American Society of Regional Anesthesia and Pain Medicine
Advancing the science and practice of regional anesthesiology and pain medicine to improve patient outcomes through research, education, and advocacy
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September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to http://www.regulations.gov

Re: ***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 Regional Anesthesia and Pain Medicine (ASRA) is a voluntary organization representing chronic and acute pain medicine physicians both nationally and internationally. In particular, we are highly dedicated to the use of evidence-based, medical therapies in treating patients with chronic and acute pain when appropriate. Our membership, of over 5,000 practitioners, includes solo practitioners, small group practice members, and practitioners in large private and academic healthcare systems. We strongly support the efforts of the Centers for Medicare and Medicaid Services (CMS) to improve quality of care and patient outcomes.

We welcome the opportunity to offer comments on the proposed rule referenced above, which include the following recommendations:

1. *Finalize CMS' proposal for ongoing separate payment for non-opioid pain management drugs and biologicals when they function as surgical supplies in ASCs.*
2. *Do not require an approved indication by the Food and Drug Administration (FDA) for pain management or analgesia, as a criterion for separate payment of non-opioid pain management drugs and biologicals in ASCs, and instead allow recognition by a medical compendium or recommendations by specialty societies or national organizations to serve as an alternative to reliance on an FDA-approved indication for pain management or analgesia.*
3. *Provide separate payment for non-opioid pain management treatments including nerve blocks, surgical injections, and neuromodulation when used in surgical procedures performed in the ASC setting.*
4. *Finalize CMS' proposal to halt the elimination of the Inpatient Only (IPO) list and to add the services removed from the IPO list for calendar year (CY) 2021 back to the IPO list in CY 2022.*
5. *Work with ASRA to develop meaningful, low-burden measures focused on pain management surgical procedures that should be used across health care settings.*

ASRA's comments reflect our strong desire to partner effectively with CMS to provide high-quality care to Medicare beneficiaries.

Packaging Policy for Non-Opioid Pain Management Treatments

Recommendation: ASRA supports ongoing separate payment for non-opioid pain management drugs and biologicals when they function as surgical supplies in ASCs, as proposed.

ASRA agrees that separate payment is necessary to ensure continued utilization of these opioid alternatives for surgeries performed in ASCs.

Recommendation: ASRA cautions against requiring FDA approval with an FDA-approved indication for pain management or analgesia as a criterion for separate payment of non-opioid pain management drugs and biologicals in ASCs. As an alternative, we support recognition by a medical compendium or recommendations of specialty societies or national organizations in lieu of an FDA-approved indication for pain management or analgesia.

ASRA has significant concerns with CMS' proposal to require FDA approval of a drug with an FDA-approved indication for pain management or analgesia as a criterion for providing separate payment of non-opioid pain management drugs and biologicals in ASC settings. FDA labelling does not always encompass all therapeutic uses of drugs; indeed, in our experience, drugs used to manage pain are routinely furnished on an off-label basis. As a result, we are concerned that CMS' proposal would create unnecessary barriers to furnishing care that would limit providers' ability to offer non-opioid drug alternatives to pain management treatments in ASC settings when they function as surgical supplies.

ASRA appreciates CMS' recognition of this dilemma in its preamble discussion, and we support – as alternate criteria – recognition by a medical compendium and recommendations established by specialty societies and national organizations regarding non-opioid pain management products that function as surgical supplies and reduce opioid use in the ASC setting. Such recognition and recommendations are the result of rigorous review based on sound clinical evidence, while also offering a nimbler approach for determining whether drugs may be appropriately used for pain management purposes.

Recommendation: ASRA recommends that CMS provide separate payment for non-opioid pain management treatments including nerve blocks, surgical injections, and neuromodulation when used in surgical procedures performed in the ASC setting.

ASRA is concerned that CMS' policy to package payment for non-drug pain management alternatives such as nerve blocks, surgical injections, and neuromodulation, when used in surgical procedures performed in the ASC, restricts access to the use of these modalities, which ASRA believes to be safe, effective, and cost-effective in reducing the sequelae of post-surgical pain, and which can serve to reduce use of opioids when furnished appropriately. In our members' experience, this problem is particularly challenging in ASCs, which receive lower payment than hospital settings while delivering comparable outcomes for the same procedural service. Allowing for separate payment of these opioid alternatives would increase access by leading to payments that are sufficient to cover associated costs.

Inpatient Only List

<u>Recommendation</u>: ASRA supports CMS' proposal to halt the elimination of the Inpatient Only (IPO) list and to add the services removed from the IPO list for CY 2021 back to the IPO list in CY 2022.

As we noted in our comments last year, ASRA has been concerned about the impact of CMS' policy to eliminate the IPO list on patient safety, particularly given the risk that hospitals and other payers might require high-risk procedures to be performed in outpatient settings in the absence of the IPO list. While we appreciated CMS' premise that physicians should use their clinical judgment to determine the most appropriate setting for care and treatment, we also recognized the risk that hospitals and other payers might limit physicians' ability to exercise our judgement through restrictive policies. We believe that reverting to previous policies – including notice and comment processes for services proposed for removal from the IPO list based on designated criteria – will help to mitigate patient safety concerns, while still providing opportunities to increase physician and patient choice regarding care settings.

ASC Quality Reporting Program: Comment Solicitation on Potential Future Measure to Assess Pain management Surgical Procedures in ASCs

<u>Recommendation</u>: CMS should work with ASRA to develop meaningful, low-burden measures focused on pain management surgical procedures that should be used across health care settings.

CMS seeks public comment on the development and future inclusion of a measure to assess pain management surgical procedures performed in ASCs. ASRA believes that such a measure could provide valuable information on quality performance related to pain management surgical procedures. For example, measurement could focus on the rate of infections associated with such procedures or related hospitalizations. However, we believe such a measure should be carefully constructed to best address meaningful quality outcomes, while also limiting associated reporting burden.

ASRA also believes that quality measurement on pain management surgical procedures should take place across health care settings, not just for ASCs. Many pain procedures such as epidural steroid injections and facet interventions can be performed in hospital including hospital outpatient department (HOPD), ambulatory surgical center, and office space settings. Understanding how outcomes associated with commonly performed procedures vary across settings can help patients as they make treatment decisions, inform payment policy, and drive improvement across settings.

With our focus on regional anesthesia and pain medicine, ASRA is uniquely qualified to assist CMS in development of a new pain management surgical procedure measure. We have extensive experience in measure development efforts, including a measure on multimodal pain management[1] and infection control practices for open interventional pain procedures,[2] among others. ASRA would be pleased to lend our experience as CMS undertakes this new measure development effort.

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[1] See measure specifications at https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_477_MIPSCQM.pdf. Accessed August 19, 2021.
[2] See measure specifications at https://www.aqihq.org/files/MIPS/2020/2020%20QCDR%20Measure%20Book.pdf. Accessed August 19, 2021.

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Conclusion

In conclusion, ASRA appreciates your consideration of our comments on the updates to the aformentioned proposed rule. We look forward to working with CMS so we can achieve our shared goals of advancing high-quality of care and improving health outcomes for Medicare beneficiaries. As part of this important work, we will continue our commitment to promote use of evidence-based, non-opioid pain management techniques in the treatment of acute and chronic pain and safe use of opioids according to evidence-based guidelines in patients for whom it is medically appropriate. If you have any questions about these comments or other issues of concern, please do not hesitate to contact Angela Stengel at 412-471-2718 or astengel@asra.com.

Sincerely,

ASRA President