

November 19, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS—3346—P, Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Proposed Rule (Vol. 83, No. 183), Sept. 20, 2018.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on burden reduction, program efficiency and transparency with regard to Medicare Conditions of Participation (CoPs). Specifically, our letter addresses proposed changes in reporting requirements, ambulatory surgery center (ASC) and hospital provisions, and proposals surrounding preoperative medical history and physical examination requirements.

The AHA commends CMS's efforts to reduce unnecessary burdens and reporting requirements. We support the proposals to allow health care systems to opt to take a system-wide approach to Quality Assurance and Performance Improvement (QAPI) and Infection Control with oversight from the system governing board; change current Medicare reapproval requirements for transplant centers; and change the frequency and nature of emergency preparedness testing requirements for hospitals.

However, we believe some of the proposed changes are not based on evidence and could potentially harm patients and hospital staff. Specifically, **we strongly oppose the removal of the requirement that ASCs have a written agreement or physician admission privileges with hospitals. Further, we have some concerns with the proposed elimination of current preoperative medical history and physical examination requirements in lieu of ASCs and hospitals establishing their own**



requirements. Chief quality officers and other clinical leaders with whom we spoke noted that each of these requirements provides important protections for patients when they are undergoing surgery or other procedures. These are times when patients may be at risk for medical errors or other problems with potentially severe consequences. Patients rely on hospitals, health systems and ASCs to have put the right processes in place to avoid such errors to the greatest extent possible.

Our detailed comments follow.

ASC WRITTEN AGREEMENT AND PHYSICIAN ADMISSION PRIVILEGES REQUIREMENT

The AHA opposes CMS's proposal to eliminate the requirement that ASCs have a written transfer agreement with a nearby hospital or ensure that its physicians have admitting privileges at a hospital. We request that CMS withdraw this proposal.

Currently, ASCs are required to have written transfer agreements in effect with a hospital or must ensure all physicians performing surgery have admitting privileges in a nearby hospital. The current CoPs play a vital role in ensuring that ASCs, as well as hospitals and their respective staffs, are well-equipped and prepared to deal with a major and potentially life-threatening complication occurring during surgery. As experience has shown, it is important to create and execute on a plan when something untoward happens during the course of any patient's care.

Most routine surgeries go well and patients fully recover as expected. However, every clinician is aware that the administration of anesthesia and the performance of a surgical procedure carry risk, such as malignant hyperthermia, excessive bleeding, or compromises to the patient's airway. While rare, complications do occur in ambulatory surgery patients, and when they do, the patient's life can depend on the existence of a plan in which the ASC team takes appropriate steps in the moment to both stabilize the patient to the extent possible and transfer the patient to a nearby hospital where additional appropriate treatment can occur. **The transfer agreement is the regulatory mechanism to ensure that there is a plan in place in such emergencies.**

These transfer agreement requirements are important for a number of reasons, including, but not limited to:

- The pathway for the patient to the most appropriate site for continued care can be anticipated, rather than having the patient need to be triaged through the emergency department (ED).
- Expectations of appropriate communication between the treating surgeon/anesthesiologist and the admitting physicians can be laid out so that the hospital team is better prepared and have more information to know what has transpired with the patient and what his/her specific needs are.

- Transfer agreements ensure patients are being sent to the hospital with the appropriate expertise and specialists based on the patients' specific medical needs.

EMTALA Does Not Sufficiently Fill the Void that will be Left

In the proposed rule, the agency relies on the existence of the Emergency Medical Treatment and Labor Act (EMTALA) to justify its stance that the current written transfer agreement requirements are duplicative.¹ We believe that the agency's reasoning is misguided. EMTALA requires that anyone coming into a hospital's ED with an emergent condition must be stabilized and treated, regardless of the individual's insurance status or ability to pay². **While EMTALA is an important safeguard for individuals in need of immediate emergency medical treatment, it is not a replacement for or duplicative of the current written transfer agreement requirements that apply to ASCs.** For the safety of the patient whose ambulatory surgery has created a significant, potentially life-threatening complication, the ASC care team and the hospital care teams have to act as one. A requirement that the hospital team receive, stabilize and treat the patient is not a plan for how the two teams could and should work together. Eliminating the requirement for such a plan is not in the best interest of the patients.

Written transfer agreements ensure that, when an emergency occurs during ambulatory surgery, patients will be admitted to a hospital that knows they are coming and is prepared to treat them. Removing the written transfer agreement requirements muddies the waters of the patient transfer process and raises the likelihood that the ED clinicians will have to run many more tests to diagnose the patient and determine appropriate treatments – taking up precious time in potentially life-threatening situations.

The goal of the CoPs should always be to require that the right structures and processes are in place to provide patients with safe and effective care. While we appreciate CMS's work in weighing this requirements against any undue burden that is placed on hospitals, other providers and their staffs, the importance of patient treatment, safety and well-being must be the primary concern. **By proposing to eliminate the need for a transfer agreement, CMS will put at risk the substantial organizational and patient safety mechanisms that written transfer agreements provide.**

In addition to removing written transfer agreement and physician admitting privilege requirements, the agency intends to require individual ASCs to establish their own protocol and procedures for the transfer of patients to hospitals in instances of an emergency. **This is problematic.** It ignores the fundamental issue that during an emergency, the patient is cared for by two teams that should perform seamlessly together. Without a standard approach like that created by standardized transfer agreements, the hospital team has no way to anticipate what has been done to or for the patient that is being sent. There is potential for significant differences in process across the ASC industry – meaning that hospitals are left to decipher and respond to

¹ 42 CFR § 489.24

² *Id.*

wide and unknown variation in the conditions of patients when patients arrive in their EDs. It is an idea that will likely end tragically for some patients undergoing surgery in ASCs.

Finally, the AHA is concerned by the potential strain that the elimination of this requirement could pose for hospital EDs. The purpose of written transfer agreements is to ensure that incoming patients are admitted directly to the hospital, ensuring that the hospital is aware and prepared to take on that specific patient immediately. Under this proposal, the lack of a written transfer agreement, and, as a result, relying solely on EMTALA, could result in patients being forced to come through hospital ED doors, which are already over-utilized and crowded.

MEDICAL HISTORY AND PHYSICAL EXAMINATION REQUIREMENTS

The AHA is cautious in its response to CMS's proposal to eliminate and replace the preoperative medical history and physical examination (H&P) requirements for hospitals and ASCs. In its proposal, the agency intends to allow individual hospitals and ASCs to make their own determination as to what types of patients and procedures could be candidates for simpler assessments, as opposed to requiring full H&Ps. **We understand and appreciate CMS's thought process in determining the burden that these requirements may create, but, ultimately, we find CMS's reasoning to be premature and, therefore, urge the agency to review the evidence to ensure removing these requirements will not negatively impact patient safety.**

Currently, a full preoperative H&P for all surgery patients, whether in ASCs or hospitals, is required to be done no more than 30 days prior to the scheduled procedure date. In its proposal, the agency intends to remove this 30-day requirement and defer to each individual facility's determination as to which types of patients require full H&Ps and on what timeline the respective H&Ps should occur. Allowing individual facilities to determine internal, service-specific policies often make sense; however, in this situation, the potential for differences in policy across the board make enforcement difficult and potentially creates an uneven playing field for those facilities that opt to be more lax in their H&P requirements.

We believe that, as currently utilized, the 30-day window requirement for preoperative H&Ps sets a reasonable standard and provides real benefit. H&Ps are a simple and straightforward process, and the 30-day window in which they must be performed fails to present a burden justifying their elimination. In fact, preoperative H&Ps sometimes yield critical medical information about surgical candidates. In those instances, this minor regulatory requirement can result in the discovery of vitally important information, allowing clinicians to make necessary changes in patient-specific surgery plans.

The AHA understands the concerns that CMS is attempting to address with this proposed change. Certainly, the amount of detail of preoperative patient history and the

value of physical examinations to obtain a reasonable estimate of perioperative risk remains unclear. **However, we urge you to remain cautious in your approach to this topic, and ask that CMS withdraw this proposal until more evidence-based guidelines become available, perhaps in the form of diagnostic and prognostic prediction studies. Until that time, the 30-day requirement for preoperative H&Ps should remain as it currently exists.**

QAPI AND INFECTION CONTROL

The AHA appreciates CMS's intentions and work to reduce burden where it makes the most sense. **Specifically, we support the agency's proposed changes to the way in which hospitals are required to address QAPI and Infection Control review.** Under this proposed "unified and integrated" standard for hospital systems, CMS recognizes the unnecessary burden that current requirements place on individual hospitals within a larger system. By allowing system-level approaches to quality assurance and improvement projects, we believe CMS is not only likely to reduce burden, but also enable systems to take full advantage of the power they have to use centralized data analytics, standardized approaches, and opportunities to share strategies across the system. We applaud CMS for proposing to allow governing bodies to be responsible and accountable for QAPI and Infection Control reporting. This proposed change would allow systems to streamline and focus their quality data collection and improvement efforts and alleviate significant stress from and work hours dedicated to hospital-level reporting. **Continued efforts to centralize functions within hospital systems allows individual hospitals to spend more time and focus more resources on patient-focused care and treatment.**

While we are generally supportive of this proposed revision, we do believe that individual hospital-specific data should still be recorded and shared with the system governing body. The availability of hospital-specific data can help to identify best practices and processes from those facilities that are excelling in a specific area. Additionally, individualized data provides the opportunity to, when necessary, account for and address outlier performance within the scope of broader hospital systems. As a result, those hospitals that need to make necessary changes and improvements would be easily identified. Further, while allowing a hospital system, under the oversight of the system governing body to handle the bulk of QAPI and Infection Control CoP requirements is a welcome relief, we recognize that there is variation in performance among hospitals and want to be sure that the boards have the opportunity to address hospital shortcomings under the umbrella of an entire system's reporting.

As CMS begins to examine other review and reporting requirements that are best suited for system governing boards, the AHA respectfully asks to be a part of those discussions. We are hopeful that the agency, in consultation with the AHA and other interested parties, will continue to prioritize revising or removing undue regulatory burdens that hospitals face. Further, it is helpful for CMS to understand good

governance practices and require actions from the boards that are consistent with good governance, providing oversight and actions from management that are more operational tasks. We have materials designed for hospitals trustees that may be of use to CMS in distinguishing between governance and management and would be happy to share those with the agency.

TRANSPLANT CENTER SPECIAL REQUIREMENTS FOR MEDICARE REAPPROVAL

The AHA supports CMS's proposed changes to the current special requirements that apply to transplant centers. Transplant centers are not only required to meet all of the CoPs that apply to hospitals, but, they also must meet a series of special requirements in order to receive Medicare approval and subsequent reapproval. As such, any effort to eliminate or revise these requirements in a meaningful way without negatively impacting patient care is deserving of serious consideration.

As discussed in the proposed rule, CMS recognizes the difficulties in accessing organs and choosing recipients created by the current Medicare reapproval system. As the list of patients in need of an organ transplant grows, transplant centers need to be better supported in caring for these patients. The AHA supports the proposed CoP changes that would allow centers to treat more patients without the negative effects of onerous and strict outcome-specific requirements that come with severe penalties. Specifically, current requirements have led to and continue to lead to medical staff recruitment and retention issues, as well as unintended negative impacts directly relating to patient access to transplantation. Transplant centers are currently far less likely to admit riskier transplant patients due to Medicare approval and reapproval quality metrics requirements. "The result is that patients with even an 80 percent chance of surviving one or more years after a transplant present too great a risk for transplant programs. Centers decline to transplant them even as they are throwing away organs that could give those patients years of additional good quality life."³

Further, a "study by [Dr. Adel] Bozorgzadeh, published by the American College of Surgeons, found that the increasing reluctance to perform transplants on the sickest patients is directly tied to the onset of the standards enforced by CMS. In the first five years after adoption of the standards, more than 4,300 transplant candidates were removed from waiting lists by hospitals. That's up 86 percent from the 2,311 patients delisted in the five years prior to the regulation."⁴ Even as CMS has moved in recent years to curb the unintended consequences from the increased regulatory oversight, "patients and doctors are still uneasy about the erosion of one of transplantation's fundamental principles: the sicker you are, the higher you move up the waiting list for donated organs."⁵

³ <https://www.bendbulletin.com/health/1641429-151/too-risky-to-transplant>

⁴ <https://www.pbs.org/newshour/health/hospitals-throwing-organs-denying-transplants-meet-federal-standards>

⁵ *Id.*

The AHA believes that sicker patients in need of transplants should not be penalized by overly burdensome CoPs. As CMS moves forward with regulatory burden relief for hospitals, we believe changes in the special requirements for transplant centers makes sense. Removing the language requiring transplant centers to submit data, clinical experience and outcome requirements for Medicare reapproval should help to remove some of the unnecessary roadblocks that currently stand in the way of centers' ability to treat patients. As mentioned above, if a hospital has the ability and resources to prolong the quality of life for a patient, even if for only a year, they should be given the opportunity to do so without the threat of a clampdown by the federal government.

The AHA supports the proposed change for transplant hospital reapproval. The agency is correct in asserting that even in the absence of these requirements, we expect that transplant centers should and will continue to focus on maintaining high standards with a focus on protecting patient health and safety, while also encouraging and producing positive outcomes for transplant patients.

EMERGENCY PREPAREDNESS

Hospitals and health systems understand and take seriously the importance of emergency preparedness plans and training. In the case of an emergency, regardless whether it is a natural disaster or man-made, hospitals and their staffs play a critical role in ensuring that, no matter the crisis, individuals receive treatment immediately. Incidents like major destructive occurrences, mass shootings or disease outbreaks are a real and present threat, and as such, hospitals and their staffs need to be well-trained and prepared to operate effectively and efficiently in those otherwise chaotic moments. **We believe CMS strikes the appropriate balance with its proposed revision to the emergency preparedness requirements.**

Specifically, we support the agency's proposals to no longer require annual reviews of emergency preparedness programs and annual emergency preparedness training, instead making the requirements biennial. Revising the requirement from annually to biennially would provide facilities with the flexibility to review and address specific programs that call for more in-depth attention based on specific need and likelihood of occurrence. Further, we agree with CMS's assessment that, in instances where an emergency preparedness program is substantially changed or updated, the facility should undergo an additional training to ensure that all staff are aware of changes and prepared for an emergency.

The AHA is reviewing additional provisions of the emergency preparedness training CoPs that may be unduly burdensome for hospitals and their staffs. For example, the requirement that hospitals have a plan in place regarding the use of volunteers during emergencies is an overly time consuming process when, in practice, volunteers are not

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used in times of emergency, even in those locations that have been subject to severe natural disasters. There also are several regulations that are duplicative of CoPs that exist elsewhere, and, therefore, warrant consideration for elimination from this section. As we continue our review, we hope to have more detailed discussions with CMS in order to address these unnecessary requirements.

Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director, policy, at mhowell@aha.org or (202) 626-2274.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development