American Society of Anesthesiologists™

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September 17, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1753-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: **[CMS-1753-P]** Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

The American Society of Anesthesiologists (ASA), on behalf of our more than 54,000 members, appreciates the opportunity to comment on the above-captioned proposed rule. Medicare is an essential program that currently provides health care benefits to 58 million Americans. ASA is committed to working with the Centers for Medicare and Medicaid Services (CMS) to promote policies that support high-quality care in a fiscally sustainable manner. We are pleased to work with the agency to create a health care system that reduces administrative burden on practicing physicians, supports the provision of high-quality, cost-effective care, and is forward thinking in the development of innovative solutions to overcome the challenges facing clinicians, patients, and the Medicare system overall. As the medical specialty representing the recognized leaders in patient safety and quality, ASA welcomes the opportunity to work with you to ensure high-quality and high-value care for our Medicare patients.

In this letter, ASA provides comments on the following issues:

- Proposed services that would be paid only as inpatient services
- Request for information on Rural Emergency Hospitals
- Proposal to expand policies for separate payment for non-opioid drugs from the ambulatory surgical environment to the hospital outpatient department
- Prior authorization process in the hospital outpatient department

Proposed Services That Would Be Paid Only as Inpatient Services (Section IX.B.)

ASA supports the agency's decision to halt the elimination of the Inpatient Only (IPO) List. We recommend the agency conduct a complete analysis of the ramifications of such a policy on patient safety and its impact on allowing physicians to use clinical judgement to determine the most appropriate sites of care. We urge the agency to work collaboratively with hospitals, health systems, ambulatory surgery centers and other stakeholders as it considers any changes to this policy.

Historically, CMS has identified services that are safely provided only in an inpatient setting and thus would not be paid by Medicare under the OPPS. Services identified as such were designated to the "inpatient only" (IPO) list. In the CY 2021 OPPS/ASC Final Rule, CMS announced that it would eliminate the IPO List over the course of three years (85 FR 86084-88). In the first year of the transition, in CY 2021, CMS removed 298 codes from the list. CMS is now proposing to stop the phased elimination of the IPO List and to add the 298 codes back beginning in CY 2022. CMS is not completely abandoning the idea of eliminating or modifying the IPO List and is seeking feedback on alternatives.

ASA was pleased that CMS proposed to halt the elimination of the IPO List. This was a significant proposal that would have impacted many services across a range of medical specialties. It entailed clinical issues related to determining medical necessity for the appropriate site of care as well as complex administrative policies that set payment rates for outpatient services. We believe a proposal of such magnitude required a more robust plan than what was originally proposed.

ASA recommends the agency review a wide range of issues as it considers eliminating or even modifying the maintenance of the IPO List.

- The IPO List has been an important safeguard for Medicare beneficiaries to ensure they are receiving care in a clinically appropriate location – especially when used in conjunction with physicians' clinical judgment. The question of whether a procedure could be safely done in the outpatient setting depends on more than the procedure itself. Specific aspects of the patient's condition, (eg, morbid obesity, sleep apnea, etc.) must also be considered. Both the procedure and the patient must be taken into account and there should be latitude for riskier patients to undergo the procedure in the in-patient setting. How would the elimination of the list or modifications to how it is maintained impact patient safety and the ability of physicians to use their clinical judgement when caring for their patients?
- Even if CMS were to provide flexibility around the application of the two-midnight rule for site of service claim denials, what kind of guidance will be provided to physicians and facilities? Physicians may receive pressure from their facilities to move services to the outpatient setting to avoid scrutiny of inpatient stays – even stays for which medical necessity supports performance in an inpatient setting.
- How does CMS plan to set payment rates for services that have historically been performed in the inpatient setting? How quickly could facilities absorb these changes in

payment rates, and could there be some unintended consequences to these payment rate changes on patient care?

As a specialty whose membership provides a wide range of procedures in the inpatient and outpatient environment, we are acutely aware of the trend to shift services from the inpatient to the outpatient environment and how technology and other advances support this change in site of service. ASA has a great deal of clinical expertise and can offer significant guidance in this area. We look forward to engaging with the agency as it continues to explore policies around the IPO List and support ongoing re-evaluation of procedures to identify all appropriate patient-focused options for care.

Request for Information on Rural Emergency Hospitals (Section XVII.)

ASA supports efforts to understand and address the unique health needs of people residing in rural America. We urge the agency to consider the type of support that will be needed around maintaining relationships with Level 1 or 2 trauma centers and resource needs, such as telehealth capacity and partnerships between systems to help address disparities in access to tertiary care such as coronary procedures.

The Consolidated Appropriations Act of 2021 (CAA) created a new type of Medicare hospital called the Rural Emergency Hospital (REH). This classification is designed to help meet the needs of rural communities that cannot adequately support a full-service hospital, but otherwise would lack emergency services. CMS seeks feedback from stakeholders as the agency defines its policies specific to REHs.

ASA is very aware and engaged in addressing the health care challenges facing rural America. We are supportive of the agency's efforts to implement provisions in the CAA of 2021 to establish REHs. ASA recommends that the agency ensures the REH model supports and promotes a means for REHs to develop and maintain meaningful relationships with Level 1 or 2 trauma centers. These REHs must be appropriately integrated into existing regional and statewide trauma systems. Such relationships will provide practical support in patient care and leadership and direction in matters related to trauma care. Access to telehealth and the capacity to have telehealth consultations will be critical. The model should also allow for partnerships with other types of tertiary health care systems that can help address areas where rural communities face disparities, such as cardiac care.[1]

Telehealth and other remote service capacities of these institutions will allow REHs to better serve the rural communities in which they reside. Currently HHS, Congress and other stakeholders are trying to determine how telehealth will function after the pandemic. The needs and priorities of institutions, such as these REHs, should be part of that conversation.

[1] Cross SH, Mehra MR, Bhatt DL, et al. Rural-Urban Differences in Cardiovascular Mortality in the U.S., 1999-2017. JAMA. 2020;323(18):1852–1854. doi:10.1001/jama.2020.2047

CMS should look to address maternal morbidity and mortality rates which are problematic in rural hospitals as well as trauma stabilization. While telehealth can play an important role, some tasks just cannot be done via telemedicine. Medicare hospital payments should provide for in-house anesthesiologists who are trained in critical care, trauma and obstetrics for deliveries, resuscitations, and stabilization of patients prior to transfer.

ASA looks forward to updates and information as the agency continues to define criteria around the establishment of REHs.

Proposal to Expand Policies for Separate Payment for Non-Opioid Drugs from the Ambulatory Surgical Environment to the Hospital Outpatient Department (Section II.A.)

ASA supports the removal of non-opioid drugs used for perioperative pain relief from packaging policies. We urge the agency to finalize its proposal to expand its policy of separate payment for non-opioid pain medications from the ambulatory surgical (ASC) environment to the hospital outpatient environment.

In the ASC environment, CMS has a policy of allowing separate payment for non-opioid pain medications used as surgical supplies. In this proposed rule CMS proposes to expand this policy to the hospital outpatient setting.

Anesthesiologists play a unique role in acute and chronic pain management, which is a priority issue for ASA. As a result of our long-standing and focused work in this area, we are a leader in the advancement of acute and chronic pain management best practices. ASA has done significant work in developing guidelines and best practices, particularly in the area of non-opioid treatment alternatives.

Over the years ASA has supported regulatory and legislative proposals for separate Medicare payment for non-opioid treatments used to treat pain in both the ASC and hospital outpatient settings. Consistent with these previous positions, ASA supports this proposal to expand the ASC policy of separate payment for non-opioid pain medications from the ASC environment to the hospital outpatient environment. This policy will ensure that there are no financial incentives to use opioids. It is consistent with the agency's overarching priority of addressing the opioid epidemic and promoting alternatives to opioids for pain management. We believe expansion of this policy that has created appropriate incentives and promotes the use of suitable alternatives to opioids in the ASC will do the same in the hospital outpatient environment.

ASA supports a multimodal and interdisciplinary approach to pain treatment and believes this policy of expanding separate payment for non-opioid alternatives to the hospital outpatient environment encourages the best possible care for patients. ASA urges CMS to finalize this policy.

Prior Authorization Process in the Hospital Outpatient Department

ASA is pleased that the agency has chosen not to expand the hospital outpatient prior authorization process in this rulemaking cycle. We urge the agency to review the current program to assess its impact on utilization, patient access to care and the administrative burden it generates. In such an evaluation we request the agency to consider the potential negative impact of the prior authorization process on other agency priorities such as Medicare beneficiary access to non-opioid alternatives for pain management.

For CY 2020, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. CMS originally applied this process to five categories of services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation) starting on July 1, 2020. As part of the CY 2021 rulemaking cycle, CMS expanded the list of services subject to the prior authorization process to include cervical fusion with disc removal and implanted spinal neurostimulators effective July 1, 2021. CMS is not proposing to supplement or otherwise change the list of services subject to prior authorization in this rulemaking.

ASA strongly opposed the agency's policy to expand the hospital outpatient prior authorization process in 2021. ASA was very concerned that the agency was proposing to expand the current authorization process without evaluating the original program that was finalized in the CY 2020 OPPS Final Rule. The agency did not have any meaningful experience with how the program affected utilization, impacted patient access to care and increased the administrative burden of the program. Prior authorization programs, if not appropriately designed, can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health and outcomes. They can also create an unnecessary administrative burden on physicians providing these services. The agency is also spending its own resources and the resources of its contractors to support its implementation. For all of these reasons, ASA reiterates its previous recommendation that CMS must re-evaluate the hospital outpatient prior authorization process.

ASA remains concerned about the impact of this program on Medicare beneficiaries' access to non-opioid alternatives. In CY 2021, CMS added implanted spinal neurostimulators to the list of services that require prior authorization when performed in the hospital outpatient setting. ASA continues to believe that this is inappropriate and will reduce access to non-opioid alternatives to pain management. When sufficient data is available, ASA strongly urges CMS to assess the impact of this policy on access to non-opioid alternatives. Implanted spinal neurostimulators are critical alternatives to manage pain for patients who are at risk for developing an opioid use disorder. ASA opposes unnecessary administrative barriers to solutions to help ensure patients have access to services that can prevent and/or replace dependence on opioids. Recent studies have found that it is likely that the COVID-19 pandemic has adversely impacted the opioid

epidemic.[2] With this in mind, we urge the agency to make policy that promotes, rather than hinders, Medicare beneficiary access to non-opioid alternatives.

In 2017, the American Medical Association and a group of other health care organizations released a set of principles for the design of an appropriate prior authorization program.[3] These principles fall into five broad categories: clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternative exemptions. ASA urges the agency to evaluate the current prior authorization program against these factors. We look forward to the agency's analysis.

Thank you for your consideration of our comments. We would be very glad to follow up with you as necessary on any issues for which you need additional information or would like further discussion. Please contact Sharon Merrick, MS, CCS-P, ASA Director of Payment and Practice Management at (202) 289-2222.

Sincerely,

Beverly K. Philip, MD, FACA, FASA
President

[2] Haley DF, Saitz R. The Opioid Epidemic During the COVID-19 Pandemic. *JAMA.* 2020;324(16):1615–1617. doi:10.1001/jama.2020.18543

[3] The American Medical Association (2017, January). *Health care coalition calls for prior authorization reform.* Retrieved from: https://www.ama-assn.org/press-center/press-releases/health-care-coalition-calls-prior-authorization-reform