



[Submitted via <http://www.regulations.gov>]

November 19, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

Dear Administrator Verma:

The American Society of Anesthesiologists® (ASA), on behalf of our 53,000 members, appreciates the opportunity to provide input on this proposed rule focused on reducing provider burden. Through its “Patients Over Paperwork” initiative, CMS has established an internal process to evaluate and streamline regulations with goals to reduce unnecessary burdens, increase efficiencies and improve the beneficiary experience. Although ASA supports the initiative, we believe that prior to any changes or implementation, the Agency should carefully weigh the proposed changes with whether the overall regulatory burden will be reduced or if the burden will be unintentionally shifted to other physicians and healthcare workers. We are providing comment on proposed changes to the Ambulatory Surgical Centers (ASCs), Hospice, Hospitals and Emergency Preparedness for Providers and Suppliers sections.

Physician anesthesiologists deliver care to patients each day in a variety of settings for surgical, therapeutic and diagnostic purposes. Anesthesiology is the practice of medicine that includes, but is not limited to, patient care before, during, and after surgery and other diagnostic and therapeutic procedures, and the management of systems and personnel that support these activities. The practice of anesthesiology includes the evaluation and optimization of preexisting medical conditions, the perioperative management of coexisting disease, the delivery of anesthesia and sedation, the management of postanesthetic recovery, the prevention and management of periprocedural complications, the practice of acute and chronic pain medicine, and the practice of critical care medicine. The most common models of anesthesia practice in the United States are anesthesia delivered personally by a physician anesthesiologist or in a

physician-led team-based model of anesthesia care. This patient-centered care is personally provided, directed, and/or supervised by the physician anesthesiologist.

For decades, CMS Conditions of Participation (CoPs) have ensured that patients receiving surgical, diagnostic and procedural care in ambulatory surgical settings, hospitals, critical access hospitals and other locations receive a certain level and expectation of care. ASA supports the current Hospital CoPs for Anesthesia Services that continues to encourage the highest standard of patient safety in anesthesia. These CoPs have also set expectations for physician responsibilities and shared decision-making and in the establishment of local policies and procedures that ensure our patients receive high quality care. Hospital CoPs for Anesthesia Services are well-balanced and offer appropriate flexibility for states and local facilities.

Ambulatory Surgical Centers

Transfer Agreements with Hospitals

CMS has proposed to remove the requirement for a written hospital transfer agreement or hospital physician admitting privileges at §416.41(b)(3). CMS has indicated that in the absence of a transfer agreement or admitting privileges, ASCs would continue to have access to local emergency services to transfer patients to the nearest appropriate hospital for continued care. Hospitals would continue to be required to provide appropriate screening and stabilizing treatment for patients experiencing emergency medical conditions in accordance with the regulations set forth at §489.24.

ASA cautions CMS against removing the regulation for ASC transfer agreements with hospitals without appropriate safeguards in place. Removing this requirement, we fear, could jeopardize the safety of ASC patients in several unintended ways. Transfer agreements and physician admitting privileges allow for urgent transfer of patients in life-threatening situations. While these situations are rare, as indicated by CMS they occur in 1.25 per every 1,000 ASC patient, they can arise in otherwise healthy patients, are unpredictable and often directly related to surgical or anesthetic complications. These situations require immediate responses and treatment which many times can only be provided in a hospital setting. Policies, or lack of policies, that cause even a small delay in the immediate transfer of these patients will put these patients at significant and unnecessary risk.

On the hospital side of the transfer arrangements, the elimination of the ASC requirement to have relationships with hospitals would require hospitals and clinicians to manage patients of whom they have no context or understanding of the quality of care of the transferring facility. Hospitals and attending clinicians value these agreements to ensure reasonable coordination of

care and allow hospitals to align with facilities that are performing appropriate procedures at the level the ASC can handle.

Instead of removing these requirements for all ASCs, **ASA recommends that CMS consider a proposal targeted specifically at the ASCs who are experiencing issues with written transfer agreements.**

Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

CMS has proposed to remove the current requirements at §416.52(a) and replace them with requirements that “defer to the facility’s established policies for pre-surgical medical histories and physical examinations (including any associated testing) and the ‘*operating physician’s clinical judgment*’ [emphasis added], to ensure patients receive the appropriate pre-surgical assessments that are tailored for the patient and the type of surgery being performed.” CMS has likewise proposed to require each ASC to establish and implement a policy that identifies patients who require an H&P prior to surgery. Such policies would allow flexibility for the 30-day H&P policy that has existed in regulation since 2008 as well as patient age, diagnoses and type and number of surgeries that are scheduled to be performed at one time. CMS cited cataract surgeries and a common misperception that “the ‘vast majority’ of outpatient surgeries are performed in ASCs because they involve extremely low risk of complications due either to preexisting conditions or to the risk of the surgical procedure itself” as reasons to propose these changes.

ASA strongly opposes the proposed revisions to §416.52(a) regarding Comprehensive Medical History and Physical Assessment (H&P) requirements.

The removal of standard ASC policies and procedures for H&Ps will not diminish the regulatory burden but will shift the regulatory burden from surgeons and proceduralists to the anesthesiologist. CMS is proposing that ASCs permit pre-surgery/pre-procedure assessments, when appropriate, in lieu of H&Ps. Such a shift would be detrimental to patient safety and optimal care because, in those cases where an H&P was dismissed or not required by policy, the patient would not have been reliably assessed in a way to determine if there are specific medical conditions that would directly or indirectly impact the outcome of the surgical procedure itself. This scenario would influence an anesthesiologist’s decision-making on proceeding immediately, delay pending optimization or cancelling the case altogether.

Comprehensive and accurate H&Ps completed in a timely fashion allow the anesthesiologist to prepare for cases before and on the day of surgery. On the day of surgery, the anesthesiologist is focused intently on medical risk and immediate safety of the patient. The H&P, with the

anesthesia pre-assessment, allows the anesthesiologist to better understand the patient's pathophysiology, make monitoring and management decisions and determine strategies for mitigating the impact of the anesthetic on the individual patient. The H&P also allows the anesthesiologist to anticipate the needs of the surgeon and the effect the procedure will have on underlying patient conditions during the intraoperative and immediate postoperative period. ASA recognizes that H&Ps are only as good as the surgeon providing the information to the anesthesiologist. An H&P conducted and communicated to the anesthesiologist ahead of time decreases the chance of case cancellations and increases the opportunities for physicians and other healthcare workers to appropriately treat patients in a timely and effective manner.

In moving away from established regulations, CMS would be shifting a significant amount of risk from the surgeon, who had previously been responsible for H&Ps, to the anesthesiologist – the physician most responsible for pre-procedure assessments. If CMS finalizes this rule, ASA would strongly urge CMS to consider how physician payment for conducting the H&Ps is assigned, especially if the anesthesiologist will now be the de facto verifier of a patient's physical and medical status during the pre-procedure assessment. This work is not included in the value assigned to an anesthesia service and, under current billing standards, is not separately reportable from an anesthesia service if performed on the same day of service. National Correct Coding Initiative (NCCI) edits specifically and absolutely prohibit reporting an anesthesia service and an Evaluation and Management (E/M) code on the same date. If a physician anesthesiologist is called upon to perform this additional service, the value s/he contributes and the risk s/he assumes should be recognized by allowing separate reporting of that additional work.

The proposed revisions for the H&P requirements will lead to more delayed cases and cancellations as anesthesiologists may identify patient health issues on the day of surgery that were missed by H&Ps not being completed in a timely or consistent fashion.

ASA often fields questions from our members who feel pressure from surgeons and proceduralists intent on beginning a procedure even if the anesthesiologist does not believe the patient can be safely operated on either because of patient medical characteristics or whether the patient is having the procedure in the appropriate facility. Anesthesiologists, as advocates and champions for patient safety, make those difficult and necessary decisions daily. Case delays and cancellations, caused by a patient not being properly assessed or instructed by a surgeon prior to their procedure, will decrease patient satisfaction and place an additional burden on patients and their caregivers. Patients and their caregivers often take time off from work for their surgery and recovery. Should this proposal be finalized, more patients and caregivers may be exposed to such disruptions to their surgical plans.

The CMS proposal inappropriately vests too much authority and responsibility in the “operating physician’s clinical judgement.” **ASA believes that allowing the operating physician solely to determine appropriate pre-surgical assessments will limit the care a patient receives and confuse facility policies related to who should make the decision on pre-procedure testing.** Anesthesiologists are well aware that pre-procedure testing should be carefully considered and, when deemed unnecessary, avoided. The *first two* recommendations of the [Anesthesiology Choosing Wisely](#) campaign explicitly state for anesthesiologists and other physicians to not conduct certain, unnecessary tests that waste resources and do not contribute to quality care or patient safety. Such decisions on pre-procedural testing are best made in collaboration between multiple specialties, including anesthesiologists, surgeons and other medical consultants as well as patients and their families.

Encouraging greater communication between surgeons, anesthesiologists, other clinicians and patients can best be accomplished through local innovation and leadership rather than through broad regulatory changes. The Perioperative Surgical Home, a patient-centric, team-based model of care created by leaders within the ASA, is a clear example of how anesthesiologists, surgeons, specialists and other healthcare workers can work collaboratively to define roles and responsibilities that reflect their clinical workflows and patient needs. The current CoPs offer a framework for such organizations using the Perioperative Surgical Home model to create efficient workflows, enhance communication and hone leadership skills that drive innovation and patient outcomes while maintaining adherence to current regulation.

Permitting ASCs to develop their individual policies and procedures for circumstances that do not require comprehensive H&Ps will create new burdens for facilities and healthcare workers by increasing compliance requirements in ASCs. The replacement obligations would require ASCs to establish policies for assessments that vary based on a variety of factors that include, but are not limited to, patient age, comorbidities and anesthesia type. CMS also indicates that the ASC should follow nationally recognized standards of practice and guidelines, and applicable State and local health and safety laws. We hope that CMS provides enough guidance for individual ASCs to determine which guideline to use when practice parameters governing a procedure are not aligned or consistent with one another. CMS should provide sufficient deference to guidelines based upon a specialty’s scope and expertise. As currently written, the CMS proposal will easily create a situation where an ASC increases the chance that they deviate from their own policies and unintentionally increase their compliance burden.

In addition, **the difference in policy requirements from one ASC to another would result in inefficiencies and lead to substantial variations in standards of care from facility to facility.** ASCs developing their own individual policies and procedures on appropriate

circumstances for pre-surgical assessments and intraoperative care will complicate patient care for physicians and other healthcare workers who work at multiple ASCs. Anesthesiologists often practice in multiple settings and locations. In moving from one ASC to another, these proposed policy and procedure changes would confuse and complicate how an anesthesiologist should assess a patient's H&P.

Ultimately, these proposed changes to the ASC CoPs related to H&Ps will jeopardize patient safety and undermine patient safety culture. First, patients, physicians and other healthcare workers will encounter different standards of care and assessments across multiple facilities. This may lead to healthcare workers debating proper protocols to use at their facility instead of focusing on patient needs. Second, shifting the burden from surgeons to anesthesiologists in verifying pre-procedural assessments will lead to anesthesiologists identifying additional co-morbidities and conditions that should have been addressed prior to surgery. Such assessments may lead to more case cancellations and delays – a process that could erode the important, professional relationship between surgeons and anesthesiologists. The sweeping changes of this proposed rule would also upend common policies and procedures and increase the risk of a poor culture of safety in ASCs where anesthesiologists, surgeons and patients may not speak up when they have legitimate concerns about the patient's well-being. Last, developing policies that are specific to certain conditions, age of the patient and anesthesia type do not take into consideration individual patient needs. Instead, it would create a culture of carve outs for some patients and requirements for others – especially when a patient has overriding physiological considerations. This confusion would engender more debate and discord locally regarding the type of care a patient should and will receive.

ASA strongly opposes the proposed revisions to §416.52(a) regarding History and Physical (H&P) requirements.

CMS should NOT finalize the proposal changes to Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4)).

Hospice

Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment

CMS is proposing to eliminate the documentation requirement for interdisciplinary group conversations on administration of drugs and biologicals. Anesthesiologists are often called upon to evaluate hospice patients and are included in these interdisciplinary group consultations. ASA believes that continuing the practice of comprehensively assessing patients

on a regular schedule or on an as-needed basis while decreasing the documentation requirements will decrease clinician burden while maintaining a high standard of patient care.

CMS is also proposing to replace the requirement that hospices provide a physical paper copy of policies and procedures to patients and caregivers with a requirement that hospices instead provide information regarding the use, storage and disposal of controlled drugs to the patient (or patient representative) and family that is tailored to the needs of the patient and caregiver(s). CMS explains that this proposal works to eliminate excessive staff time spent explaining complicated technical terms and complex policies and procedures. ASA agrees with CMS that information communicated to patients and families should be accessible and understandable irrespective of literacy level.

ASA strongly recommends that CMS encourage the use of pictorial infographics to disseminate critical information which may be more effective than purely written handouts or verbal communications. Pictorial infographics have been shown to be an effective method of communication of important instructions to patients.¹ ASA recommends these materials be available in both print and electronic large print format for patients, caregivers and family.

ASA believes that this user-friendly approach is a critical opportunity for increased patient and family education about safe opioid storage and the prevention of drug diversion. Policies and instructions on disposal should include information about counting of medication and returning medications to a qualified take-back center instead of disposing them through other methods. ASA has developed materials that can help communicate the extreme importance of safe handling, storage and disposal of opioids and other medications.

We welcome any and all opportunities to work with CMS and other stakeholders to develop patient-centered and understandable materials related to safe opioid use, storage and disposal.

Hospitals

Quality Assessment and Performance Improvement Program (§ 482.21)

CMS has proposed to offer flexibility and regulatory burden reduction to a hospital's Quality Assessment and Performance Improvement (QAPI) program as an option for system governing bodies that directly control and are legally responsible for two or more separately certified hospitals. As with CMS's allowances for system governing bodies and unified medical staffs

¹ McCrorie, A.D., Donnelly, C., McGlade, K.J., *Infographics: Healthcare Communication for the Digital Age*, Ulster Med. J., May 2016, Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4920488/>.

noted previously, the Agency believes that system governing bodies be given the flexibility to determine which model of a QAPI program works best for their individual member and separately certified hospitals.

ASA supports this proposed burden reduction on a unified QAPI and believes that a revised CoP may allow for innovation and updated perspectives beyond a single facility.

We believe that the initial alignment process could be more cumbersome and expensive than CMS estimates but know that common policies and procedures may save money and time over a longer period. Should CMS finalize this rule, we ask that the Agency solicit feedback from different physicians and healthcare workers who work in different facilities under the same health system regarding the efficacy of this rule in future years.

Hospital Medical History and Physical Examination Requirements

The proposed updates of the current requirements at §482.22, §482.24 and §482.51 for comprehensive medical histories and physical examinations will be detrimental to patient safety and will lead to only more complex and burdensome requirements in hospitals. The CMS Hospital CoPs, as currently written, require that a comprehensive medical history and physical evaluation (H&P) be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration but prior to surgery or a procedure requiring anesthesia. CMS is proposing that hospitals could opt to develop and maintain policies that would identify patients not requiring an H&P prior to specific outpatient surgical or procedural services. Unlike the ASC proposal, changes to the Hospital H&P requirements reflect a more nuanced approach as it takes into consideration three different CoPs.

ASA strongly opposes the proposed revisions regarding H&P requirements as described in the Hospital Medical History and Physician Examination Requirements section.

The removal of standard Hospital H&P policies and procedures will not diminish the regulatory burden but will shift the regulatory burden from surgeons and proceduralists to the anesthesiologist. CMS is proposing that Hospitals permit pre-surgery/pre-procedure assessments, when appropriate, in lieu of H&Ps. Such a shift would be detrimental to patient safety and optimal care because, in those cases where an H&P was dismissed or not required by policy, the patient would not have been reliably assessed in a way to determine if there are specific medical conditions that would directly or indirectly impact the outcome of the surgical procedure itself. This scenario would influence an anesthesiologist's decision-making on proceeding immediately, delay pending optimization or cancelling the case altogether.

Comprehensive and accurate H&Ps completed in a timely fashion allow the anesthesiologist to prepare for cases before and on the day of surgery. As currently stated in the CoPs, a complete history and physical examination “in all cases, except for emergencies, must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.” On the day of surgery, the anesthesiologist is focused intently on medical risk and immediate safety of the patient. The H&P, with the anesthesia pre-assessment, allows the anesthesiologist to better understand the patient’s pathophysiology, make monitoring and management decisions and determine strategies for mitigating the impact of the anesthetic on the individual patient. The H&P also allows the anesthesiologist to anticipate the needs of the surgeon and the effect the procedure will have on underlying patient conditions during the intraoperative and immediate postoperative period. ASA recognizes that H&Ps are only as good as the surgeon providing the information to the anesthesiologist. An H&P conducted and communicated to the anesthesiologist ahead of time decreases the chance of case cancellations and increases the opportunities for physicians and other healthcare workers to appropriately treat patients in a timely and effective manner.

CMS must recognize the critical role of the anesthesiologist to care for the patient and to make appropriate assessments of the patient prior to surgery. The term “pre-surgical” is not precise and will likely lead to confusion and misunderstandings between healthcare personnel and hospital policy. The current Conditions of Participation for Hospitals for Anesthesia Services § 482.52(b)(1) require that a preanesthesia evaluation be conducted and verified within 48 hours prior to the procedure. CMS allows for some of the individual elements contributing to the preanesthesia evaluation to be performed *prior* to the 48-hour timeframe but that the elements be reviewed with updates documented *during* the 48-hour timeframe.

In moving away from established regulations, CMS would be shifting a significant amount of risk from the surgeon, who had previously been responsible for H&Ps, to the anesthesiologist – the physician most responsible for pre-surgical assessments. Even though CMS intends that this would only apply to outpatient surgical or procedural services, if CMS nonetheless finalizes this rule, ASA would strongly urge CMS to consider how physician payment for conducting the H&P is assigned, especially if the anesthesiologist will now be the *de facto* verifier of a patient’s physical and medical status during the pre-surgical/procedure assessment. Such work is not included in the value assigned to an anesthesia service and, under current billing standards, is not separately reportable from an anesthesia service if performed on the same day of service. National Correct Coding Initiative (NCCI) edits specifically and absolutely prohibit reporting an anesthesia service and an Evaluation and Management (E/M) code on the same date. If a physician anesthesiologist is called upon to perform this additional service, the value s/he contributes and the risk s/he assumes should be recognized by allowing separate reporting of that additional work.

The proposed revisions for the H&P requirements will lead to more delayed cases and cancellations as anesthesiologists may identify patient health issues on the day of surgery that were missed by H&Ps not being completed in a timely or consistent fashion.

Anesthesiologists, as advocates for patient safety and enhanced recovery, make difficult and necessary decisions daily regarding whether the case should begin, be delayed or cancelled. Case delays and cancellations, caused by a patient not being properly assessed or instructed by a surgeon prior to their procedure, will decrease patient satisfaction and place an additional burden on patients and caregivers. Patients and their families often take time off from work for their surgery and recovery. Should this proposal be finalized, more patients and caregivers may be exposed to such disruptions to their surgical plans.

Encouraging greater communication between surgeons, anesthesiologists, other clinicians and patients can best be accomplished through local innovation and leadership rather than through broad regulatory changes. The Perioperative Surgical Home, a patient-centric, team-based model of care created by leaders within the ASA, is a clear example of how anesthesiologists, surgeons, specialists and other healthcare workers can work collaboratively to define roles and responsibilities that reflect their clinical workflows and patient needs. The current CoPs offer a framework for such organizations using the Perioperative Surgical Home model to create efficient workflows, enhance communication and hone leadership skills that drive innovation and patient outcomes while maintaining adherence to current regulation.

CMS has also requested “whether there are any evidence-based exceptions or specific guidelines, such as for particular patient conditions or surgical procedures, that would prohibit this level of discretion for determining those hospital outpatient surgery patients who would not require a comprehensive H&P prior to outpatient surgeries or procedures.” Each patient has unique co-morbidities and physiological features and each procedure comes with its associated surgical or procedural risk. Although guidelines and other practice parameters may illustrate a starting point for determining whether or not an H&P should or should not be required, applying any sort of blanket opt-out of an H&P would be arbitrary in nature, leading to confusion among staff whether the H&P was needed or not.

Permitting medical staff to develop and maintain policies and procedures for circumstances that do not require H&Ps will create new burdens by increasing compliance requirements for hospitals. The replacement obligations would require hospitals to establish policies for assessments that vary based on a range of factors including, but not limited to, patient age, comorbidities and anesthesia type. This could easily create a situation where a hospital increases the chance that they deviate from their own policies while increasing their compliance burden.

Ultimately, these proposed changes to the Hospital H&P CoPs will jeopardize patient safety and undermine patient safety culture. First, patients, physicians and other healthcare workers will encounter different standards of care and assessments when using or working in different hospitals. This may lead to healthcare workers debating proper protocols to use at their facility instead of focusing on acute patient needs. Second, shifting the burden from surgeons to anesthesiologists in verifying pre-procedural assessments will lead to anesthesiologists identifying additional co-morbidities and conditions that should have been addressed prior to surgery. Such assessments may lead to more case cancellations and delays – a process that could adversely affect the important, professional relationship between surgeons and anesthesiologists. Last, developing policies that are specific to certain conditions, age of the patient and anesthesia type do not take into consideration individual patient needs. Instead, it would create a culture of carve outs for some patients and requirements for others – especially when a patient has overriding physiological considerations. This confusion would engender more debate and discord locally regarding the type of care a patient should and will receive.

ASA strongly opposes the proposed revisions regarding H&P requirements as described in the Hospital Medical History and Physician Examination Requirements section.

CMS should NOT finalize any proposed changes to the Hospital Medical History and Physical Examination Requirements.

Hospital Infection Control Program (§482.42)

CMS is proposing to allow hospitals that are part of a hospital system to elect to have a unified and integrated infection control program for all the member hospitals, if allowed by State and local laws. ASA believes this proposal would not have an adverse effect on patient safety. The policy, however, may lead to decreased influence from departments at more remote locations of the health system. We hope that CMS will finalize policy that takes into consideration certain mandatory items in an infection control program that may not align with different types of facilities in a hospital system. For example, a surgery center may not have the “linen chute,” which may be found in the hospital. The infection control program covering the hospital system would need to be sufficiently broad to account for such variation. We would encourage physicians and others at those locations to take advantage of opportunities to work with administrators and infection prevention professionals within the system to identify local facility needs as allowed under this proposal.

Emergency Preparedness for Providers and Suppliers

CMS has proposed several changes to emergency preparedness requirements in an effort to reduce regulatory and documentary burdens. **ASA opposes the CMS proposal to eliminate the requirement for facilities to document efforts to contact local, tribal, regional, State and Federal emergency preparedness officials and facilities' participation in collaborative and cooperative planning efforts.** Hospitals and healthcare systems are part of a larger community that may be impacted by significant medical emergencies and mass casualty events. Should an emergency situation or mass casualty event occur, it is important that community institutions, including hospitals, have established lines of communication and expectations. In emergency situations, anesthesiologists are often leaders in triaging patients and in the efficient coordination of operating room and intensive care unit personnel and resources. Without that established communication or documentation, we believe that frontline healthcare workers, including anesthesiologists, would not have all the tools necessary to save lives and protect patient safety. The proposed change to this regulation lacks a sense of responsibility and accountability for either healthcare workers or community members in protecting public safety.

Annual Review of Emergency Preparedness Program

ASA opposes changes to the regulation that requires facilities to annually review their emergency preparedness which includes a review of their emergency plan, policies and procedures, communication plan and training and testing programs. Although the change from an annual review to a review of their program “at least every 2 years” does not appear significant, the less frequent training opportunities may lead unintentionally to decreased physician and hospital staff readiness and vigilance. In addition, we question whether a significant number of physicians and healthcare workers are satisfied with the training they have received on emergency preparedness and mass casualty events.

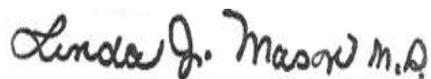
This CMS proposal conflicts with the goals of “Patients Over Paperwork” as the ASA does not see the clear benefits of ensuring patient safety in comparison with reducing regulatory burden. Prioritizing a perceived physician burden over training and readiness could result in worse patient outcomes after a mass casualty situation. The decrement in training that is proposed to improve patient care may do exactly the opposite. Such a proposal would be analogous to training less frequently for Advanced Cardiac Life Support, Advanced Trauma Life Support or other training programs that patients may require even though these skills may not be used on a routine basis. Anesthesiologists and other healthcare professionals cannot predict when an unanticipated emergency event will occur. CMS should also consider the instances of mass casualty and emergency events in the United States, both man-made and those occurring in nature that have affected how often hospitals have updated their policies and procedures.

Most hospital employees today, including anesthesiologists, who need to be involved in a mass casualty response, may not be adequately prepared. In most locations, a significant amount of the training is only done with emergency department personnel and hospital leadership. Although the written plan may include other departments and personnel, these departments do not necessarily or completely participate in such drills and training. Staff who work in or are responsible for the operating room, intensive care unit, facilities, electrical and water back-up systems, infection control, information technology and other areas of critical importance should be included in annual training.

As CMS further hones their regulation related to emergency preparedness communication and training, we acknowledge that some hospitals may be more susceptible to experiencing natural disasters and mass casualty events. We recommend future CMS policy proposals be tailored to address such differences in region and whether hospital staff training can be developed that takes into account local needs and responsibilities. For example, a hospital situated in a highly populated area that is at risk for hurricanes will require different emergency preparedness tools and training than a facility in a rural region far from the coastline. Other states or areas with limited resources may require a broader training and implementation program that spans hospitals and other local or regional resources.

ASA thanks CMS for consideration of our comments. For further discussion, please contact Matthew Popovich, Ph.D., ASA Director of Quality and Regulatory Affairs at m.popovich@asahq.org or Beth Quill, J.D., Senior Regulatory Affairs Specialist at e.quill@asahq.org. They may also be reached at 202-289-2222.

Respectfully submitted,



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