November 19, 2018

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-3346-P: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America’s Essential Hospitals appreciates the Centers for Medicare & Medicaid Services’ (CMS’) work to streamline Medicare’s conditions of participation (CoPs) and other requirements for participation for facilities. Simplification of these requirements allows essentials hospitals to devote already scarce resources to more efficiently meet the health and safety needs of the nation’s vulnerable.

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to providing high-quality care to all. While our members represent just 6 percent of hospitals nationally, they provide 20 percent of all charity care nationwide, or about $3.5 billion, and 14.4 percent of all uncompensated care, or about $5.5 billion.¹ The high cost of providing care to low-income and uninsured patients leaves essential hospitals with limited financial resources. Even with their limited means, our member hospitals demonstrate an ongoing commitment to serving vulnerable patients. Essential hospitals provide specialized services that their communities otherwise would lack (e.g., trauma centers, emergency psychiatric facilities, burn care); expand access with extensive networks of on-campus and community-based clinics; furnish culturally and linguistically appropriate care; train health care professionals; supplement social support services; and offer public health programs.

Essential hospitals 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. Our members’ ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

1. **CMS should finalize proposals to refine emergency preparedness requirements by allowing flexibility in training, testing, and reviewing of emergency programs.**

The services that essential hospitals offer are vital in emergency response efforts nationwide. Essential hospitals, many of which are level I trauma centers, are well-prepared to protect the patients and communities they serve. For example, many of our members have fully staffed command centers for dealing with weather-related issues. This enables the hospital to strategically and methodically tackle problems while maintaining standard operating procedures.

As previously finalized, participating providers and suppliers in Medicare and Medicaid must ensure health care facilities are prepared during natural and man-made disasters and public health emergencies. Specifically, hospitals must maintain and update emergency plans, as well as provide training and testing of same. Facilities are required annually to review their emergency preparedness program, including their emergency plan, policies and procedures, communication plan, and training and testing program. CMS proposes to alter the frequency of this review to at least every two years. **We support proposals to eliminate unnecessary burdens and provide facilities flexibility to review their programs as they deem necessary.**

Further, CMS proposes to eliminate the requirement that facilities document efforts to contact local, tribal, regional, state, and federal emergency officials and facilities in collaborative and cooperative planning efforts. **We agree with the agency that this requirement is overly burdensome and support its removal.** Essential hospitals have dedicated already limited resources to maintaining systems for preparedness and have worked to build partnerships with local services and emergency preparedness teams. Documentation of these efforts would only add administrative burden to essential hospitals already operating on margins below the national average.

2. **CMS should finalize its proposal to allow a unified and integrated infection control program and Quality Assessment and Performance Improvement (QAPI) program for multihospital systems to promote quality, safety, and efficiency.**

Essential hospitals and health systems provide a variety of inpatient and outpatient services for millions of patients across the country. Providing safe, efficient, and effective care in these complex settings is difficult. Integrated care delivery is a critical tool for overcoming these challenges and helping essential hospitals achieve cost-efficient, quality care and focus on population health. CMS continues to encourage hospitals and providers to participate in integrated delivery models that promote value-based care. Many essential hospital systems have made significant investments in developing a system governing body and a unified medical staff to further these
integrated models. **We support CMS’ proposals to allow multihospital systems to have a unified and integrated QAPI and/or infection control program.** This should be an option, not a requirement; each health system should decide to use a unified program based on whether such an approach would lead to better outcomes and resource use.

Essential hospitals are committed to eliminating the occurrence of health care–associated infections (HAIs). Our members are at the forefront of using evidence-based guidelines to prevent HAIs and improve the overall patient experience. Dissemination of innovations and solutions for patient care, through a unified program, would provide the flexibility and ease of management to more readily adopt best practices. Evidence-based interventions have successfully reduced central line–associated bloodstream infections, surgical site infections, and *Clostridium difficile* in many acute-care hospitals, partly because of resourceful, diverse, and skillful hospital infection prevention teams. For example, an essential hospital in Dallas recognized the importance of standardization of care in the recognition and treatment of sepsis. The hospital launched a systemwide initiative to prevent HAIs and sepsis mortality using predictive analysis software in the emergency department that can generate an initial best practice advisory for the treating physician. Since its inception, the initiative has spread to other areas of the hospital. We support CMS’ proposal to allow unification of improvement mechanisms in individual hospitals so that hospital leaders can leverage information and resources across a health system. Again, the decision to structure a program in this way should remain at the discretion of the health system—CMS should not impose this requirement on all hospitals.

3. **CMS should give hospitals the option to develop policies for a simplified patient assessment—in some cases, in lieu of a comprehensive medical history and physical examination—to alleviate undue burden on clinicians, hospitals, and patients.**

Hospital medical staff bylaws currently must require the completion and documentation of a comprehensive medical history and physical exam for each patient; this exam should take place no more than 30 days before or 24 hours after admission or registration, but before surgery or a procedure requiring anesthesia services. Requirements, such as CoPs, must keep pace with the evolving health care delivery system for hospitals to provide the best, most efficient care. For example, certain procedures and certain patients might not benefit from a comprehensive medical history and physical exam, in regard to patient safety or outcomes; for these cases, performing the exam might only increase compliance burden.

CMS should allow hospitals to establish a medical staff policy describing the circumstances under which providers can forego a comprehensive medical history and physical exam for a less burdensome assessment for an outpatient, administered before surgery or a procedure. Hospitals could use such flexibility to develop assessments based on a patient’s proposed procedure(s), in conjunction with a review of their clinical

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presentation and application of the appropriate standards of care, to streamline care in instances that might not warrant a more comprehensive exam. **We support CMS’ proposal to allow a hospital and its medical staff to exercise their clinical judgment in determining the best course of care for patients before specific outpatient surgical or procedural services.**

4. **CMS should continue to refine the CoPs for hospitals and mitigate the administrative burden that remains across all programs.**

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; they were put in place to protect the health and safety of patients. However, some of the requirements might become obsolete as the health care system evolves over time. In addition, compliance with frequently changing CoPs can place administrative burden on some hospitals, as well as financial stress to invest funds into compliance efforts. **CMS should continue to review and revise obsolete, unnecessary, or burdensome provisions in CoPs to ensure continued patient safety, as well as reduced regulatory burden on essential hospitals.** Overall, we urge CMS to provide hospitals the flexibility to shape their programs and policies in the way that best and most efficiently serves the needs of their patients, particularly as hospitals consider new and innovative ways to deliver care to their communities.

The proposals in this rule provide some flexibility to essential hospitals in their efforts to serve the health care needs of the most vulnerable. America’s Essential Hospitals welcomes the opportunity to work with CMS and others to remove outstanding administrative and regulatory burdens, including by streamlining quality measurement and reporting; modernizing fraud and abuse laws in this era of value-based care; and addressing interoperability challenges related to the exchange of health information.

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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,

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President and CEO