



AMERICA'S ESSENTIAL HOSPITALS

August 12, 2019

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 Ave. SW
Washington, DC 20201

Ref: CMS-6082-NC: Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the referenced request for information. America's Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services' (CMS) continued work to highlight areas for reduction of administrative burden regarding clinical documentation, health information technology usability and user experience, electronic health records reporting, and public health reporting.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our 300 member hospitals provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth that of other hospitals—1.6 percent on average compared with 7.8 percent for all hospitals nationwide.¹ Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.² Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients. These

¹ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey*. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed August 12, 2019.

² Ibid.

circumstances, however, compound essential hospitals' challenges and strain their resources, necessitating flexibility to ensure they are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

We applaud the administration's efforts to reduce regulatory burdens through the Patients Over Paperwork initiative. We are hopeful the results of this effort will allow essential hospitals to focus more of their time and resources on patient care instead of on onerous administratively burdensome actions. To ensure our members have sufficient resources to continue their work and are not unfairly disadvantaged for providing comprehensive care to complex patients, CMS should consider the following recommendations as it develops future regulatory proposals or subregulatory guidance.

- 1. CMS should examine ways to account for social risk factors in Medicare programs and continuously engage stakeholders to ensure transparency and reduced administrative burden.**

While the health of the U.S. population overall has improved, socioeconomically disadvantaged populations continue to experience a disproportionate share of many diseases and adverse health conditions. Essential hospitals fulfill the complex clinical and social needs of all patients that come through their doors. Our members treat a high proportion of patients with social risk factors—circumstances outside the control of the hospital, such as lack of transportation for follow-up care or limited access to nutritious food—that can affect health outcomes.

Essential hospitals support quality and accountability. What they want—and what their patients and communities deserve—is to be on equal footing with other hospitals for purposes of evaluating quality. When evaluating quality, Medicare programs should account for the socioeconomic and sociodemographic complexities of vulnerable populations to ensure hospitals are assessed on their work, rather than on the complexities of the patients they serve. Differences in patients' backgrounds might affect complication rates and other outcome measures; by ignoring these differences, CMS will skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured.

The failure to risk adjust causes hospitals treating a large proportion of complex patients to face penalties at an increased rate, further diminishing resources at hospitals that often operate at a loss.³ One study found that some programs—like the Hospital Readmissions Reduction Program (HRRP)—lead to persistent penalization for certain hospitals and limited capacity to reduce penalty burden. It is important to strive for quality and performance improvement, and essential hospitals show they are doing that every day in innovative ways and with limited resources. But these penalties might be counterproductive for essential hospitals that treat patients who often are sicker and higher utilizers than those at other hospitals. Further, failing to appropriately risk adjust can mislead and confuse patients, payers, and policymakers by not accounting for the effect of community factors that contribute to worse outcomes. Alternative

³ Reiter KL, Jiang HJ, Wang J. Facing the Recession: How Did Safety-Net Hospitals Fare Financially Compared with Their Peers? *Health Services Research*. 2014;49(6):1747-1766.

structures, that risk adjust as appropriate, might prevent persistent penalization, while motivating hospitals to reduce hospital readmissions.⁴

CMS should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level. Identifying which social risk factors might drive outcomes, such as readmissions, and determining how to best measure and incorporate those factors into payment systems is a complex task but doing so is necessary to ensure better outcomes, healthier populations, and lower costs.

America’s Essential Hospitals urges CMS to include socioeconomic factors—including sociodemographic status, language, and postdischarge support structure—in measure development and risk-adjustment methodology. We look forward to working with the agency to account for social risk factors across Medicare programs.

2. CMS should streamline quality measures across its programs and focus on a core set of high-impact, high-value measures that are meaningful to patients.

Essential hospitals have long supported quality measurement and pay-for-performance initiatives as vitally important tools for improving value. However, continued work to reduce the number of measures and reporting requirements is needed. Although some measures provide useful information, a lack of focus, consistency, and organization has limited their overall effectiveness in improving health system performance. Further, a lack of consistency often leads to inaccurate comparisons of providers and confusion for patients and consumers.

CMS should promote policies that streamline the number of measures used in hospital quality reporting and pay-for-performance programs and focus on high-impact, high-value quality measures. Further, the agency should seek to reduce duplicative data collection activities for quality measurement, such as collecting data once for multiple purposes and programs whenever possible. Also, a set or several sets of “core measures” should be identified that could be used across CMS hospital quality programs and private payer pay-for-performance programs. We applaud CMS’ efforts, through its Meaningful Measures Initiative, to increase measure alignment across programs and reduce provider reporting burden. This is a step in the right direction for quality measurement—to come to a consensus on a set of meaningful measures across providers, patients, and payers—but more work is needed.

Measures should seek to align the efforts of hospitals, physicians, and others along the care continuum, as well as with the data collection efforts of the other providers. Measures also should be administratively simple to collect and report and, to the greatest extent possible, be derived from electronic health records data. Additionally, risk adjustment must be rigorous and account for all factors beyond the control of providers, including socioeconomic and sociodemographic factors where appropriate.

⁴ Thompson M, et al. Most Hospitals Received Annual Penalties For Excess Readmissions, But Some Fared Better Than Others. *Health Affairs*. 2017;36(5):893–901.

We applaud CMS' efforts to increase measure alignment across programs and reduce provider reporting burden. We encourage the agency to continue this work, with input from all stakeholders, to promote improved outcomes while minimizing costs.

3. CMS should work to address interoperability concerns and encourage improved communication between providers and patients without putting further burden on essential hospitals.

America's Essential Hospitals supports efforts to improve interoperability among providers, as well as the use of electronic health record (EHR) technology to improve the information flow between providers and patients. Our members have implemented innovations, including using information technology (IT) to improve population health, using telehealth to reach patients who face barriers to transportation, and using data collected in EHRs to reduce unnecessary readmissions and achieve other improvements in health outcomes. While they have been able to achieve these successes, they also are overly focused on meeting regulatory requirements; this drains staff time and resources that could better be spent delivering high-quality, patient-centered care. As CMS works to reduce administrative and regulatory burden, **we encourage the agency to consider revisions to existing federal programs that will enable providers to fully leverage the potential of health IT while not being constrained by rigid program requirements.**

Most notably, CMS requires electronic clinical quality measure (eCQM) reporting in the Hospital Inpatient Quality Reporting Program and the Promoting Interoperability Program. **Before expanding the number of eCQMs hospitals must report in federal reporting programs, HHS should verify that these measures are reliable and valid and have accurate specifications.** HHS should work with EHR vendors to make electronic reporting of measures a viable option for all hospitals. The data extracted from EHRs differs from the data obtained from chart-abstracted measures and, therefore, is not reliable for display in a publicly reported program. Due to the differences between data extracted from eCQMs and chart-abstracted quality measures, HHS should adopt a validation process and conduct robust testing to ensure data extracted from eCQMs is accurate and comparable to chart-abstracted information. **We urge HHS to ease eCQM reporting requirements until eCQMs are proved reliable and can be reported with minimal disruption to provider workflows.**

It is imperative to also have mature standards and requisite testing of these standards. HHS should ensure rigorous certification criteria for and oversight of EHRs with built-in electronic prior authorization capabilities so software developers deliver functional, safe products. Mature standards also are critical to ensuring patient privacy and secure transmission of confidential patient health information. Cybersecurity threats in the health care space, including through ransomware attacks on providers, point to a need to ensure the security of new capabilities before rushing into implementation.

4. CMS should ensure comprehensive, coordinated substance use treatment and care through alignment of 42 Code of Federal Regulations (CFR), Part 2, with the Health Insurance Portability and Accountability Act (HIPAA) to ensure harmonization and promote integration and coordination of care.

America's Essential Hospitals recognizes the complexity and importance of addressing behavioral health issues, particularly as they relate to improving care for our nation's vulnerable patients. Essential hospitals work to meet the behavioral and mental health needs of their patients by expanding behavioral health services within community health centers, as well as training primary care providers to provide moderate psychiatric interventions themselves. While essential hospitals have deployed innovative approaches to treat patients with opioid and substance use disorders, they continue to face challenges.

As the health community, along with policymakers, builds out an addiction treatment infrastructure, it is imperative for it to integrate substance use disorder, mental health, and primary care services to produce the best patient outcomes and establish the most effective approach to caring for people with complex health care needs. **The modernization of privacy regulations and medical records for people with substance use disorders is a critical component for tackling the opioid crisis and will improve the overall coordination of care in the nation.**

Efforts to revise privacy regulation to support care coordination will be hampered without harmonizing 42 CFR, Part 2 (Part 2) with HIPAA for purposes of treatment, payment, and health care operations. Part 2—federal regulations that govern confidentiality of drug and alcohol treatment and prevention records—sets requirements limiting the use and disclosure of patients' substance use records from certain substance use programs. Separation of a patient's addiction record from the rest of their medical record creates several problems and impedes safe, effective, high-quality substance use treatment and coordinated care.

When patients visit doctors and hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use that need to be factored into treatment and prescribing. However, due to requirements imposed by Part 2, providers are limited in their use of patients' substance use records for certain substance use treatment programs. Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care. As a result, many providers often learn of addiction problems only after an adverse event or an overdose. Part 2 regulations also might lead to a physician treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person had a substance use disorder.

Modifying Part 2 to ensure that HIPAA-covered entities have access to a patient's entire medical record will improve patient safety, treatment, and outcomes across the care delivery spectrum. Further, aligning Part 2 with HIPAA will allow appropriate access to patient information essential to providing safe, effective, whole-person care while protecting this information against unlawful disclosure and use. Without harmonizing

the varying requirements, it will be challenging, if not impossible, to know whether responding to a specific request is, in fact, allowed by applicable law.

The Substance Abuse and Mental Health Services Administration released a final regulation, as well as informational materials and fact sheets on its website, clarifying how Part 2 relates to the exchange of information between providers. However, these steps do not go far enough to mitigate provider concerns. **HHS should work with lawmakers to modify Part 2, allowing for appropriate levels of access for providers to have a complete picture of their patients.**

- 5. CMS should work to ensure fraud and abuse laws, which originally were intended to protect patients from the misuse or use of unnecessary services, do not thwart hospitals' efforts to connect patients to nonmedical care or to foster innovative collaboration outside the hospital walls.**

Under value-based payment models, essential hospitals no longer are expected simply to treat a diagnosis and episode, but to take responsibility for the overall health and outcomes of their patients. Regulatory uncertainty has put essential hospitals in an untenable position. The very activities that essential hospitals undertake to support new delivery system and payment models—activities Congress and CMS have encouraged— increase their exposure under the anti-kickback statute (AKS) and patient inducement civil monetary penalty law, as well as the physician self-referral law, or “Stark law.”

The success of many alternative payment models (APMs) is dependent on patients receiving care from a network of providers who are aligned, integrated, and applying the same evidence-based practices. Under current law, efforts to encourage care within a specific network are viewed with suspicion because referrals are necessarily influenced. Essential hospitals understand non-health care social services (e.g., food banks, counseling, housing and transportation assistance) are critical to achieving effective care transitions and improved outcomes, including reduced readmissions. However, current anti-kickback and patient inducement laws create a chilling effect on innovation and impede necessary alignment between hospitals, physicians, community providers, and patients.

In recent years, the Department of Health and Human Services (HHS) and CMS have adopted program-specific waivers from the Stark law and other fraud and abuse laws to accommodate new payment and care models, including the Medicare Shared Savings Program (MSSP).⁵ The prescriptive nature of these new protections has limited the way providers can organize and collaborate to promote quality, efficiency, value, and access.

Overall, there is a need for clear and comprehensive protection under Stark law, and other fraud and abuse laws for financial relationships designed to:

- foster collaboration and coordination in the delivery of health care;

⁵ 42 CFR Chapter IV, Office of Inspector General, 42 CFR Chapter V, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule. Department of Health and Human Services. October 29, 2015. <https://www.gpo.gov/fdsys/pkg/FR-2015-10-29/pdf/2015-27599.pdf>. Accessed July 24, 2019.

- link payment to quality or outcomes;
- promote accountability for the overall care of patients;
- reward efficiencies;
- enhance access; and/or
- address social determinants of health.

Additionally, with regard to patient inducement under the AKS, protection is needed for incentives that promote:

- patient adherence to treatment plans and healthy behaviors;
- management of chronic diseases;
- appropriate use of health care (e.g., avoiding unnecessary ED visits);
- care within the provider network participating in a value-based payment arrangement or APM; and
- access to nonmedical services that promote health.

Fraud and abuse laws must strike the right balance between preventing harmful and fraudulent conduct and promoting a health care system that does not limit a hospital's ability to provide the full scale of assistance patients might need to maintain optimal health. **We urge HHS to support alignment of fraud and abuse laws with the value-driven health care system of today and, just as importantly, of tomorrow.**

Further, there are no fraud and abuse waivers available for the Medicaid program or uninsured populations, which present unique challenges for essential hospitals. Unlike Medicare, for which the MSSP and similar programs are national models with uniform requirements across the country, reform efforts in Medicaid and for the uninsured vary from state to state, and even from locality to locality. The Medicaid program is meant to allow states to act as laboratories for innovation, testing different models and approaches to payment and delivery system reform for low-income populations. A fraud and abuse waiver or exception that is crafted to protect Medicaid APMs or related activities in one state might not work for another requiring broader protections and greater flexibility to support providers' efforts to transform care for Medicaid and uninsured patients. It is critical that these patient populations and the essential hospitals that care for them are not left out of the movement to value-based payment and APMs. **We urge HHS to think outside the box and consider broader fraud and abuse protections than it has adopted in the past to ensure payment and delivery system reform efforts reach the Medicaid and uninsured populations.**

6. CMS should improve the accessibility and presentation of CMS requirements for public reporting and ensure information presented to the public is accurate and meaningful.

America's Essential Hospitals is committed to transparency and improving the quality of care for our patients. Public health data systems, including those used by the Centers for Disease Control and Prevention, are critical in monitoring quality improvement and driving health outcomes. **We urge CMS to modernize public health data systems to improve data collection and simplify reporting by providers.** Further, we encourage the agency to enhance interoperability of current systems with health information

technology, including the development of standards that ensure the seamless exchange and use of health information and adequate testing of these standards.

Additionally, we urge CMS to engage in robust dialogue with clinicians about their clinical workflows and data collection methods using different submission systems, as well as challenges they have in collection and reporting of quality data. For example, hospitals often must contract with (and pay for) external vendors to collect and report data, which is costly and burdensome. For essential hospitals already operating on low margins, these costs have significant implications. Through this type of information sharing, the day-to-day “costs” of quality reporting can be captured and incorporated into considerations for removal of measures.

Increasingly, patients and providers are working as a team in the delivery of care. As such, both parties must be confident that the information they are presented is accurate and meaningful to ensure the shared decision-making process is not confusing or misleading. It is crucial that the information provided to consumers, including through CMS’ Hospital Compare website, be accurate so it can help them make important decisions about their health care. The use of overall hospital star ratings is not an appropriate measure of quality and can lead to unintended consequences and consumer confusion. Given significant issues with the overall hospital star ratings system, we are concerned it does not serve consumers well, as the information is inaccurate and misleading. **We urge CMS to reexamine the star ratings program and make changes to the methodology to ensure validity and fairness of information reported to consumers.**

7. CMS should provide adequate time for meaningful response from stakeholders on proposed policies, along with enough time to implement such policies, and prioritize the development of interpretive guidance after a rule is finalized.

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 encourage CMS to provide adequate time for all stakeholders to respond to proposed policies through the rulemaking process. Further, CMS should engage in the timely development and release of interpretive guidance.**

Newly finalized rules, such as changes to the conditions of participation for Medicare and Medicaid providers, often become effective before interpretive guidance is released. Essential hospitals that already operate on low margins might invest scarce time and resources to implement a new regulation without clear expectations about how to meet the standards. **We urge CMS to prioritize the development of interpretive guidance after a rule is finalized.** In doing so, the agency will mitigate the possibility that essential hospitals will need to modify implementation efforts once the guidance is eventually released. Further, we encourage CMS to allow providers the opportunity to review, ask questions, and identify

potential unintended consequences of new policy guidance before its release.
Additionally, we urge CMS to provide stakeholders a reasonable timetable for compliance with new standards.

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.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO