American Society *of* Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

81 Lakeview Drive, Paducah, KY 42001
Phone: (270) 554-9412 - Fax: (270) 554-5394
www.asipp.org

Society *of* Interventional Pain Management Surgery Centers Inc.

81 Lakeview Drive, Paducah, KY 42001
Phone: (270) 554-9412 - Fax: (270) 554-5394
www.sipms.org

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: File Code CMS–1734–P. Medicare Program; CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs: Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule.

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–1734–P: Medicare Program; CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies.

At the outset, we would like to thank CMS for numerous bold steps taken during the pandemic. We greatly appreciate what you have done in reference to Telehealth and specifically adding telephone only codes during the pandemic, now which is extended to December 20, 2021. We would like to see that this will be extended into the future indefinitely. In addition, we would like to request you to encourage all Medicare Advantage Plans, other governmental programs such as TriCare, Champus, VA, all Medicaid plans including Managed Care Medicaid, and, finally, implementation to require the commercial health insurers to follow the same.

In addition, we also commend CMS for the bold steps they continue to take in reducing bureaucracy and making the practice of medicine easier. However, with the raging pandemic, in combination with the opioid epidemic, and multiple regulations with declining services, and reduced physician fee, fraud and abuse investigations continue to rage despite CMS' actions to limit them. A multitude of audits by AdvanceMed and other RAC organizations must be stopped, at least until December 20, 2021. These are only enriching these contractors, not helping anyone, specifically not improving the access.

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

- 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.

♦ 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. 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.

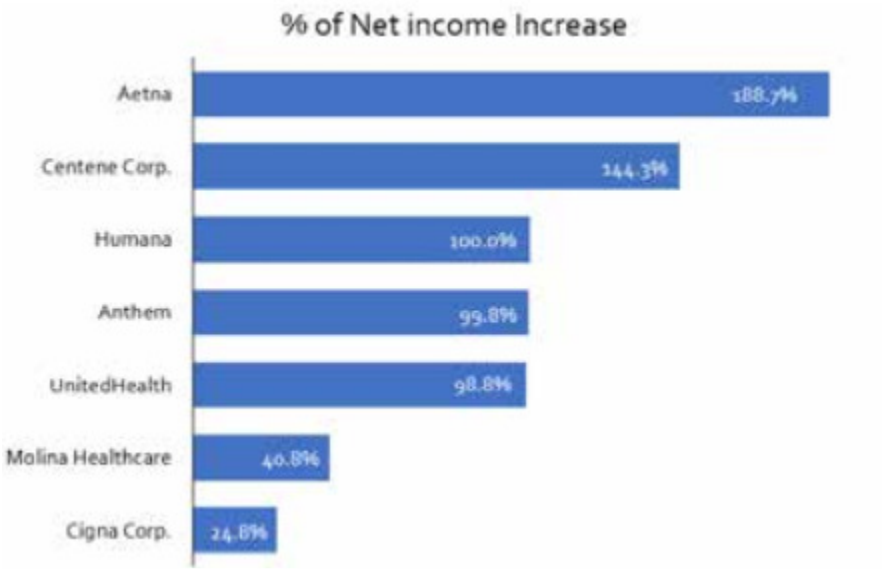
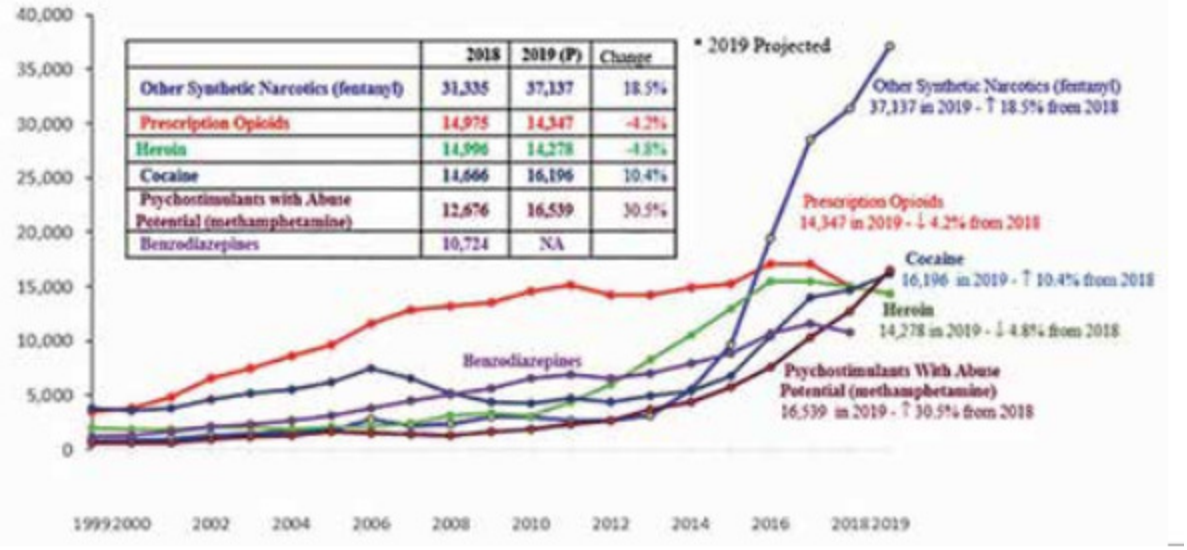


Fig. 2. *Percent of net income for second quarter of 2019 versus 2020.*

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

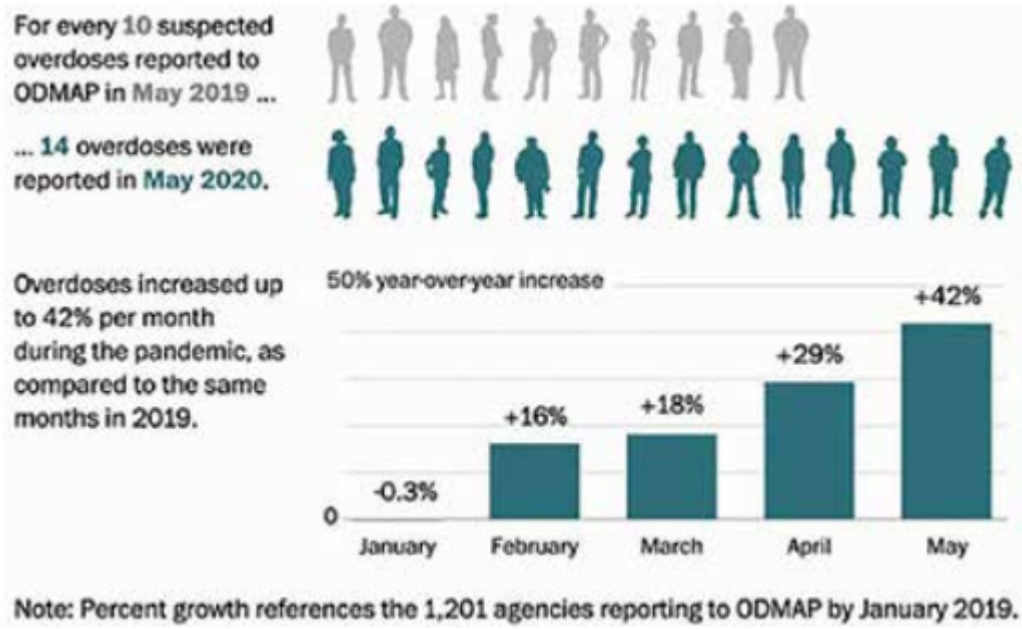


Fig. 4. *Dramatic growth in monthly overdoses during pandemic.*

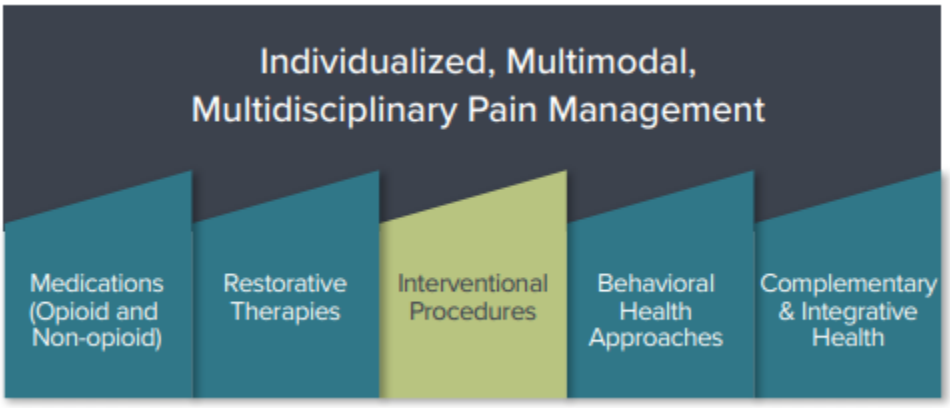


Fig. 5. *Chronic pain management consists of five treatment approaches informed by four critical topics*.

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

While there are numerous important proposals in this proposed rule which we provide comments on relevant issues below, we are particularly focused on four issues similar to AMA and other organizations. First, the calendar year (CY) 2021 rate setting and conversion factor deliver a significant decrease overall to physician payment. The proposals related to relative value units (RVUs), office and outpatient evaluation and management (E/M) visits, and the application of budget neutrality together result in a conversion factor that poses a very real threat to the ability of many physicians to deliver healthcare services to their patients. ASIPP, SIPMS and all our state societies and the entire membership strongly supports implementation of CMS' new office visit policy and believes it will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today. However, we are deeply concerned that the corresponding budget neutrality cuts are deeply problematic during or immediately after the SARS-CoV-2 or COVID public health emergency (PHE), during which physician practices have experienced severe reductions in revenue. The almost 11 percent cut to physician payment is impactful in a most harmful way, especially during these unprecedented times. We urge CMS to use its authority to waive budget neutrality, and to bring physician payment up to a level commensurate with their service. We offer several recommendations on how the impact of the conversion factor can be lessened.

COMMENTS:
Our comments are related to physician payments for payment policies for interventional procedures performed in multiple settings and in-office, laboratory fee schedule, and the quality payment program.

1. PHYSICIAN FEE SCHEDULE

ASIPP strongly supports January 1, 2021 implementation of the improvements to E/M office visits, including those bundled into the postoperative period of surgical procedures. However, physician payment cuts due to the budget neutrality adjustments cannot take effect. CMS should exercise the full breath and depth of its administrative authority to avert, or at a minimum, mitigate these devastating payment cuts. Multiple organizations, including ours, have offered several alternatives as follows:

- **ASIPP urges CMS to continue** and make permanent several telehealth services, including telephone only services, CPT codes 99441, 99442, 99443, to remove barriers to access based on geography and site of service, and to continue the coverage and payment policies that it has put in place for audio-video and audio only services during the COVID-19 public health emergency through the end of the year following the year in which PHE ends.
- ASIPP requests that these telehealth services, including audio only, should be mandated to be followed by all governmental insurances, including Medicare Advantage Plans, VA, Champus, TriCare, etc., Medicaid and Medicaid Managed Care Plans, and also all types of providers including commercial insurers.
- ASIPP supports the opioid use disorder policies, including the expansions of the monthly bundled payment codes to all substance use disorders and the payment of physicians in all settings to stabilize patients with withdrawal symptoms.

2. PROCEDURAL PAYMENT POLICIES

Numerous discrepancies continue with the site of service differentials in office, hospital outpatient department (HOPD) and ambulatory surgery centers (ASCs). The majority of the procedures performed in an office setting are synonymous to HOPD procedures, because most procedures in hospital settings are performed in their offices. In fact, office setting conditions may be superior to those provided in hospitals. Surgery centers, of course, require additional requirements and an overwhelming majority of the procedures are performed in an operating room. For interventional pain management procedures performed in hospital settings, hospitals often **do not** utilize operating rooms. Consequently, their estimations are much lower than what it would be if they were performed in an operating room and these inaccurate prices are translated to ASCs at a much lower rate, which in turn are translated to physician payment policies.

Despite multiple recommendations from MedPAC and the Office of Inspector General, it appears that CMS is unable to change these policies.

Overall, physicians are facing as high as 11% cuts in their reimbursement for providing interventional techniques, which is extremely difficult to handle considering the pandemic and a perfect storm created by numerous factors.

i. Peripheral Nerve Blocks and Neurolytic Blocks

We appreciate addition of new codes for genicular nerves, sacroiliac joint nerve blocks, and denervation with appropriate evaluation of these codes and increase in price levels. We are hoping that CMS will further refine and provide us with improved final schedule.

However, the bad news is that CMS has proposed major draconian cuts for some of the procedures, **which is extremely hard to believe based on any reasonableness** during perfect storm as follows:

1. Multiple intercostal nerve blocks (CPT 64421) have been reduced with their fee of 72.3% in a facility setting (ASC or HOPD) from $95.14 to $26.35, a 72.3% drastic reduction in 2020. Similar policies with additional reductions of 9% continue in proposed rule for 2021.

   For the same code, CPT 64421, when performed in an office setting, which also includes supplies, etc., non-facility fee has been reduced from $160.73 to $35.01, a drastic reduction of 78.2% in 2020. Similar policies continue in proposed rule for 2021.

2. Pudendal nerve block performed for chronic persistent pelvic pain (CPT 64430) has been drastically reduced in reimbursement in a facility setting for physicians (ASC or HOPD) from $82.89 to $57.38, a 30.8% drastic reduction in 2020. Similar policies continue in proposed rule for 2021, with additional 9% cut.

   The same code, CPT 64430, when performed in an office setting (non-facility) has been reduced from $149.20 to $92.75, a 37.8% reduction in 2020. Similar policies continue in proposed rule for 2021.

3. Greater occipital nerve, CPT 64405, performed for occipital headache have been reduced 13.8% from $85.41 when performed in a non-facility or office setting to $73.62, a 13.8% decrease in 2020. Similar policies continue in proposed rule for 2021, with additional cuts of 8%.

4. CPT 64400, trigeminal nerve block, has been reduced in a non-facility setting (office) from $139.83 to $107.55, a 23.1% cut. The same code has been reduced when in a facility setting for physicians performing in ASC or HOPD from $74.96 to $51.25, a 31.6% reduction in 2020. Similar policies continue in proposed rule for 2021, with additional 7.5% cuts.

5. CPT 64425, iliohypogastric nerve injection, has been reduced in a non-facility setting (office) from $141.63 to $115.13, a 18.7% cut. The same code has been reduced when in a facility setting for physicians performing in ASC or HOPD from $98.03 to $57.74, a 41.1% reduction in 2020. Similar policies continue in proposed rule for 2021, with additional 9% cuts.

The government should provide general funds to Medicare to avoid budget neutrality payments and do not cut payments for interventional techniques.

3. REMOTE PATIENT MONITORING TECHNOLOGY

1. CMS' proposal requiring physiologic data to be "electronically (i.e. automatically) collected and transmitted rather than self-reported" effectively eliminates important physiologic parameters such as pain and mood from the treatment management services made possible by remote patient monitoring.
2. The 20 minutes of time requirement for CPT codes 99457 and 99458 should include time for all treatment management services and should not be limited to synchronous audio communication.
   The reimbursement associated with the RPM codes is simply not enough to support all of the other work of treatment management services PLUS 20 minutes of synchronous audio communication.
   Patients should be allowed the flexibility to communicate with their providers about their conditions in whatever way works best for them, rather than be limited to phone conversations.
3. The determination of how many data recordings per 30 days are optimal for a particular patient with a particular condition should be left to the medical judgment of the treating practitioner.
4. CMS should clarify that the "programmed alert(s) transmissions" referenced in the code descriptor for CPT Code 99454 may also count towards the minimum "16 days" of monitoring in order to report CPT codes 99453 and 99454.

The code descriptors for both CPT codes 99453 and 99454 read: "daily recording(s) or programmed alert(s) transmission, each 30 days."

5. The reporting periods for CPT Codes 99453, 99454, 99457, and 99458 should be aligned for all four RPM codes to reduce operational burden, confusion, and inefficiencies.

4. QUALITY MANAGEMENT PROGRAM

Even though CMS has made significant changes in this program, making it much easier to administer, it still needs numerous improvements with:

i. Complete elimination of meaningful or often meaningless use and numerous issues related to the EMRs. CMS must focus on reducing all the regulations so that the prices can come down to pre-stimulus package era of President Obama. The price gouging was based on supplementation from CMS to purchase EMRs.

ii. CMS should move towards a simplified scoring system.

iii. We strongly urge CMS to modify cost category and remain flexible on weights for the next 10 years while CMS is working on methodology to appropriately calculate the cost. Until then, there should be zero weight for the cost category or at least we should settle for 5%.

5. CLINICAL LABORATORY FEE SCHEDULE

ASIPP continues to have ongoing concerns about the potential impact of cuts to payment rates for clinical testing services paid on the clinical laboratory fee schedule.

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

Laxmaiah Manchikanti, MD
Chairman of the Board and Chief Executive Officer, ASIPP, SIPMS
Co-Director, Pain Management Centers of America
Medical Director, Pain Management Centers of Paducah and Marion,
Ambulatory Surgery Center and Pain Care Surgery Center
Clinical Professor, Anesthesiology and Perioperative Medicine
University of Louisville, Kentucky
Professor of Anesthesiology-Research
Department of Anesthesiology, School of Medicine
LSU Health Sciences Center
2831 Lone Oak Road
Paducah, KY 42003
270-554-8373 ext. 4101
drm@asipp.org

Harold Cordner, MD
President, ASIPP
Florida Pain Management Associates
13825 U.S. Hwy 1
Sebastian, FL 32958
gassdoc@aol.com

Amol Soin, MD
President Elect, ASIPP
President, SIPMS
Ohio Pain Clinic
8934 Kingsridge Drive, Suite 101
Centerville, OH 45458
937-760-7246
ohiopainclinic@gmail.com

Sudhir Diwan, MD
Past President, ASIPP
President, Park Avenue Spine and Pain
185 Madison Avenue
New York, NY 10016
sudhir.diwan63@gmail.com

Mahendra Sanapati, MD
Secretary, ASIPP
Vice President, SIPMS
Co-Director, Pain Management Centers of America
Medical Director, Advanced Care Pain Clinic
Evansville, IN 47714
Phone: (812) 477-7246
Fax: (812) 477-7240
Email: msanapati@gmail.com