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October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1736-P: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-owned Hospitals

Dear Administrator Verma:

On behalf of the Board of Directors of American Society of Interventional Pain Physicians (ASIPP), 50 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-1736-P: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process.

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).

- In 2012, MedPAC recommended that if the same service can be safely provided in different settings, a prudent purchaser should not pay more for that service in one setting than in another.
    - MedPAC was also concerned that payment violations across settings may encourage arrangements among providers that result in care being provided in higher paying settings, thereby increasing the total Medicare spending and beneficiary cost sharing.
    - The Office of Inspector General (OIG) of Health and Human Services (HHS) also reinforced the concerns of MEDPAC and recommended that site of service differentials be eliminated.
    - Data from MedPAC has shown significant increases in HOPD payments compared to freestanding offices or ASCs. It now also appears that there is a reversal of the site of services with HOPDs now dominating.
    - Based on multiple regulations related to the Affordable Care Act (ACA), Accountable Care Organizations (ACOs), and Merit-Based Incentive Payment System (MIPS) services will be migrating to HOPDs.

- HOPDs are ineffective at cost control and they provide the same level of quality as a physician office which may be inferior and less safe than a fully equipped and credentialed operating room in the ASC. The setup of ASCs are oftentimes significantly more robust in terms of sterility, infection control, circulation airflow, and life safety requirements of a fully equipped surgical suite. HOPD pain management suites are often not fully equipped surgical suites.

    - The majority of the IPM procedures in HOPDs are performed outside the surgical suite in areas that do not meet to same rigid life safety standards, whereas the very significant majority of the ASC procedures are performed in surgical suites.

    - Despite these differences, hospitals are reimbursed over 85% more than ASCs for the procedures while being performed in less safe areas. Currently CMS compensates hospitals at significantly larger rates while delivering care in facilities that may have significantly lower life safety standards.

- 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 public health emergencies due to the COVID-19 epidemic, the exacerbation of the existing opioid epidemic, the addition of a epidemic of economic consequences, and a tsunami of deleterious payer policies leading to a perfect storm.

    - During this period, elective surgeries were reduced as high as 88%, pain related prescriptions were reduced 15.1%, with an overall decrease of utilization of health care services (Fig. 1).

- The re-opening costs are skyrocketing with 50% to 60% patient load, with 110% to 150% of staff expenses with screenings, extra cleaning, testing, and quarantining of employees; 600% to 1,500% increase in personal protective equipment (PPE) expenses due to increased costs and usage.

Fig. 1. *Weekly elective procedures as a % of baseline. Estimated amounts for latest 2 weeks applied based on likely claims still to be received due to data latency or claim processing delays.*

Source: IQVIA: Medical Claims Data Analysis, 2020; Baseline = Average of procedures for period W/E 1/10/2020-2/28/2020. Elective procedures based on IQVIA custom analysis.

- Despite significant reductions in utilization patterns during the COVID-19 lockdown which increased profit margins (Fig. 2), insurers have incorporated significant increases of premiums, copays, and deductibles along with reductions in services, coupled with reductions in provider fees.

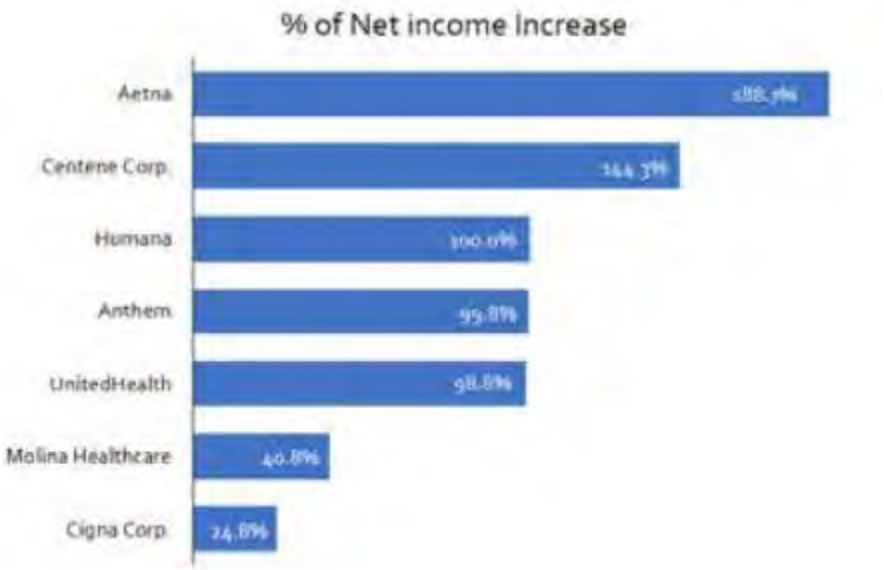

Fig. 2. *Percent of net income for second quarter of 2019 versus 2020.*

Consequently, to improve access to chronic pain management and stabilize interventional pain management practices, CMS must implement multiple modalities to curtail the opioid epidemic, without curbing access to therapeutic opioids through the incorporation of interventional pain management practices (Figs. 3 & 4). In fact, HHS Best Practices study showed the importance of interventional pain management practices, also providing appropriate use of opioids without curbing the access (Fig. 5). The proposed schedules can make this happen and avoid another major opioid epidemic, which has decelerating with 5% increase in 2019 and 13% in 2020 due to COVID-19 epidemic increasing deaths and overdoses increasing almost 50%.

	2018	2019 (P)	Change
Other Synthetic Narcotics (fentanyl)	31,335	37,137	18.5%
Prescription Opioids	14,975	14,347	-4.2%
Heroin	14,996	14,278	-4.8%
Cocaine	14,666	16,196	10.4%
Psychostimulants with Abuse Potential (methamphetamine)	12,676	16,539	30.5%
Benzodiazepines	10,724	NA	

Fig. 3. N*umber of opioid overdose deaths by category, 1999 to 2019.*

Source(s): For 1999-2018 – National Institute on Drug Abuse. Overdose death rates. May 7, 2020 https://www.drugabuse.gov/relatedtopics/trends-statistics/overdose-death-rates.
For 2019 - Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics, 2020. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdosedata.htm

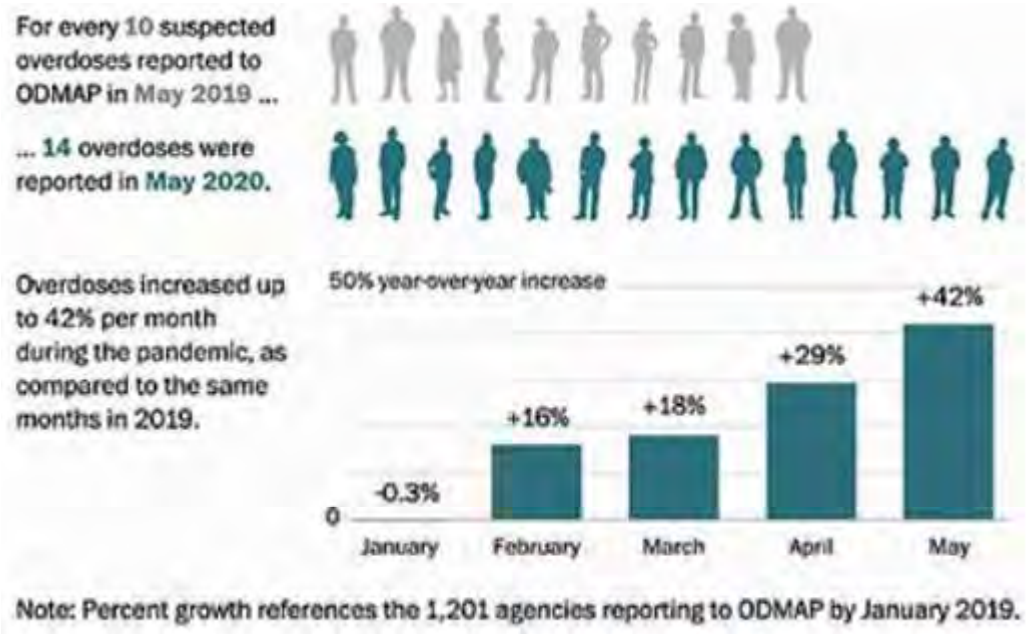

Fig. 4. *Dramatic growth in monthly overdoses during pandemic.*

Fig. 5. *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.

Available from: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

I. ASC PROPOSED RULE

1. 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 $9,779.68. Proposed schedule shows some increase from $9,779.68 to $10,439.97 with 5.7% increase – still 17.1% reduction from 2019. This continues to be significant deterioration in reimbursement.

Considering that this procedure 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 needed individuals with hampering of the access.

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

2. DISC DECOMPRESSION

CPT 62287 disc decompression was reduced with reimbursement by 58.7% from $1,919.87 to $792.67, which made it impossible for ASCs to offer this service. Proposed scheduled increased 1%.

Percutaneous disc decompression is offered in outpatient settings for patients with small discs not requiring surgical intervention, yet they have symptoms.

This procedure is a major surgical type of procedure with extensive sterile preparation, monitored anesthesia care, equipment and personnel. The costs of maintaining a large OR with extensive supplies, equipment, and trained personnel are expensive.

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

3. PERIPHERAL NERVE BLOCKS AND NEUROLYTIC BLOCKS

- The addition of new codes for sacroiliac joint nerve blocks and sacroiliac joint radiofrequency is appreciated.

    - However, it appears that there is an error in calculating the reimbursement for genicular nerve blocks and radiofrequency neurotomy of the genicular nerves. As you know, this involves in each patient, 3 nerves.

    - For CPT code 64454- injection genicular nerve branches with imaging, new code is reimbursed for ASCs at $162.92, whereas sacroiliac joint nerves innervating the sacroiliac joint with image guidance, CPT 64451 is reimbursed at $320.41.

      Both procedures require the same skill labor intensity and operating room preparation and equipment. Consequently, both should be the same. We request CMS to increase the reimbursement and make it uniform with sacroiliac joint nerves.

    - CPT 64624 is the second code related to genicular nerve neurolysis with image guidance. The proposed reimbursement is $316.15. On the same token, radiofrequency ablation or injection of neurolytic agent for sacroiliac joint CPT 64625 is reimbursed at $804.45.

      Consequently, both regions or 4 procedures should be reimbursed at the same level. We request that CMS assess this appropriately and increase the payment amount.

- In reference to peripheral nerve blocks and neurolytic blocks, CPT 64450 has been reimbursed at a substantially lower level. Similarly, CPT 64640 which represents the neurolytic code is substantially under reimbursed.

  These procedures are performed in a sterile fashion specifically in reference to the neurolytic blocks, similar to radiofrequency neurotomy of facet joints. Consequently, peripheral nerve blocks and neurolytic blocks also should be reimbursed at a higher level.

There is disproportionate payment variable with site-of-service differential which needs to be addressed.

4. PERIPHERAL NEUROSTIMULATION

CPT 64575 describing incision for implantation of neurostimulator electrode array shows significant reductions in payment from $15,671.06 to $10,797.22 – a 31.1% 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 also other peripheral nerves such as suprascapular nerve, etc. At this time, we request that prices be increased to 2020 levels.

II. HOPD PROPOSED RULE

For HOPD proposed rule we have 2 major concerns in relation to payment policies for interspinous prosthesis and preauthorization requirements for spinal cord stimulator trials and implants.

i. Interspinous Prosthesis

As described earlier in ASC proposed rule, Superion interspinous prosthesis is an appropriate treatment for moderate and symptomatic spinal stenosis with outcomes from randomized controlled trial, as well as real world evidence. The procedure is facing significant reimbursement reduction from $15,402.50 to $11,899.40. 2021 proposed rule does increase it by 5.5% to $12,550.60. However, as described in ASC rule, this requires major preparation and OR time. Consequently, it is not feasible for hospital outpatient settings to offer this procedure to moderate spinal stenosis patients.

Consequently, we request that the rates be reverted to 2019 with $15,402.50.

ii. Spinal Cord Stimulation Preauthorization Requirement

Spinal cord stimulation represents a technique that has been shown to decrease pain as well as decrease the utilization of opioid pain medications. It is a needed non-opioid therapy to treat pain in refractory chronic patients. By creating an additional prior authorization hurdle, it may decrease access to this therapy, which may have a negative impact on our citizens ability to maintain function, ADLs, and have a non-opioid treatment option.

We know that spinal cord stimulation has been shown to decrease opioid use post implant.

We would also like to note that a successful spinal cord stimulator trial is needed prior to receiving a permanent spinal cord stimulation, and only 65% of those who receive the trial actually get a

permanent device. This trial period is a mechanism to prevent over-utilization of implantation of the device.

There is currently a national coverage designation for spinal cord stimulators that defines what is required to implant the device, including the failure of conservative care, trying alternatives first, as well as the successful psychological evaluation. These things are already being done prior to the trial and permanent implants. ***The addition of a prior authorization requirement reflecting what is already required in the national coverage designation simply represents an extra burden that will increase the cost of care for practicing physicians and hospitals who now have to do the duplicative work.*** As you know, if you look at the national coverage designation, NCD160.7, you can see that spinal cord stimulation therapy is reserved for patients who have failed other treatments and is considered a late last resort therapy.

As a result of the Coronavirus Pandemic, hospitals and physician practices are already under a significant strain financially and otherwise. Thus, it makes little sense to increase burdens further with a new regulatory requirement for which ultimate may decrease access to care. We are concerned that prior authorization would create an undue hurdle for providers/patients, while creating a barrier to non-opioid alternatives. The Coronavirus Pandemic has significantly changed and affected how hospitals, physicians, and patients manage medical care. Increasing the cost of care and stress on physician practices and hospitals while decreasing access to a therapy that is clinically beneficial, improves pain, function, and decreases opioids seems counterproductive to our citizens well-being who are under increased stressors due to COVID 19.

This new policy may result in a delay in care because the prior authorization process will likely take some time which could further worsen patients' conditions.

ASIPP and SIPMS feels that this unnecessary addition may significantly reduce the access and does not curb overutilization if it did exist.

Thank you for your involvement in our efforts to correct cuts in the reimbursement of interventional techniques, allowing us to provide nonopioid techniques to our patients to keep opioid usage at a minimum (as elimination is impossible). Correcting these cuts will also reduce numerous adverse consequences related to patient access, employee layoffs, reduced quality of care, increased opioid adherence monitoring usage costs with drug testing, as well as evaluation and management services.

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

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