June 3, 2019

Seema Verma, MPH
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-9115-P: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals welcomes the Centers for Medicare & Medicaid Services' (CMS') work to promote interoperability and facilitate the access, exchange, and use of health information. We appreciate the agency prioritizing patients' access to their health information by considering the role of a variety of stakeholders in sharing this information. Essential hospitals are committed to using health information technology (IT) to improve the lives of their patients, through population health efforts, telehealth to reach patients who face transportation barriers, and electronic health record (EHR) data to reduce unnecessary readmissions and improve outcomes. Despite these successes, burdensome regulatory requirements drain staff time and resources that hospitals could better spend on delivering high-quality, patient-centered care. As CMS develops policies to advance interoperability and facilitate patients' access to their health information, we encourage the agency to do so in a way that is cognizant of the unique challenges essential hospitals face and that is consistent with the agency's goals of reducing unnecessary provider burden.

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

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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 electronic patient information, 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 they are committed to serving these vulnerable patients. These 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.

America's Essential Hospitals agrees there is a need for the seamless flow of health information across providers, patients, and payers. We appreciate CMS putting forth policies that attempt to achieve this goal. In developing policies for information exchange, we urge the agency to carefully consider the readiness of health IT infrastructure for these requirements, as well as the potential for these policies to create excessive regulatory burdens on providers. Below, we offer recommendations to reduce burden on providers and ease their ability to exchange information with patients, as well as other providers and entities involved in the provision of health care.

1. **CMS should not add health information exchange requirements to the Medicare conditions of participation.**

CMS proposes to revise the Medicare conditions of participation (CoPs) to require hospitals electronically exchange information with other health care facilities or community providers in the form of electronic event notifications upon a patient's admission, discharge, or transfer. **We strongly urge the agency to withdraw this proposal and to identify other means through which it can advance interoperability and information exchange.** We support the agency's efforts to improve interoperability among providers and the use of EHR technology to improve the flow of information between providers and patients. However, the CoPs are not the appropriate policy lever for achieving this goal. The proposed changes do not account for essential hospitals' unique patient populations or the existing challenges to interoperability and information exchange that have yet to be addressed. Further, these changes would create administrative burden and duplicative reporting requirements.

Many challenges remain to attaining a truly interoperable nationwide health IT infrastructure. There are multiple private- and public-sector initiatives to improve the interoperability landscape, but there still is much work to be done to enable providers to easily exchange information. Requiring such information exchange through CoPs—for which noncompliance could result in the removal from the Medicare and Medicaid

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[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 April 15, 2019.
[2] Ibid.

programs—would hold providers to an exacting standard for health information exchange that is not in line with the reality of nationwide progress with this technology.

    a.   <u>Additional health information exchange requirements under the CoPs will duplicate existing requirements, increase provider burden, and detract from ongoing efforts to achieve interoperability.</u>

CMS has prioritized relieving administrative and regulatory burden from providers. Through its Patients over Paperwork initiative, the agency aims to reduce unnecessary burden, increase efficiency, and improve the beneficiary experience. We applaud the administration's efforts to allow essential hospitals to focus more of their time and resources on patient care instead of onerous, administratively burdensome actions. However, **the addition of new CoPs would be a step backward and a new administrative challenge for essential hospitals.**

As major providers of care to Medicaid and Medicare patients, essential hospitals adhere to the regulatory requirements and CoPs they must meet to participate in these programs. CoPs are process-oriented and cover every hospital service and department. These requirements were put in place to protect the health and safety of patients. However, compliance with frequently changing CoPs can place administrative burden on some hospitals, as well as financial stress to invest funds into compliance efforts. CoPs also are typically restrictive in acceptable approaches for meeting the condition, thereby limiting essential hospitals' flexibility to test and implement novel approaches based on the unique patient populations they treat.

CMS already requires hospitals to electronically exchange information with other providers and to provide patients access to their health records as part of the Promoting Interoperability Program (PIP). If they fail to meet these requirements, they face financial penalties. CMS now proposes to add CoPs for hospitals to send electronic patient event notifications to other providers. Imposing duplicative requirements through CoPs would force essential hospitals to use resources to report the same information twice and would not benefit patients. **The addition of CoPs to improve the electronic exchange of information is overly burdensome to hospitals and an inappropriate means to promote interoperability.**

Moreover, adding requirements for health information exchange and patient access through CoPs is premature, given that hospitals currently are focused on meeting PIP Stage 3 requirements. Stage 3 added new requirements for health information exchange and patient access, including the use of application programming interfaces (APIs) to enable patients to access their records. Stage 3 also includes requirements for hospitals to both send and receive health information from other providers. **As such, CMS should not impose similar requirements through CoPs while hospitals work to ensure they are meeting Stage 3 information exchange requirements.**

b. <u>CMS should recognize and mitigate the barriers that prevent health information exchange before imposing new requirements.</u>

Essential hospitals struggle with difficult measures in the PIP, such as the measure requiring electronic exchange of a summary-of-care document and the measure requiring a certain percentage of patients electronically access their health information. The consequences for failing to report or meet benchmarks through CoPs would be even more damaging to hospitals. The result of noncompliance with CoPs is far more punitive when compared with the PIP and could result in hospitals losing the ability to participate in the Medicare program. With the multitude of challenges essential hospitals still face in properly implementing their EHR technology, the use of CoPs in this area could have devastating results to the communities these hospitals serve.

CMS' proposal also is premature given there are no certification criteria for the patient event notifications it would require, meaning hospital EHRs do not necessarily have the functionality to exchange information with other providers through event notifications. Other community providers receiving these notifications similarly might not have the functionality or might not even have certified EHR technology (CEHRT), such as in the case of post-acute care providers and others that have not yet attained the same level of EHR implementation as acute-care hospitals.

Further, CMS has failed to define important terms for how interoperability requirements in CoPs affect essential hospitals. CMS left considerable ambiguity regarding which providers a hospital would have to send event notifications to, other than those who "have an established care relationship with a patient relevant to his or her care." CMS suggests hospitals might consider requesting information from patients or caregivers upon their arrival to the hospital or trying to identify relevant providers through the patient's record. Hospitals will face considerable administrative burden in having to develop processes to identify the recipient of these notifications without clear guidance on who should receive such notices.

The Office of the National Coordinator for Health IT (ONC) has conducted important work in promoting new technology for providers and encouraging increased interoperability. As directed in the 21st Century Cures Act, ONC in January 2018 released the draft Trusted Exchange Framework and Common Agreement (TEFCA), which outlines a set of principles for trusted exchange to enable interoperability.[3] ONC is expected to release a final version of the TEFCA later this year. CMS should allow ONC to continue its work of promoting interoperability before CMS proposes new information exchange requirements.

In addition to creating the TEFCA, CMS must allow ONC to complete additional work as directed in the 21st Century Cures Act—including rulemaking on information blocking and APIs—before taking further action on interoperability. ONC released a companion rule on information blocking and information exchange that addresses many of the important barriers and imposes new requirements on providers and EHR

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[3] Office of the National Coordinator for Health Information Technology. Draft Trusted Exchange Framework and Common Agreement. January 2018. https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf. Accessed April 16, 2019.

developers. CMS should allow stakeholders to respond to this rulemaking and take necessary steps to implement its requirements before imposing additional requirements through CoPs. **Without the required rulemaking from ONC and sufficient clarity from CMS, adding interoperability requirements into CoPs would result in significant confusion and additional burden for essential hospitals.**

    c. <u>CMS should encourage patient-centered care and care transitions while recognizing the challenges essential hospitals face in caring for vulnerable patients with complex postdischarge needs and in implementing CEHRT.</u>

In 2015, CMS proposed revisions to discharge planning requirements for hospitals. In response, America's Essential Hospitals urged CMS to consider the additional challenges faced by essential hospitals and their patients in the discharge planning process. The patients treated at essential hospitals are among the most vulnerable and require extensive time and resources to ensure the discharge planning process is tailored to their clinical needs. Discharge planning for this population also requires consideration of social risk factors outside the control of the hospital, such as homelessness, cultural and linguistic barriers, and low literacy. CMS notes that it is planning on releasing the final rule on discharge planning later this year.

Members of America's Essential Hospitals understand the critical contribution non–health care social services make toward achieving effective care transitions and improved outcomes, including reduced readmissions. One essential hospital in Missouri developed a care transitions program that reduced hospital admissions, ED visits, and costs. This essential hospital identified the need for a multidisciplinary team, bringing together licensed clinical social workers, client-community liaisons, and advanced-practice registered nurses, among other staff, to meet the clinical and social needs of their patient population.

In caring for vulnerable populations, essential hospitals face special challenges, such as identifying a patient's or caregiver's capability and availability to provide necessary postdischarge care, as well as the availability of community-based support, including transportation, meals, housing, and other non–health care services. For example, the successful transfer of patients from one level of care to another, or from one setting to another, requires careful attention to patient care goals and treatment preferences, in combination with consideration of the availability of postdischarge services. Further, patients served by essential hospitals might have language-related and other cultural access barriers. As such, **identifying language needs is important in accurately capturing the patient's care goals and treatment preferences, which form the core of the discharge planning process.**

CMS' discharge planning proposed rule has not yet been finalized, yet the agency's proposals under this request go beyond the proposed rule to require electronic sharing of discharge planning information. This introduces additional complexity and resource allocation issues for essential hospitals. Existing EHR technology remains a challenge for essential hospitals as they adapt to the PIP. While many essential hospitals are leaders in implementing CEHRT, the health care field in general has not reached a

point at which CMS can reasonably expect the seamless sharing of information, particularly between hospitals and community providers.

2. CMS should ensure the security and privacy of data disseminated through APIs.

Throughout the rule, CMS proposes the use of open APIs, whether for insurers, Medicaid state agencies, or providers. APIs are a promising tool that can give patients access to their health information through mobile applications. However, much work remains for ONC to develop certification criteria that ensure these APIs meet program requirements and have mature standards. CMS and ONC have taken some steps in their interoperability rules that would create standards for the use of APIs. However, there are still serious privacy and security concerns about the use of APIs and third-party applications. Recent cybersecurity threats to providers, including in the form of ransomware attacks, are a reminder of the need to ensure the security of new capabilities before rushing into their implementation. CMS must thoroughly vet these issues before APIs are ready for widespread use.

America's Essential Hospitals supports the concept of leveraging APIs to improve information exchange among providers and with patients. Making patient information available to third-party applications, however, could implicate grave security and privacy concerns. While ONC is working on standards for APIs, there are no guardrails for how third-party applications are to leverage and secure patient data once they have received the data through the API. Due to the proliferation of mobile applications, a patient could request access through any application that has not been thoroughly vetted and is new to the market; this could lead to privacy and security concerns. In fact, the health care sector can learn from recent examples in other industries in which user information accessed by third-party applications was compromised.[4] For these reasons, we urge CMS to continue to work with ONC on API and third-party application security standards.

3. CMS should ensure provider directories contain meaningful information that will facilitate health information exchange.

CMS proposes to require hospitals and other providers to update their contact information in the National Plan and Provider Enumeration System (NPPES) to include their digital contact information. Digital contact information can be in any form, including a Direct address. We are encouraged that CMS is taking this step to toward lifting barriers to exchanging information through the Direct Project standard. Direct exchange is a standard for secure transmission between providers and is one method through which providers can exchange information for the purposes of the electronic exchange measure. EHR developers must be certified to enable the use of Direct exchange. However, while developer software is required to be Direct certified, many products have specific requirements for sending and receiving Direct messages

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[4] Fiegerman S. CNN. Hundreds of millions of Facebook records exposed on Amazon cloud servers. April 3, 2019. https://www.cnn.com/2019/04/03/tech/facebook-records-exposed-amazon/index.html. Accessed on May 17, 2019.

that are incompatible with other developer EHRs. Additionally, each provider has a Direct address to be used for transmitting data, but there currently is no centralized directory of Direct addresses that providers can use to locate a receiving provider's Direct address. **CMS' proposal to include digital contact information in the NPPES would be a step toward enabling providers to easily locate other providers' Direct addresses before sending a document.**

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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.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO