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September 10, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-1850

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:

On behalf of the Board of Directors of American Society of Interventional Pain Physicians (ASIPP), 49 state societies and the Puerto Rico Society of Interventional Pain Physicians, Society of Interventional Pain Management Surgery Centers (SIPMS), as well as the entire membership of ASIPP and SIPMS, we would like to thank you for providing the opportunity to comment on 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.

BACKGROUND

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

SIPMS is a not-for-profit professional organization founded in 2005, with membership involving surgical centers focusing on interventional pain management, dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic pain. There are approximately 500 surgery centers across the nation approved by Medicare providing or solely or an overwhelming majority of interventional pain management services.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09, www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf).

Interventional pain management techniques are minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://www.medpac.gov/documents/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0

An overwhelming majority of the interventional techniques are performed in outpatient settings, either in physician's offices, hospital outpatient departments (HOPDs), or ambulatory surgery centers (ASCs).

- A perfect storm has arisen due to a rare combination of adverse factors, including the coronavirus pandemic, which has catapulted the country into one of the deepest recessions in the United States' history. The decimation of multiple medical services, a convergence of concurrent PHEs due to the COVID-19 epidemic, the exacerbation of the existing opioid epidemic, the addition of an epidemic of economic consequences, and a tsunami of deleterious payer policies has led us into a perfect storm.

  - Providers in many sectors, specifically in interventional pain management, continue to see significant reductions in their patient load for any type of interventional procedure, ranging on average from 20% to 25%, with escalating costs in providing care, and with impending cuts for Medicare and other insurers.

  - We have had discussions concerning the opioid epidemic in the past and CMS is aware of it.

    Impending cuts, increases in providing care, and the elimination of telephone only services will lead to extensive disastrous situations for both patients and physicians including an escalation of the opioid epidemic.

  - The importance of interventional techniques and curtailing the opioid epidemic has been an important issue for CMS and other agencies, including congress and the administration. In fact, the document from the Department of Health and Human Services (DHHS), Pain Management Best Practices Interagency Task Force Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations, published on May 19, 2019, clearly outlines the role of interventional techniques.

    The reduction in interventional pain management services is a great disservice to chronic pain patients who have suffered more than their share during the COVID-19 epidemic and these patients will continue to suffer. The elimination of convenient opportunities for this vulnerable population is inappropriate and will force patients into more expensive settings such as hospitals, since many pain physicians will be shifting to hospital-based practices. With few tangible choices, many other physicians have already relocated their practices to hospitals. Hospitals and corporations control 70% of physician practices. This only increases the expenses rather than reducing them and ultimately renders the Medicare program vulnerable.

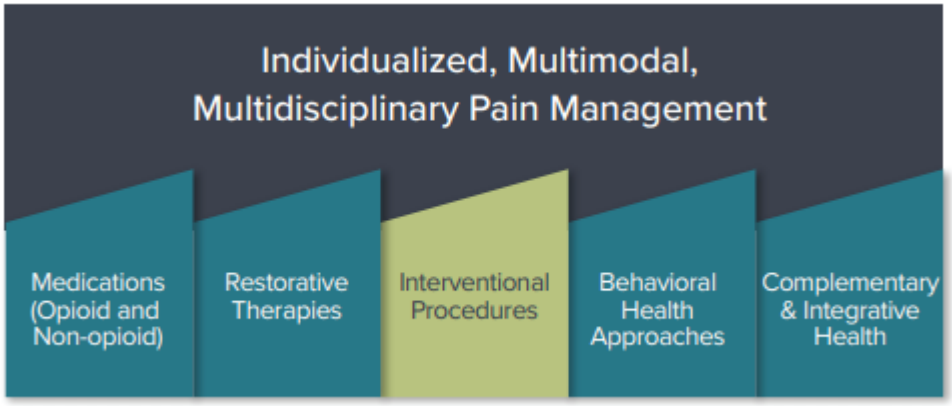

Fig. 1. *Chronic pain management consists of five treatment approaches informed by four critical topics*.

Source: U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force. Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019.

COMMENTS:

Our comments are pertaining to ambulatory surgical centers.

1. AVERAGE RATE OF DATA

We appreciate CMS finally utilizing reasonable process to update ASC rates, similar to HOPD, improving the conversion factor.

We also request that CMS not to change any of the published rates downwards during the final phase ruling.

2. PROPOSED POSITIVE DEVICES – INTENSIVE PROCEDURE POLICY FOR ASC'S

We applaud CMSs proposal of a positive policy change that device offset percent will be calculated using ASC rates, not HOPD rates, as was previous practice. This essentially means we are hoping that any procedures in which the device cost is 30% of the overall ASC procedure rate, will receive device intensive status.

We also appreciate the fact that if a device receives HOPD device-intensive status, the device will also be device-intensive in the ASC setting. Under the device intensive procedure policy, we have the following comments:

i. Interspinous Prosthesis

The price changes for interspinous prosthesis already had severe deleterious effects on this procedure being offered to patients suffering with moderate spinal stenosis. CPT 22869, interspinous prosthesis, offered with Superion is supported by significant body of clinical and real-world evidence demonstrating its safety and effectiveness. In fact, 2-year follow-up results shows 90% patient satisfaction rate and an 85% drop in the proportion of patients using opioids to manage pain at 5 years post procedure. This is crucial in the era of opioid epidemic, which is escalating beyond anyone's imagination. We are also losing control with numerous regulations and controls in attempting to curb the opioid epidemic. We have succeeded in reducing the number of prescriptions.

Overall, it is a clinically proven, minimally invasive solution intended to deliver long-term relief from neurogenic intermittent claudication secondary to moderate lumbar spinal stenosis, sometimes referred to as symptomatic lumbar spinal stenosis. Offering this option for the selected symptomatic lumbar spinal stenosis patients, improves access and another modality avoiding surgery and extensive opioids.

This procedure faced reductions of 22.4% compared to 2019 from $12,569.88 to $10,576.47. Proposed schedule shows some increase compared to 2020 from $9,873.89 to $10,576.47, still 16% reduction from 2019. This continues to be significant deterioration in reimbursement.

Considering that this is a device-intensive procedure and requires extensive training for the physicians, in addition, it also requires in an ASC with major surgical setup, including extensive sterile preparation, monitored anesthesia care with close to being general anesthesia, equipment and personnel. The costs of maintaining a large OR with extensive supplies and trained personnel are expensive. In addition, prosthesis is expensive. At the present rate, the margin for profit is extremely low.

These expenses, coupled with the cost of the implant, prohibit offering this service to individuals in need, by hampering access to care.

At this time, we request that prices be increased to 2019 levels.

ii. Percutaneous Injection of Allogenic Cellular Product

We are pleased that CMS made appropriate APC classifications for percutaneous injection of allogenic cellular and/or tissue-based product CPT 0627T-0630T. These codes are assigned to comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator "J1" for the CY2022 OPPS. We agree with CMS's assignment as APC 5115 reflect the resource costs adequately.

We are concerned; however, the resource costs might not be reflected adequately in ASC settings.

We consider this procedure to be a "device-intensive" procedure with the cost of the product at $8,000 which satisfied the 31% threshold device intensive status.

We urge CMS to assign CPT 0627T and CPT 0629T device-intensive status to capture the significant device related resource costs and allow sufficient reimbursement for the procedure in the ASC site-of-service.

iii. Peripheral Neurostimulation

CPT 64575 describing incision for implantation of neurostimulator electrode array shows significant reductions in payment from $15,671.06 for to $10,298.84 – a 34% reduction. This is a major procedure requiring significant supplies and OR time and the costs of the implant. If approved properly and done properly, this will be extremely useful in a wide array of patients suffering with intractable neuropathic pain involving peripheral nerves in extremities and other peripheral nerves such as suprascapular nerve, etc. At this time, we request that prices be increased to 2020 levels.

3. PROPOSED REMOVAL OF ASC CODES

Our specific concerns involve the removal of the following codes from the ASC payment system: CPT 62351, 63011, 63012, 63035, and 63040. We ask that these codes NOT be removed and continue to be allowed in the ASC.

If you have any questions, please feel free to contact us.

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