systems.

The FAH urges CMS to ensure that any additional data elements, template changes, and other requirements tied to data collection efforts are clearly connected to mitigating COVID-19 and to validate the absolute need of the changes and additions contemplated against the investment of effort and resources on the part of hospitals.

For small and rural hospitals, the jump from approximately 30 to 100 required data fields was an unprecedented and substantial burden. Small and rural hospitals have fewer resources and staff with the expertise required to implement these reporting requirements. In these cases, hospitals have to leverage staff members across multiple departments, including front line clinicians, to collect the data, which takes them away from patient care during a critical time. With decreased volume of staffing and COVID-19 surges, small and rural hospitals face extraordinary challenges to fulfill these requirements daily. For health systems with multiple small and rural hospitals, system level and automated reporting is also challenging as many of these hospitals have variable and/or legacy EMRs. The strain of this burden, the constancy of seven day a week reporting, while still caring for patients, puts our healthcare providers at further risk of burnout. This is particularly concerning in underserved rural areas.

Help Desk Responsiveness and Subject Matter Expertise

Helpdesk responsiveness is key to successful data submission and collection efforts, and the FAH appreciates that the TeleTracking™ helpdesk has been very responsive. However, the level of support and training of the TeleTracking™ helpdesk differs from that which hospitals were accustomed to with CDC NHSN. With CDC NHSN, there was access to contacts with subject matter expertise in infection control. The TeleTracking™ helpdesk focuses mostly on data entry technicalities and may serve as the middleman between hospitals and those with subject matter expertise. This has led to misinterpretation of data queries, as well as to miscommunication between HHS communications to providers and the TeleTracking™ help desk responses to hospitals. In particular, when the first informational round of letters via emails went out, many of the hospitals reaching out to TeleTracking™ were erroneously told that they did not receive the email due to their high rates of compliance. This was decidedly misleading as during the informational call on October 6, 2020 it was stated that all hospitals for which HHS had contact information would receive an a letter via email describing the guidance and letting them know whether or not they would be considered in compliance. This experience revealed a breakdown in the delivery of the informational email letter – with potentially severe implications if the issue is not resolved prior to the period when enforcement begins on November 19, 2020.

The FAH urges HHS and CMS to implement validation and correction strategies when TeleTracking™ helpdesk personnel respond to hospitals with information that is incorrect or are unable to answer a query in a timely fashion. The access to subject matter experts and correct answers are vital to successful reporting – and of dire importance when hospitals are facing decertification from Medicare when out of compliance with the CoP.

Reporting Feedback

The reporting system, as it has been set up to date, does not provide feedback to hospitals on the success and completeness of their submission to HHS. Feedback on reporting is a basic tenet of data submission processes, and one to which hospitals are accustomed to through their vast experience with submitting data to CMS and CDC for quality reporting and performance programs. Without visibility into the receipt of their submission to HHS, hospitals are unable to validate any aspect of the data delivery process, making this inappropriate to tie to a CoP. This raises the obvious concern among hospitals as to whether their submissions successfully traverse the data pipeline and are received by HHS.

Although there is no information about providing feedback to hospitals in the IFC or the guidance, HHS indicated during an informational call on October 6, 2020, and via the webinars of October 20 and 22, 2020, that they intend to provide hospitals with feedback on their submission receipts issue a release of reports indicating submission of data by hospitals. The data on completeness of data received by HHS from hospital submissions went live on October 27 on a public website.

While hospitals have been complying with the reporting requirements at high rates, there has been substantial error in the recognition of that success on the part of HHS due to the complexity of the aforementioned data pipeline. In a process so prone to and riddled with processing errors, and for which guidance to hospitals was both delayed and provided and in piecemeal fashion, the chances are high that the public release of hospital reporting data will be error-prone, confusing, and ripe for misinterpretation. In addition, while the FAH applauds CMS for reducing the frequency of reporting by psychiatric and rehabilitation hospitals to weekly and reducing the frequency in which certain fields need to be reported for acute care hospitals and CAHs from daily to weekly, it is not clear that the general public would be aware of these details and thus could misconstrue published reporting frequencies.

While the FAH strongly supports and encourages HHS and CMS to provide hospitals with feedback on their reporting efforts, we question the value of doing so through a publicly accessible interface. At a minimum, any publicly reported data should first be shared with the facilities to address errors, and the FAH also urges HHS and CMS to be explicit about how to interpret the data through the public interface to ensure it is not misconstrued by the public.

Recommendations

A successful reporting platform should have at a minimum the following features:

- The functionality to allow updates and corrections to historical data since the time of implementation. If errors are encountered in the process of data entry or processing, the ability to issue corrections is important to ensure data integrity;
- The functionality that allows systems to report on behalf of their hospitals at the enterprise level in batch format, prior to requiring data submission;
- The functionality to issue validation reports upon successful receipt of data;

- Up-to-date and accurate hospital identification data that is validated regularly to ensure correctness and currency;
- A proper data dictionary: clear definitions for each data item requested that leave no room for interpretation, removes the ambiguity of the data collection effort, and ensures the validity of the data for purposes of national comparison;
- A clear and duplicative communication strategy to all reporting hospitals by email outlining anticipated changes with enough time to allow for hospital implementation changes;
- Responsive and substantive helpdesk personnel; and
- Regular educational webinars and listening sessions.

The FAH respectfully requests that HHS and CMS implement the above recommendations.

C. Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19

Under the IFC all laboratories that perform or analyze COVID-19 tests are required to report test data, all negative and positive results, regardless of method used or CLIA certificate held by the laboratory. In addition, facilities using point-of-care COVID-19 testing devices under a CLIA waiver are also required to report. Beginning September 23, 2020, reporting failures result in a condition-level violation of the CLIA regulations with a civil monetary penalty (CMP) of $1,000 for the first day of noncompliance followed by an additional $500 for each subsequent day of noncompliance. At the end of August, CMS issued surveyor guidance for reporting COVID-19 laboratory test results for CLIA-certified laboratories. The reporting requirement and ensuing penalties for noncompliance will continue for up to one year after the end of the PHE.

The FAH is disappointed that guidance related to the requirements for laboratory reporting were not included in the guidance released on October 6, 2020. There are currently many questions that continue to go unanswered that hinder hospital's ability to respond to the requirement. ***The FAH urges CMS to delay any enforcement activity until interpretive guidance is available, listening sessions are conducted and laboratories have sufficient time to comply.***

<u>System-Level Uploads and Feedback Reports</u>

The lab reporting solution currently offers no option for system-level uploads nor does it provide hospitals and laboratories with feedback reports of successful receipt of submission. Health systems with many hospitals across many states have an infrastructure set up that provides central system-level reporting for the hospitals. Without the option for these large health systems to submit for the various hospitals, the burden on hospitals is severely augmented.

In addition, as with hospital reporting, hospitals that must rely on the state for reporting have no way of validating the submission or its content. As hospitals are the only ones in the data submission pipeline held at risk of penalties, it is necessary for them to receive these notifications.

Finally, the cost to health systems for the development of interfaces for each state in which they operate is substantial. It would be more efficient to have one central platform to which hospitals can report to.

The FAH strongly urges CMS and HHS to enable a federal-level solution that supports centralized reporting for laboratories such as the AIMS platform or TeleTracking™.

Communications

There has not been sufficient access to subject matter experts to answer questions related to laboratory reporting. This has left hospitals unable to get the support they need to understand the requirements or interpretation of certain data elements. In addition, the Protect-ServiceDesk has at times issued conflicting information. For example, a hospital was told that its state would be reporting COVID-19 electronic laboratory data on behalf of the hospital and that the hospital would not need to report data directly through the HHS Protect Form. Twenty days later, the lab reporting working group issued a notice stating that this same state was not yet sending the COVID-19 electronic laboratory reporting and that the hospital should continue to report laboratory data directly through the HHS Protect Form. It is unrealistic to expect hospitals to succeed when the very instructions they receive are conflicting and unpredictable.

The FAH requests that HHS and CMS host listening sessions and/or webinars to support facilities taking steps to come into compliance and that HHS ensure the help desk and other subject matter experts are aligned in their messaging.

Placing States in the Critical Path Before They had the Necessary Capacity

Lab reporting efforts experienced challenges with state submissions, as states were lagging in acquiring the capability to report. There has been no clear guidance on whether laboratories in states who were not ready to receive the information would be exempt from the reporting. To address this issue some laboratories began to save faxes as proof of reporting. However, the IFC discounts faxes and pdfs and requires laboratories to report despite some states not having the ability to receive data. As an interim solution, these labs received a web link where they would manually have to enter the data until the states could enable their functionality. Also, the manual reporting weblink is less efficient forcing health systems to develop a process for manual entry instead of reporting as one file for an entire system.

The FAH requests that HHS and CMS ensure that states have the proper functionality in place when providing a state-based reporting option.

D. Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing (VBP) Programs in Response to the PHE for COVID-19, and Update to the Performance Period for the FY 2022 Skilled Nursing Facility (SNF) VBP Program

On March 22, 2020, CMS issued ECEs in four quality programs in an effort to remove the data collection and reporting burden placed on hospitals for these programs during the COVID-19 pandemic. These programs include the End-Stage Renal Disease Quality Incentive

Program (ESRD QIP), the Hospital-Acquired Condition (HAC) Reduction Program, the Hospital Readmissions Reduction Program (HRRP), and the Hospital Value-Based Purchasing (HVBP) Program. CMS provided a national level exception for reporting data for these programs for the Q4 2019, Q1 2020, and Q2 2020. Data could still be voluntarily submitted and, if so, would be used for scoring in the programs. This IFC modifies the ECEs granted such that CMS will continue to score any data optionally submitted for Q4 2019 but not use any data for Q1 2020 and Q2 2020 due to concerns about the comparability and representativeness of the voluntarily reported data for these quarters during which the PHE was in effect. In addition, CMS announced that upon determination that there is not sufficient data to reliably measure performance, it may propose through rulemaking not to calculate performance scores or make payment adjustments.

The FAH appreciates CMS choice not to use data that is not comparable or representative in the face of a global pandemic. However, given the unpredictability of upcoming ECE requests and the impact of blanket waivers on healthcare utilization and of physical-distancing requirements on access, the FAH requests that CMS provide public access to its analyses evaluating the reliability of these data by which CMS makes assessments about whether to calculate performance scores or make payment adjustments.

I. Merit-Based Incentive Payment System (MIPS) Updates

The IFC includes changes to beneficiary assignment under MIPS as well as allowing improvement activity credit for clinicians reporting COVID-19 patient data to clinical data registries. CMS expanded the definition of primary care services to include telehealth and communications technology-based services (CTBS) that are already considered primary care services, as well as additional codes that will be treated as primary care services for the duration of the COVID-19 PHE. This expanded definition applies to quality data reporting through the CMS Web Interface or the CAHPS for MIPS survey for the MIPS 2020 performance year and any subsequent year that starts during the COVID-19 PHE. CMS will also allow clinicians who are caring for COVID-19 patients outside of clinical trials to receive improvement activity credit for submitting patient data to a clinical data registry.

The FAH supports these changes and appreciates CMS' recognition of the care delivery changes brought about by the COVID-19 pandemic as well as the importance of incentivizing clinical data registry reporting.

If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,