



AMERICA'S ESSENTIAL HOSPITALS

August 15, 2016

Mr. Andrew Slavitt
Acting 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-3295-P: Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Care

Dear Mr. Slavitt:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services' (CMS') work to improve quality of care; reduce incidence of hospital-acquired conditions (HACs), including the reduction of health care-associated infections; promote appropriate use of antibiotics; and reduce discriminatory behavior in health care.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Filling a vital role in their communities, our nearly 275 member hospitals provide a disproportionate share of the nation's uncompensated care and devote approximately half of their inpatient and outpatient care to Medicaid beneficiaries or uninsured patients. Through their integrated health systems, members of America's Essential Hospitals offer primary through quaternary care, including trauma care, outpatient care in ambulatory clinics, public health services, mental health and substance abuse services, and wraparound services that are vital to vulnerable patients.

As major providers of care to Medicaid and Medicare patients, our members adhere to the regulatory requirements that hospitals must meet in order to participate in these programs—the Medicare conditions of participation (CoPs) for hospitals. These requirements are process-oriented and cover every hospital service and department. These requirements were put in place to protect the health and safety of patients. As the administration and delivery of health care evolves, it makes sense

to review and revise obsolete, unnecessary, or burdensome provisions in CoPs to ensure continued patient safety, as well as reduce the regulatory burden placed on essential hospitals.

Members of America's Essential Hospitals work daily to improve care quality through a broad variety of initiatives—from reducing readmissions to preventing falls, blood stream infections, and other patient harm events. They have created programs to break down language barriers and engage patients and families to improve the care experience.

As you finalize this rule, we urge you to consider the following comments of particular concern to essential hospitals.

1. CMS should finalize the requirements to ensure non-discrimination of patients on the basis of race, color, national origin, sex (including gender identity), age, or disability, consistent with Section 1557 of the Affordable Care Act (ACA), as well as finalize the proposed expansion of these protections to sexual orientation and religion.

Equitable access to health services is essential to better care, healthier individuals and populations, and lower costs. There is no explicit prohibition of discrimination contained within the current hospital and CAH CoPs. CMS proposes to make explicit the prohibition on discriminatory behavior (perceived or real) by providers, which might be a barrier to seeking care by individuals who fear such discrimination. **America's Essential Hospitals strongly supports CMS in its efforts to reduce discriminatory behavior through explicit prohibition of discrimination within the CoPs. Additionally, we support CMS' proposed extension of these protections to require that hospitals not discriminate on the basis of sexual orientation or religion.**

Research has shown that discrimination of individuals seeking health care can lead to lower quality of care and health outcomes. Two seminal reports from the Institute of Medicine (IOM)—*Crossing the Quality Chasm*¹ and *Unequal Treatment*²—outlined the factors that produce racial and ethnic disparities in health care. In *Crossing the Quality Chasm*, IOM stressed the importance of equity in care as one of the six pillars of quality health care, along with efficiency, effectiveness, safety, timeliness, and patient-centeredness. Indeed, *Unequal Treatment* found that even with the same insurance and socioeconomic status, and when controlling for comorbidities, stage of presentation, and other confounders, minorities often receive lower-quality health care than their white counterparts.

Eliminating health disparities in the United States has risen to the top of the national health care research agenda, and the U.S. Department of Health and

¹ Institute of Medicine Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.

² Institute of Medicine. Smedley BD, Stith AY, Nelson AR, eds. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academy Press; 2002. <https://iom.nationalacademies.org/Reports/2002/Unequal-Treatment-Confronting-Racial-and-Ethnic-Disparities-in-Health-Care.aspx>. Accessed January 2016.

Human Services has identified it as a foundational goal of Healthy People 2020.³ In 2011, America's Essential Hospitals stood with its hospital association peers in a National Call to Action to eliminate health care disparities by increasing cultural competency training, diversity in governance and leadership, and collection and use of race, ethnicity, and language preference data. Additional actions at the national level—by The Joint Commission and National Quality Forum (NQF), and under the ACA—have further underscored the need for providers and facilities to more closely examine health care disparities and identify solutions that provide more equitable care.

We support CMS in its efforts to explicitly prohibit discriminatory behavior through alignment of the hospital and CAH CoPs with the well-established Title VI of the Civil Rights Act of 1964, as well as Section 1557 of the ACA. Section 1557 is the first federal civil rights law to prohibit discrimination based on sex, including gender identity, in covered health programs. While CMS does make specific reference to Section 1557 in the preamble of the proposed rule, we urge the agency to make clear the alignment to Section 1557 in the finalized CoPs to ensure consistency in application of non-discrimination protections.

America's Essential Hospitals believes in the importance of collecting race, ethnicity, and language (REAL) data, which would allow health care organizations to monitor and improve the quality of care for diverse populations. As such, America's Essential Hospitals offers a tool to standardize REAL data collection and show hospital staff how to collect REAL data in culturally appropriate ways⁴—the Ask Every Patient: REAL module. This module supports adherence to standards set by The Joint Commission (TJC) and is accessible through TJC's Resources website.⁵ We support CMS' proposed requirement that hospitals make each patient aware, in a language they can understand, of the right to be free from discrimination against them and to inform the patient on how they can seek assistance if they encounter discrimination.

2. Allow for flexibility in development of infection prevention and control and antibiotic stewardship (AS) programs and adopt a broader approach—i.e., leadership and non-leadership—when considering recommendations for leaders of the AS programs and a designated infection preventionist/infection control professional.

Under the proposed rule, hospitals would be required to develop and maintain an AS program to improve hospital antibiotic prescribing practices; reduce the risk for infections, such as *Clostridium difficile* (*C. diff*); and demonstrate adherence to nationally recognized guidelines for infection prevention and control and best

³ U.S. Department of Health and Human Services. About Healthy People. <http://www.healthypeople.gov/2020/About-Healthy-People>. Accessed January 2016.

⁴ America's Essential Hospitals. Ask Every Patient: REAL. An eLearning Module for Training Staff in REAL Data Collection. Help Sheet, October 2014. <http://essentialhospitals.org/wp-content/uploads/2014/11/Help-Sheet-eLearning-Works-for-Collection-of-REAL-Data.pdf>. Accessed January 2016.

⁵ Joint Commission Resources. Ask Every Patient: REAL Training Module. <http://www.jcrinc.com/ask-every-patient-real-training-module/>. Accessed July 2016.

practices for improving antibiotic use. Additionally, hospitals would be required to appoint both an infection preventionist/infection control professional and a leader of the AS program.

A robust AS program, under the proposed rule, must demonstrate coordination of all components of hospital antibiotic use, including the Quality Assessment and Performance Improvement (QAPI) program, medical staff, and infection control program; document evidence-based use of antibiotics in all departments; and demonstrate improvement and reduction of inappropriate antibiotic use, including reduction in *C. diff* infections.

- a. CMS should allow for flexibility in hospitals' development of their AS programs to promote innovation, advance robust and successful AS efforts, and avoid impeding existing efforts.

It is important that providers have the ability to develop—or continue—their AS program in a way that is tailored to the needs of the populations they serve and consistent with their resources. **America's Essential Hospitals supports CMS' proposed flexibility in allowing hospitals to choose which guideline(s) to adopt as part of their AS program.** Allowing such flexibility is instrumental to the success of a hospital's AS program—both in implementation and resulting outcomes. This flexibility is also important for hospitals and CAHs that already have a program in place.

CMS proposes requirements that hospitals improve their internal coordination among all components responsible for antibiotic use. Our members are already demonstrating that improved connection between hospital departments and medical staff will lead to better quality and healthier patients. For example, in California, one essential hospital brought together seven departments—infectious disease, medicine, emergency, surgery, microbiology laboratory, pharmacy, and quality—to foster antimicrobial stewardship and tackle the hospital's rate of *C. diff* due to antibiotic exposure. Using this collaborative approach, the hospital reduced its rate of *C. diff* due to antibiotic exposure by 68.2 percent between 2010 and the second quarter of 2014. This essential hospital, and its ongoing work to reduce inappropriate antibiotic use, demonstrates both the value of collaborative efforts and the time and resources necessary to bring together hospital departments to produce sustained results. There is the need for flexibility in not only program development to promote antimicrobial stewardship but the timeframe in which hospitals would be expected to show results of such efforts.

Recently, NQF convened key experts to develop a “playbook” for antibiotic stewardship in acute care.⁶ The playbook offers a variety of potential solutions and practices that have been successfully implemented in various acute-care situations and settings. While we support such new efforts by the health care community to provide guidance to hospitals in the area of AS program development, we also recognize that established guidelines from organizations, including the Infectious

⁶ National Quality Forum. Antibiotic Stewardship in Acute Care: A Practical Playbook. NQF Antibiotic Stewardship Action Team, 2016.

Diseases Society of America, Society for Healthcare Epidemiology of America, and the Centers for Disease Control and Prevention (CDC), have already been adopted by many essential hospitals. In particular, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) has formed an Antibiotic Stewardship Workgroup to develop points to consider regarding antibiotic stewardship for antibiotic guidelines. This work by HICPAC will also incorporate elements from previous CDC guidance on antibiotic stewardship.⁷ It is important that CMS finalize its CoPs in a manner that does not disrupt or hinder current practices in AS and allows for flexibility to incorporate future practices that might be put forth. **We encourage CMS to allow hospitals the ability to select and integrate, as needed, those standards that best suit their individual AS programs.**

- b. CMS should allow hospitals discretion in choosing who will provide recommendations for selection of designated leaders for their AS and infection prevention and control programs.

Under the proposed rule, CMS would require that hospitals appoint a qualified (through education, training, experience, or certification) infection preventionist/infection control professional as well as a leader for the AS program. CMS reasons that the proposed requirements for leadership involvement in the selection of these leaders is to enhance accountability and promote a hospital-wide culture of safety and quality.

While we support CMS' efforts to incite change from the top-down—as a means to foster a productive relationship between AS and executive leadership—we **encourage the agency to allow hospitals the flexibility to involve non-leadership staff in the selection process.** For example, pharmacists who will work with the AS program leader as well as the medical leadership—i.e., department/division chief/chair—should work together, with equal influence in the selection process. If the goal of CMS in requiring hospitals designate leadership in both the infection prevention and control program and the AS program is to also encourage collaboration between the two program leaders, it is important to adopt a broad approach to solicitation of recommendations for selection of those leaders. Further, essential hospital members with existing robust AS programs state that collaboration between infectious disease practitioners and clinical pharmacy specialists has improved communication between many previously disparate departments, including the microbiology laboratory, emergency department, and nursing.

Additionally, we encourage CMS to examine other models that might exist—e.g., telehealth/telemedicine with remote consultative services—that allow hospitals to bring the expertise of an infectious disease physician to a hospital's AS program. Hospitals require discretion in the selection of who is most qualified to lead an AS program given the ever-evolving nature of patient care and delivery.

⁷ CDC. *Core Elements of Antibiotic Stewardship Programs*. 2014. <http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf>. Accessed July 2016.

3. CMS should provide clarification of the quality data points required to be incorporated into a hospital's QAPI Program to minimize unnecessary data collection and reporting burden.

Under the proposed rule, CMS would require that hospitals incorporate “quality indicator data” into their QAPI program. These data would include, but not be limited to, patient care data submitted to/received from quality reporting programs such as the inpatient HAC reduction program and the inpatient hospital readmissions reduction program.

We understand that hospitals are already collecting and reporting much of this data, which could potentially serve as a valuable resource to hospitals through incorporation in their QAPI program. However, the ability of a hospital to comply will in large part depend upon a hospital's information technology system and the interoperability of the data—i.e., how easily the data can be transferred. **We urge CMS to recognize the administrative burden that might result from hospitals having to adapt their existing health IT systems to comply with these proposed requirements.**

Additionally, as highlighted by the IOM's Committee on Core Metrics for Better Health at Lower Cost, there is a need to reduce the burden of unnecessary and unproductive reporting by reducing the number, sharpening the focus, and improving the comparability of measures.⁸ If the intent of CMS is to provide a hospital's QAPI program with valuable data to drive quality of care improvement, it is important that hospitals be given the discretion to work with their quality departments and infection prevention and control programs, and choose which data is most important, rather than spend resources reporting existing data simply in a different format. **We urge the agency to provide clarification as to the specific data that would be required to be incorporated into a hospital's QAPI program and to avoid redundancy.**

4. CMS should reduce the administrative and regulatory burdens on hospitals by ensuring that the final requirements for content of medical records are meaningful and avoid lengthy templated information.

The proposed rule would revise the current requirements for documentation to reflect all services provided to the patient in both inpatient and outpatient settings. Among the proposed updates to documentation requirements, CMS includes all practitioners' progress notes and orders, nursing notes, reports of treatments, interventions, responses to interventions, medication records, radiology and laboratory reports, vital signs, and other information necessary to monitor the patient's condition. Additionally, the proposed revisions emphasize the importance of discharge and transfer summaries by requiring hospitals to document these summaries with outcomes of all hospitalizations and provisions for follow-up care for all inpatient and outpatient visits.

⁸Institute of Medicine Committee on Core Metrics for Better Health at Lower Cost. Blumenthal D, Malphrus E, McGinnis JM. *Vital Signs: Core Metrics for Health and Health Care Progress*. Washington, DC: The National Academies Press; 2015.

While most of the elements proposed by CMS are found within the current medical record, having to collate them in a particular location or to document them in a specific way would be unduly burdensome. Additionally, and of particular concern, is the proposed requirement for discharge and transfer summaries documentation. 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 post-hospital services. The patients treated at essential hospitals are among the most vulnerable and require extensive time and resources to ensure that their discharge planning process is tailored to their clinical needs, as well as social factors outside the control of the hospital: homelessness, cultural and linguistic barriers, low literacy, and others. **We urge CMS to avoid lengthy templated information that is less helpful to receiving facilities.**

5. CMS should seek consistency and clarification in the use of Licensed Independent Practitioner terminology to avoid restrictions on hospitals in the use of their medical staff to the fullest extent, in accordance with State law.

CMS proposes changes to delete the modifying term “independent” to allow hospitals to use their physician assistants to the extent of their educational preparation and scope of practice, specifically with regard to restraint and seclusion ordering. For example, the new terminology would allow for the use of restraint or seclusion in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient and authorized by hospital policy in accordance with state law.

The proposed language modification seeks to create consistency and alignment with the movement toward team-based care delivery. Additionally, the proposed terminology might help alleviate some of the workforce shortages plaguing our health care system. **America’s Essential Hospitals supports CMS’ effort to enable practitioners to practice at the top of their license, as compliant with state law, in order for the practitioners to be an efficient and productive resource for the health system.**

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America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Erin O’Malley at 202-585-0127 or eomalley@essentialhospitals.org.