



# AMERICA'S ESSENTIAL HOSPITALS

November 2, 2020

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

**Ref: CMS-3401-IFC: 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**

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned interim final rule. America's Essential Hospitals appreciates the Centers for Medicare & Medicaid Services' (CMS') work to improve the delivery of high-quality, integrated health care across the continuum. We are deeply concerned about provisions in the interim final rule that tie COVID-19 data reporting to hospital conditions of participation (CoPs). Termination from the Medicare and Medicaid programs would have a devastating impact on essential hospitals, which provide stability and choice for people who face barriers to care. Further, these requirements come at a point when hospitals are recovering from financial losses incurred during the COVID-19 pandemic and, in many cases, still responding to ongoing surge and hotspots.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.5 percent on average compared with 7.6 percent for all hospitals nationwide.<sup>1</sup> These narrow operating margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19.

Essential hospitals are committed to serving all people, regardless of income or insurance status. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health

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<sup>1</sup> Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2018 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2020. <https://essentialdata.info/>. Accessed October 16, 2020.

literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.<sup>2</sup> Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients; however, these circumstances compound our members' challenges and strain their resources. As such, it is crucial the administration offer flexibility and consistency to ensure essential hospitals can continue to provide vital services in their communities.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. These ambulatory networks are a critical asset in essential hospitals' response to coronavirus. They have enabled essential hospitals on the front lines to screen, test, and treat COVID-19 patients. Our members have invested substantial resources in preparing for and responding to the COVID-19 public health emergency (PHE)—including by increasing capacity through alternative care sites, maintaining sufficient quantities of personal protective equipment and other critical supplies, and ensuring staff capacity. These efforts are far from over.

Hospitals have made these investments while facing double-digit drops in revenue due in part to decreasing the number of planned and elective procedures and other ancillary services to stand ready for COVID-19 patients. As a result, essential hospitals face an uncertain financial future and many other challenges as they continue to respond to and recover from the COVID-19 PHE.

**1. CMS should withdraw requirements that hospitals submit COVID-19 data as a Medicare CoP.**

Hospitals, including essential hospitals, were the first providers to voluntarily supply quality data for the public and have been doing so for more than a decade. Our members understand the value of data and have been voluntarily reporting COVID-19 data throughout the pandemic. These data on intensive care unit bed capacity, drug and personal protective equipment supply, and incidence of confirmed COVID-19 offer insight into how the federal government can work with our members to identify trends and address issues of critical importance.

On July 10, HHS issued guidance in an FAQ directing hospitals to send data regarding their patients with COVID-19 and hospital capacity to a central HHS database instead of to the Centers for Disease Control and Prevention's National Healthcare Safety Network, as hospitals had been doing for several months. Since that change in reporting method, hospitals have continued to voluntarily submit data, either directly through Teletracking, or to the state, if a state has assumed reporting responsibility.

On August 25, CMS released its interim final rule with comment period, which included requirements for hospitals effective upon the September 2 publication in the *Federal Register*. In particular, CMS established new requirements in the hospital CoPs for tracking the incidence and impact of COVID-19.

**CoPs are inappropriate levers to accomplish CMS' goal of gaining situational awareness from the field about COVID-19 impact and resource challenges.** The COVID-19 PHE has strained the health care community. Reporting requirements that carry a penalty for noncompliance, resulting in hospitals being terminated from the Medicare and

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<sup>2</sup> Ibid.

Medicaid programs, is like using a sledgehammer to crack a nut. If hospitals are unable to participate in these programs, it could result in hospital closures and irreparable harm to patients who would no longer have access to vital services.

Essential hospitals continue to pivot to address the ever-changing landscape of COVID-19 and provide reliable, high-quality care for all. By all accounts, America's hospitals have responded diligently to gather, report, and update data related to COVID-19, and will continue to do so. **CMS must ensure that the collection of COVID-19 data, as well as the data reporting process, does not add complexity and burden to a workforce already under immense pressure.**

This administration has emphasized the importance of reducing provider burden and focusing on patient care, as exemplified in its Patients Over Paperwork initiative. However, CMS' data requirements are operationally complex and bound to increase regulatory burden, straining hospital systems and staff resources. **We urge CMS to withdraw requirements that hospitals report COVID-19 and related data as part a CoPs, and to work with hospitals to ensure necessary information is voluntarily reported.**

**2. CMS should provide adequate time for meaningful response from stakeholders on policies, before implementation, and prioritize the development of interpretive guidance.**

Burden-reduction efforts should not be limited to the removal of policies; they also should address the time and resources required to interpret and implement new or existing policies. We are disappointed CMS did not give hospitals the opportunity through rulemaking to respond to proposed policies. CMS said waiving the notice-and-comment period was "in the public interest because time is of the essence in tracking the incidence and impact of COVID-19 in hospitals." However, the lapse in time between the interim rule and eventual release of guidance and FAQs ultimately created confusion and impeded hospitals' ability to transition toward reporting through Teletracking.

Pursuant to the interim final rule, the new CoPs became effective September 2, with guidance released weeks later on October 6. Essential hospitals that already operate on low margins and have been on the front lines responding to the pandemic were asked to invest scarce time and resources to interpret and implement new regulations without clear expectations about how to meet the standards or the enforcement process. **CMS should engage in the timely development and release of interpretive guidance before policies take effect.** Further, we encourage CMS to allow providers to review, ask questions, and identify potential unintended consequences of new policy guidance before its release.

**3. CMS should provide further guidance to hospitals and laboratories about the agency's measure of compliance, data completeness, and future data requests.**

America's Essential Hospitals appreciates the opportunity to communicate our members' concerns to HHS on a regular basis through stakeholder calls. For example, stakeholder engagement about reporting burden associated with supply chain elements resulted in a reduction from daily reporting to now once-per-week reporting of these data elements. This example highlights the valued partnership forged over the course of the pandemic, but also the variability of data requests from HHS. For hospitals responding to hotspots, surges, and ongoing supply shortages, this variability leads to confusion and staff time spent contacting "help desks" to troubleshoot data issues. In certain instances, our members report submitting what they, in good faith, believe is complete data to the state, but the data does not reach HHS.

In this case, there is clearly an error in the transmission of data from the state to HHS. Hospitals should not be held accountable for such errors and should have a clear, simple path for resolution.

To date, hospitals have relied on ad hoc guidance documents outlining various reporting mechanisms, deadlines, and formats. CMS notes in the interim rule that a streamlined approach to data reporting along with consistent processes will “possibly reduce future, and urgent, requests for such data.” We agree that consistent processes are critical and include specifying the channels through which hospitals will be informed about reporting formats and definitions. Essential hospitals understand the evolving nature of COVID-19 and the need for flexibility in our nation’s response. However, **our members need consistency in what is expected of them now and moving forward.** For example, CMS has yet to outline data completeness thresholds that will be used as part of the enforcement process outlined in the October 6 guidance. It also is unclear how information provided to CMS will be used to monitor the impact of COVID-19, address resource concerns, and mitigate disparities.

Further, CMS states in the interim rule that the list of data elements required is not exhaustive and the rule gives the HHS secretary discretion to add elements. We already saw this discretion exercised in the October 6 guidance and FAQ document, with the addition of six data fields related to influenza. **The decision to add data elements should include stakeholder input.** Given that most states collect, compile, and analyze information on flu activity year-round, with weekly reports during flu season (October through May), **we urge CMS to use existing public health data reporting methods to the greatest extent possible,** so hospitals can focus on patient care and response to the COVID-19 PHE.

CMS also finalizes requirements that during the COVID-19 PHE, each laboratory that performs a SARS-CoV-2 test must report results in “such form and manner, and at such timing and frequency, as the Secretary may prescribe.” Failure to report will result in a condition level violation of the Clinical Laboratory Improvement Amendments regulations and imposition of civil monetary penalties.

Laboratories have yet to receive detailed guidance related to these requirements. A June 4 FAQ document describes certain data elements as “required” as opposed to “requested,” which is confusing and should be clarified.<sup>3</sup> Further, the interim final rule does not detail a three-week grace period as noted in CMS’ press release.<sup>4</sup> Guidance should explicitly note this grace period, provide specific compliance dates, and set forth an enforcement timeline. **We urge CMS immediately to release detailed interpretive guidance for laboratories.**

#### **4. CMS should consider the unintended consequences of placing limits on COVID-19 and related testing and address concerns about the effect of such a policy on access to care.**

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<sup>3</sup> Frequently Asked Questions: Laboratory Data Reporting for COVID-19 Testing. Centers for Medicare & Medicaid Services. June 4, 2020. <https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf>. Accessed October 26, 2020.

<sup>4</sup> Trump Administration Strengthens COVID-19 Surveillance with New Reporting and Testing Requirements for Nursing Homes, Other Providers. Centers for Medicare & Medicaid Services. August 25, 2020. <https://www.cms.gov/newsroom/press-releases/trump-administration-strengthens-covid-19-surveillance-new-reporting-and-testing-requirements>. Accessed October 26, 2020.

In its May 8 COVID-19 interim rule, CMS allowed broad coverage of multiple instances of testing for a single beneficiary without a physician order.<sup>5</sup> CMS believed broad flexibility in testing and payment was critical given the “heightened risk that the disease presents to Medicare beneficiaries during the PHE for COVID-19.”

In the interim final rule, CMS revises its testing policy and establishes that one COVID-19 diagnostic test and one of each other related test (e.g., influenza related codes) without an order from a physician or other practitioner is reasonable and necessary for Medicare payment purposes. Further testing now will require an order. The agency notes that the policy in the May 8 interim rule was developed based on what was known at the time, and additional information has become available, such that the policies now require modification. However, CMS does not provide further detail as to what information it is relying on when making the decision to pull back coverage of COVID-19 testing without an order.

The agency’s revision of its prior policy has the potential to undermine the nation’s public health response to COVID-19. In its rationale for limiting testing without an order, CMS states that “one test without an order will allow beneficiaries access to urgent testing.” It is unclear what is meant by “urgent testing” and why subsequent testing could not also be deemed “urgent.” CMS’ policy to limit COVID-19 and related testing without an order has the unintended consequence of jeopardizing access to care at a time when patients and communities require stable, consistent health care. **CMS should provide flexibility in its testing policies and avoid creating unnecessary obstacles to receiving timely testing that places patients and communities at risk.**

**5. CMS should make updates to the extraordinary circumstances exception (ECE) granted for value-based purchasing programs and be transparent about data and analyses relied upon to make assessments about future updates across the quality reporting programs.**

America’s Essential Hospitals appreciates CMS providing some administrative burden relief, through the use of the ECE policy during the COVID-19 PHE. This policy also ensures that data from the time of the COVID-19 PHE that are not representative of true performance are not used in public reporting. Specifically, CMS has excluded first and second quarter 2020 qualifying claims from the claims-based measures in its hospital quality reporting and value-based purchasing programs.<sup>6</sup> We support the application of the ECE policy, given the adverse impact COVID-19 could have on quality performance, leading to a decrease in reimbursement.

However, the ECE granted for quality reporting and value-based purchasing programs has ended, with data collection and reporting requirements resuming July 1. We encourage CMS to consider whether applying the ECE policy for additional quarters might be warranted, given the ongoing nature of the pandemic. Even if CMS does not extend the ECE to cover the third and

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<sup>5</sup> Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. Centers for Medicare & Medicaid Services. May 8, 2020. <https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf>. Accessed October 26, 2020.

<sup>6</sup> Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID-19. Centers for Medicare & Medicaid Services. March 27, 2020. <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>. Accessed October 26, 2020.

fourth quarters of 2020, there still is a possibility that a majority of providers will submit ECE requests for those quarters, thereby impeding CMS' ability to make fair comparisons nationally.

There are potential implications of exempting quarters of data from reporting, such as measure reliability and accuracy in future public reporting. It is important to closely examine performance measures or policies in Medicare that are tied to payment. CMS must ensure accuracy and completeness of data submitted. **We urge CMS to conduct measure reliability analyses using shortened performance periods to ensure it has sufficient data to calculate performance accurately. The agency also should make public the results of any such analysis.**

Likewise, as noted in the interim final rule, if CMS does not have enough data to reliably compare national performance on measures, it might propose to not score facilities for the affected program year or suspend prospective application of program penalties or payment adjustments. In these instances, **we request transparency in the data and analyses used to make such determinations.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or [eomalley@essentialhospitals.org](mailto:eomalley@essentialhospitals.org).

Sincerely,

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President and CEO