



AMERICA'S ESSENTIAL HOSPITALS

September 1, 2016

CMS Desk Officer, CMS-10611; OMB control number 0938-New
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St. NW
Washington, DC 20503

Ref: CMS-10611; OMB control number 0938-New; Public Comments for the Medicare Outpatient Observation Notice

Dear CMS Desk Officer:

Thank you for the opportunity to submit comments on the above-captioned proposed standardized notice for purposes of the “Notice of Observation Treatment and Implication for Care Eligibility Act” (NOTICE Act). America’s Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services’ (CMS’) work to encourage improved care delivery, as well as patient involvement and understanding of services provided across settings. We are concerned that portions of the proposed Medicare Outpatient Observation Notice (MOON) related to its administration and estimated information collection burden might have a negative effect on essential hospitals—those that serve vulnerable patients, first and foremost. With that in mind, America’s Essential Hospitals asks the Office of Management and Budget (OMB) to consider, in its review of the proposed MOON, the unique challenges inherent in caring for these patient populations.

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 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 vital to vulnerable patients.

We ask that OMB take into consideration the following comments as it reviews the

proposed MOON.

1. The MOON should be administered in a manner that ensures comprehension by all beneficiaries and, in particular, those with limited English proficiency (LEP).

The growing number of U.S. patients with LEP experience significant communication barriers when they enter the health care system.¹ For example, successful communication of discharge instructions and paperwork for patients who have LEP has been shown to play a role in those patients' understanding about their follow-up appointments, self-care instructions, and medications.² To improve communication, many essential hospitals have committed to systematically identifying LEP patients and providing language assistance when patients are admitted. With this understanding of the importance of identifying the needs of patient populations, America's Essential Hospitals developed and deployed the Ask Every Patient: REAL training module to show hospital staff how to collect race, ethnicity, and language (REAL) data in culturally appropriate ways.³

We are concerned that neither the current MOON form nor the instructions for its administration address language barriers and low health literacy among patients served by essential hospitals. Essential hospitals treat a population that often has a combination of low educational completion along with a language barrier, which places many LEP patients at double the risk of not understanding critical information. Therefore, it is important that the administration of the MOON—both the text and the oral explanation—be carried out in a language understood by the beneficiary or the beneficiary's representative. **We urge OMB to ensure that the MOON form uses terminology crafted in a way that enhances comprehension by all beneficiaries and, in particular, populations served by essential hospitals.** Additionally, **we encourage OMB to require that the MOON be made available to hospitals in various languages to assist in its administration to patients.**

2. CMS' estimate of collection burden is insufficient.

CMS estimates that delivery of the two-page MOON, including oral examination, will take approximately 15 minutes. It is with this time allocation in mind that CMS calculated the MOON's estimated collection burden. However, we do not believe this estimate of time is sufficient as it does not consider the administrative time necessary to file (hard copy) or enter (electronically) the MOON to document its administration in the patient's medical record. Further, as highlighted above, the populations that essential hospitals treat are likely to require more resources in the

¹ Hasnain-Wynia R, Yonek J, Pierce D, et al. Hospital language services for patients with limited English proficiency: Results from a national survey. Health Research & Educational Trust and National Health Law Program; 2006.

² Karliner LS, Auerbach A, Napoles A, et al. Language Barriers and Understanding of Hospital Discharge Instructions. *Med Care*. 2012; 50(4):283-289.

³ 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.

administration of the MOON, both in staff time dedicated to oral explanation and the use of interpreters, as needed. It is important to fully capture these factors of MOON administration and to minimize their effect on essential hospitals, which already operate with limited resources.

3. The MOON retention requirements need clarification and might be redundant.

Hospitals will be required to retain a copy of the signed MOON and could store the MOON electronically if electronic health records (EHR) are maintained. We seek clarification: If a hospital administers the MOON electronically, will it be required to retain a hard copy in addition to the electronically stored and digitally signed copy in the patient's EHR? Likewise, if the MOON is administered in hard copy, but ultimately stored electronically in the patient's EHR, it is unclear whether the hospital would be required to also store the hard copy version. **We urge OMB to remove redundancy in the retention of the MOON and to simply require that hospitals store one copy of the signed MOON "within the patient's medical record," whether that be in hard copy or in the patient's EHR.** To require storage in both formats would be redundant and a burden to hospitals, and would add a significant time burden.

Further, in the event that a beneficiary has a representative who is not physically present and the hospital administers the MOON by telephone, it is unclear how the hospital would be able to fulfill the requirement for retention of a signed copy of the MOON—i.e., in the case of telephonic administration, there would be no means of obtaining signature. Additionally, we have concerns about the proper identification and verification of a beneficiary's representative, in the event the MOON is administered by telephone, and how such verification should be obtained in a way that ensures patient protections without added burden to hospitals administering the MOON.

4. Notation of beneficiary refusal to sign the notice should be incorporated explicitly into the MOON.

In its notice instructions, CMS describes page two of the proposed MOON form, which has a section for "Additional Information" that can include, but it is not limited to, a notation that a beneficiary refused to sign the notice. There is an important distinction between a beneficiary who has been provided the MOON and refuses to sign versus a hospital not providing the MOON at all. To not explicitly incorporate this notation into the two-page MOON form could lead to unintended consequences, such as hospitals being improperly accused of not providing notice to beneficiaries. Therefore, we urge OMB to require that the notation of a beneficiary's refusal to sign be incorporated as a specific part of the MOON, not as optional additional information. **We encourage OMB to approve a form that includes a section for notation of refusal to sign, located in the area of the MOON form specified for beneficiary signature.**

5. Automation, to the extent possible, should be the goal of the MOON.

Manual processes are resource-intensive for both hospitals and CMS. CMS should work with stakeholders to develop an automated process that appropriately captures information required under the NOTICE Act and encourages beneficiary engagement, while avoiding intense resource use by hospitals. **We urge OMB to perform ongoing analysis of the current notice process to identify any issues that might arise with administration of the MOON, and to encourage CMS to engage stakeholders in the development of an automated process.**

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Erin O'Malley, director of policy, at 202-585-0127.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO