September 11, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: 42 CFR Parts 416 and 419 [CMS-1678-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies and the Puerto Rico Society of Interventional Pain Physicians, as well as the entire membership of ASIPP; and Society of Interventional Pain Management Surgery (SIPMS) and the entire membership of SIPMS we would like to thank you for providing an opportunity to comment on 42 CFR Parts 416 and 419 [CMS-1678-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

Based on the review of the proposed rule and numerous adverse consequences from the continued cuts to access to patient care, reduction in quality, and escalating opioid epidemic with explosive death counts, we request that CMS modify the proposed rule appropriately to follow the payments provided in 2016 for 6 CPT codes describing epidural injection, facet joint nerve blocks, sacroiliac joint injections, and percutaneous adhesiolysis or simply add fluoroscopy component of $70 which has been removed with equal payment for procedure performed with or without fluoroscopy indicating major flaws in analysis.

- CPT 62321 Cervicothoracic epidural (formerly 62310) change 2017 reimbursement of $273.83 to 2016 reimbursement of $327.22
- CPT 62323 Lumbosacral epidural (formerly 62311) change 2017 reimbursement of $273.83 to 2016 reimbursement of $327.22
- CPT 64490 Cervicothoracic facet joint injection change 2017 reimbursement of $344.95 to $459.71
- CPT 64493 Lumbosacral facet joint injection change 2017 reimbursement of $344.95 to $459.71
- CPT G0620 Sacroiliac joint injection change 2017 reimbursement of $273.83 to $327.22
- CPT 62264 Percutaneous adhesiolysis – 1 day change 2017 reimbursement of $344.95 to $459.71

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 disectomy, 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 physician offices and are probably somewhat inferior because of the setup of ASCs.
  - The majority of the IPM procedures in HOPDs are performed outside the surgical suite, whereas the majority of the ASC procedures are performed in surgical suites.
  - Despite these differences, hospitals are reimbursed over 85% more than ASCs for the procedures which are approved for ASCs.

ASC PROPOSED RULE
As described earlier, the ASC proposed rule shows various payments in which hospital outpatient departments are reimbursed at over 85% more than ASCs for ASC approved procedures.

As we have contacted in the past, and had meetings with CMS our concern continue in relation to drastic cuts implemented in 2017 ranging from 16% to 25% for commonly performed interventional techniques in ASCs, and essentially carried in the proposed rule.

As we have presented to you the final rule of hospital outpatient prospective payment published in November 2016 (effective January 1, 2017), established cuts of 16.3% for epidurals, 25% for facet joint injections, 25% for adhesiolysis, and 16% for sacroiliac joint injections compared to 2016 for facility fee
in ASCs. Further, these cuts compound those of 2014 and 2015– around 26%. Above all, these cuts are far greater than in the proposed rule of July 2016. We are extremely disappointed that proposed rule for 2018 carries the same methodological flaws with continuation of drastic cuts for most commonly performed interventional procedures.

As described above, the proposed rule for 2018 continues to follow the same flawed methodology and without significant reprieve for the commonly performed procedures.

**REDUCTION FOR EPIDURAL INJECTIONS: 23% REDUCTION FROM 2015 AND 13% REDUCTION FROM 2016**

Epidural injections described here include interlaminar and caudal epidural injections with CPT codes 62310 and 62311 until December 2016. Since January 1, 2017, new CPT codes have been implemented, these CPT codes are from 62320-62323. Instead of 2 codes there are 4 codes provided in this new CPT coding system. One code in each region cervical and thoracic or lumbar and caudal involve imaging guidance. Consequently, one would expect higher reimbursement for the code with imaging guidance. However, CMS has proposed the same pricing of $308.43 for all 4 codes. Despite multiple comments, the final rule showed a reduction of 11.2% from the proposed rule to $273.83, with the same rate for all regions with or without fluoroscopy. CMS has not taken into consideration the fluoroscopy (x-ray viewing) and regional complexity in cervicothoracic region with increased expense. The same codes without a description regarding the use of fluoroscopy were reimbursed at $370.07 in 2014, $327.22 in 2016 with a total reduction in reimbursement of 26% from 2014, 16% from 2016, and 11.2% reduction from the proposed rule, which appears to be extremely unusual.

Epidural injections were classified as Level III nerve injections in 2000 based on a proposal presented by ASIPP at an Ambulatory Payment Classification (APC) Committee meeting. Since then, these have fluctuated substantially. The following shows fluctuating rates of ASC facility fees for epidural injections since 2013. The same procedures were reimbursed at $370.07 in 2014 with a reduction of 26% in 2017.

The proposed rule continues to be 23% less than 2015 and 13% less than 2016.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018(P)</th>
<th>% of change from 2015 to 2018(P)</th>
<th>% of change from 2016 to 2018(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>62321</td>
<td>C/T epidural (62310)</td>
<td>$317.46</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$327.22</td>
<td>$273.83</td>
<td>$285.16</td>
<td>-23%</td>
<td>-13%</td>
</tr>
<tr>
<td>62323</td>
<td>L/S epidural (62311)</td>
<td>$317.46</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$327.22</td>
<td>$273.83</td>
<td>$285.16</td>
<td>-23%</td>
<td>-13%</td>
</tr>
</tbody>
</table>

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Utilization has been implicated as a reason for being caught in a CMS screen ultimately leading to a decrease in reimbursement rates. However, based on Medicare data, interlaminar epidural injections shown above have not increased substantially compared to transformaminal epidural injections, which are not included in this discussion.

Overall, interlaminar epidural injections have decreased from 2009 to 2019. The decreases were 20.1% per 100,000 Medicare population with an annual decrease of 3.1%. In contrast, transformaminal epidural injections have increased 0.9% from 2009 to 2016 per 100,000 Medicare population with a 0.1% annual increase which is less than reductions of interlaminar epidural injections. Finally, overall epidural injections including interlaminar epidural injections and transformaminal epidural injections have decrease 12.0% per 100,000 Medicare population from 2008 to 2014 with an annual decrease of 1.8%.

The following table shows utilization of interlaminar and transformaminal epidurals in the fee-for-service Medicare population from 2009-2016 (Only for Primary codes)
Interlaminar Epidurals
CPTs 62310, 62311
(62320, 62321, 62322, 62323)

Transforaminal Epidurals
CPTs 64479, 64483

All Epidurals
CPTs 62310, 62311, 64479, 64483
(62320, 62321, 62322, 62323)

<table>
<thead>
<tr>
<th>Year</th>
<th>Service</th>
<th>Rate (Per 100,000)</th>
<th>Change from previous year</th>
<th>Services</th>
<th>Rate (Per 100,000)</th>
<th>Change from previous year</th>
<th>Services</th>
<th>Rate (Per 100,000)</th>
<th>Change from previous year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,063,669</td>
<td>2,322</td>
<td>-1.5%</td>
<td>669,670</td>
<td>1,462</td>
<td>9.8%</td>
<td>1,733,339</td>
<td>3,785</td>
<td>2.6%</td>
</tr>
<tr>
<td>2010</td>
<td>1,073,171</td>
<td>2,288</td>
<td>-1.5%</td>
<td>719,120</td>
<td>1,533</td>
<td>4.8%</td>
<td>1,792,291</td>
<td>3,820</td>
<td>0.9%</td>
</tr>
<tr>
<td>2011</td>
<td>1,114,458</td>
<td>2,307</td>
<td>0.9%</td>
<td>749,608</td>
<td>1,552</td>
<td>1.2%</td>
<td>1,864,066</td>
<td>3,859</td>
<td>1.0%</td>
</tr>
<tr>
<td>2012</td>
<td>1,138,569</td>
<td>2,264</td>
<td>-1.9%</td>
<td>754,382</td>
<td>1,500</td>
<td>-3.4%</td>
<td>1,892,951</td>
<td>3,763</td>
<td>-2.5%</td>
</tr>
<tr>
<td>2013</td>
<td>1,118,861</td>
<td>2,156</td>
<td>-4.8%</td>
<td>735,519</td>
<td>1,417</td>
<td>-5.5%</td>
<td>1,854,380</td>
<td>3,573</td>
<td>-5.1%</td>
</tr>
<tr>
<td>2014</td>
<td>1,024,599</td>
<td>1,915</td>
<td>-11.2%</td>
<td>801,737</td>
<td>1,499</td>
<td>5.7%</td>
<td>1,826,336</td>
<td>3,414</td>
<td>-4.5%</td>
</tr>
<tr>
<td>2015</td>
<td>1,036,124</td>
<td>1,887</td>
<td>-1.5%</td>
<td>809,480</td>
<td>1,474</td>
<td>-1.6%</td>
<td>1,845,604</td>
<td>3,362</td>
<td>-1.5%</td>
</tr>
<tr>
<td>2016</td>
<td>1,048,940</td>
<td>1,857</td>
<td>-1.6%</td>
<td>833,329</td>
<td>1,475</td>
<td>0.0%</td>
<td>1,882,269</td>
<td>3,331</td>
<td>-0.9%</td>
</tr>
</tbody>
</table>

Percent change from 2009-2016: -1.4% -20.1% 24.4% 0.9% 8.6% -12.0%
Geometric average change: -0.2% -3.1% 3.2% 0.1% 1.2% -1.8%

Consequently, the inappropriate reimbursement continues which is not based on utilization patterns and also is not based on appropriate assessment of intensity required services as these were calculated from HOPD settings which were performed in hospital outpatient offices, very similar to physician offices are even at times inferior with difficult access and also extremely expensive for follow-up visits too.

In addition, the reimbursement for transforaminal epidural injections also has not kept pace with inflation practice expenses for facilities, which continues to be less than 2014 and 2015 reimbursement.

An additional inappropriate issue is related with or without fluoroscopy. Fluoroscopy is expensive with the equipment, preparation of the room, and fluoroscopic technician averaging $60 per procedure. Consequently, even if CMS increases the reimbursement rates by $70 to include appropriately the cost of fluoroscopy, it will increase to $355.16, which will be more reasonable, and same as continuous epidurals.

Continuous epidural injections is also an issue. These are overwhelmingly performed without fluoroscopic guidance, generally outside the operating room for different purposes rather than chronic pain management. These are reimbursed at a higher level. The epidural injections under fluoroscopic guidance must be reimbursed at the same level.
Consequently, either utilizing fluoroscopic guidance with a cost of $70 which brings the total to $355.16 or the same reimbursement as for continuous epidural catheterization of $355.31 with reduction of non-fluoroscopic continuous epidurals to $285.16 and keeping non-fluoroscopic epidurals at $285.16 will be the most appropriate solution at the present time.

In respect to physician payment schedule, CMS has gotten this right and have reimbursed for non-facility setting procedures (in-office) $80 less than fluoroscopy. Philosophically this is accurate even though it is inadequate payment for office settings also. The same philosophy must be applied in ASCs with higher payments for procedures performed under fluoroscopic guidance with addition of $70 as described above.

**REDUCTION FOR FACET JOINT INJECTIONS REIMBURSEMENT: 23% FROM 2016**

Facet joint injections performed in the cervical and thoracic regions are coded as follows: CPT 64490 (1st level), 64491 (2nd level), and 64492 (3rd level).

Facet joint injections performed in the lumbar and sacral regions are coded as follows: CPT 64493 (1st level), 64494 (2nd level), and 64495 (3rd level).

The facet joint nerve injections which were classified as Level 4 nerve injections by CMS in 2000 are more complicated. Traditionally, Medicare has reimbursed ASCs for the first procedure and a lower reimbursement for second and third levels as additional procedures. In 2014, CMS changed the reimbursement pattern and combined all add-on codes into primary code by reimbursing only the first level. Consequently, the first level reimbursement increased in 2014 to $370.07 and to $459.71 in 2016, which was decreased to $382.99 in the 2017 proposed rule and the final rule included another 9.9% reduction from the proposed rule to a final payment rate of $344.95 indicating a reduction of 25% from 2016.

The proposed rule of 2018 continues the same philosophy with continued 23% reduction compared to 2016 with only a 3% increase from 2017.

Overall, the reimbursement for these codes has been as follows:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018 (P)</th>
<th>% of change from 2016 to 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>64490</td>
<td>C/T facet joints, 1st Level</td>
<td>$317.46</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$459.71</td>
<td>$344.95</td>
<td>$355.31</td>
<td>-23%</td>
</tr>
<tr>
<td>64491</td>
<td>C/T facet joints, 2nd Level</td>
<td>$102.47</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64492</td>
<td>C/T facet joints, 3rd Level</td>
<td>$102.47</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64493</td>
<td>L/S facet joints, 1st Level</td>
<td>$317.46</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$459.71</td>
<td>$344.95</td>
<td>$355.31</td>
<td>-23%</td>
</tr>
<tr>
<td>64494</td>
<td>L/S facet joints, 2nd Level</td>
<td>$102.47</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64495</td>
<td>L/S facet joints, 3rd Level</td>
<td>$102.47</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

(P): Proposed

Utilization patterns have shown significant increases for facet joint injections at a rate of 363% per 100,000 Medicare population for cervicothoracic facet joint blocks (64470 or 64490) and 255% per 100,000 Medicare population for lumbosacral facet joint blocks (64475 or 64493) from 2000 to 2016.

Consequently, following the same flawed methodology of calculating hospital outpatient office expenses and paying them 85% more than ASCs is an issue which needs to be immediately addressed.

**REDUCTION FOR PERCUTANEOUS ADHESIOLYSIS: 25% FROM 2016**

Percutaneous adhesiolysis procedure has suffered significant negative changes over the years. This code was included in Level V nerve injections, which included other neurolytic blocks and radiofrequency thermoneurolysis, etc. These codes involve CPT code 62264 and 62263, one-day or multiple day procedures. The reimbursement for these procedures has gradually declined from 2014 for 62263 and also...
was miscalculated for 62264. However, both procedures are performed with same intensity. Further, the required supplies, personnel, and facility setting is more cost intensive than for epidural injections. The reimbursement is at $344.95 with a 25% reduction from 2016 and 10% reduction from proposed rule, which is the same as a simple epidural. This procedure has been classified in the nerve block category in APC classification with radiofrequency neurotomy procedures, which are reimbursed at $788.19 in 2017 with a 56% underpayment.

The 2018 proposed rule also follows the same flawed methodology with an increase of 3%, retaining a 25% reduction from 2016.

Overall, the reimbursement for percutaneous adhesiolysis has been as follows since 2013:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018(P)</th>
<th>% of change from 2016 to 2018(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>62263</td>
<td>Adhesiolysis - 2 or 3 days</td>
<td>$480.71</td>
<td>$853.53</td>
<td>$805.75</td>
<td>$459.71</td>
<td>$344.95</td>
<td>$355.31</td>
<td>-23%</td>
</tr>
<tr>
<td>62264</td>
<td>Adhesiolysis – 1 day</td>
<td>$480.71</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$459.71</td>
<td>$344.95</td>
<td>$355.31</td>
<td>-23%</td>
</tr>
</tbody>
</table>

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In contrast to multiple other procedures in interventional pain management, the use of the percutaneous adhesiolysis procedure has declined substantially with 97% decline for 3-day procedure from 2000 to 2016 per 100,000 Medicare recipients and fee-for-service and 3% decline for one-day procedure from 2001 to 2016 per 100,000 Medicare recipients and fee-for-service.

Consequently, the reductions are not based on utilization and only are based on flawed methodology utilized similar to other procedures where these are performed in hospital office settings rather than surgery settings and these rates are translated at a lower rate to surgical settings in ASCs.

**REDUCTION FOR SACROILIAC JOINT INJECTIONS: 23% REDUCTION FROM 2015 AND 13% REDUCTION FROM 2016**

These were classified as Level III nerve injections. However, over the years, the reimbursement patterns have changed substantially for this code. The data below shows various changes. Overall, the highest reimbursement was $370.07 in 2014, which declined to $327.22 in 2016 and from there to $308.43 in the proposed rule of 2017, and, finally, to $273.83 in the final rule of 2017 with a 16% reduction from 2016 and 11% reduction from 2017 proposed rule. Further, compared to 2014, there was a 26% reduction.

The proposed rule of 2018 continues to follow the same flawed methodology and philosophy with a 4.1% increase which leaves us with a 23% reduction compared to 2015 and a 13% reduction compared to 2016.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018(P)</th>
<th>% of change from 2015 to 2018(P)</th>
<th>% of change from 2016 to 2018(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0260</td>
<td>Sacroiliac joint</td>
<td>$317.46</td>
<td>$370.07</td>
<td>$368.37</td>
<td>$327.22</td>
<td>$273.83</td>
<td>$285.16</td>
<td>-23%</td>
<td>-13%</td>
</tr>
</tbody>
</table>

(P): Proposed

The use of sacroiliac joint injections has increased significantly over the years, 346.6% from 2000 to 2016 per 100,000 Medicare recipients and fee-for-service. They were 49,554 services or 125 per 100,000 Medicare population in 2000 compared to 315,480 services or 558 per 100,000 Medicare population showing an obvious reduction.
Thus based on flawed methodology for other procedures utilized, these reimbursement patterns are inaccurate and inadequate.

**OTHER REIMBURSEMENTS**

For vertebral augmentation procedures, the reimbursement rates were significantly lower in 2017 compared to 2016 with 8% to 20% reduction in payments. 2018 proposed schedules for these procedures shows a 2.7% and 3.6% increase for vertebroplasty and kyphoplasty procedures respectively. Consequently, it continues to be difficult for ASCs to perform these procedures as overhead expenses continue to creep up. The reimbursement for ASCs must be in par with office procedures or higher which are reimbursed at much higher level including reimbursement for multiple procedures. This indicates the beginning of multiple miscalculation and application of flawed data which pays more in an office setting which is traditionally paid much less than hospital outpatient and less than ASCs. These procedures continue to be more expensive to be performed in HOPD settings, as well as office settings.

Other issues are related to a multitude of other procedures. It is surprising that ASC rates for trigger point injections, as well as small joint injections have been increased significantly. However, these may not make any difference when these are performed along with other procedures as Medicare tends to bundle them with other procedures. However, for single procedures, these will increase reimbursements and also increase the program cost. This pattern of reimbursement also increases the cost substantially higher than office setting. The appropriate solution would be to keep the reimbursements for ASCs at the levels they were and reduce HOPD reimbursements to the same levels as ASCs. These codes are described under CPT 20526 to 20610. As an additional comment, these reimbursements are even higher than peripheral nerve blocks, which again shows flawed methodology.

**THE PATTERN OF REIMBURSEMENT**

The pattern of reimbursement from CMS has changed and continues to change over the years, not only from year to year, but also significantly from proposed rule to final rule as summarized in Table 1. We are unable to discern any logic to the change, outside of possible errors on the part of CMS.

Another major issue is related to the calculation of the costs of procedures. It appears that CMS is looking at 6 million procedures or so in arriving at prices for hospital outpatient departments and then reducing them by 40% to 50% for ASCs. The critical flaw with this manner of calculation is the majority of IPM procedures in HOPDs are performed outside the surgical suite, whereas the majority of the ASC procedures are performed in surgical suites.

To accurately determine HOPD rates, not only for interventional techniques, but for all HOPD procedures, CMS must utilize only the procedures performed in surgical suites in the hospital setting and calculate the reimbursement based on that data.

Further, CMS should reduce the payment for HOPDs, which are not performed in surgery suites, but in an office setting. Office settings in hospitals are significantly inferior to surgical suites in the hospital operating rooms or ambulatory surgical centers and equivalent to private office settings.

Consequently, based on the evidence presented thus far with apparent miscalculations and wild fluctuations, we request the CMS to implement the following:

- Implement 2016 payment rates for interventional procedures, specifically epidural injections, percutaneous adhesiolysis, facet joint injections, and sacroiliac joint injections.
- Update cost calculations of HOPDs once every 3 years
- Separate the procedures performed in operating suites and in-office settings in HOPD settings
  - Reimburse accordingly based on the site of service, either surgical suite or office setting in HOPD rules.
  - Similar to HOPDs reduce the reimbursement for ASCs, which did not perform the procedures in surgical suites.
Hopefully these comments will be effective in conjunction with previous meetings with CMS officials. We have found the official comments have been very ineffective and rather counterproductive in the past. We are hoping that the patterns will be reversed with appropriate application of methodologies.

It is crucial to reverse these cuts implemented from January 1, 2017 in the final rule to be effective January 1, 2018. Without reversal of the cuts, the consequences will be rather disastrous:

- Staff layoffs reducing the quality of care.
- Interventional pain management ASC closures.
- Reduced access to interventional pain management procedures.
- Exacerbation of opioid epidemic.
- Exacerbation of heroin and fentanyl epidemic as demonstrated by recent data (shown in figure below).
- Extensive increases in use of monitoring for opioid and other controlled drug therapy with increasing use of monitoring with exploding costs, often total costs exceeding by 300% to 400% than cost of interventional pain management services.
- Increase in evaluation and management services.

![Graph of Drugs involved in U.S. overdose deaths, 2000 to 2016](image)


Further, as we have discussed in the past and written to you, there has been significant evidence in these matters to avoid sudden extensive cuts to providers.

- As an example, the Medicare Modernization Act applied a new ASC payment methodology to be implemented between January 2006 and January 2008.
• Recommendation was for Centers for Medicare and Medicaid Services (CMS) to implement ASCs based on outpatient prospective payment system (OPPS).
• The proposed extensive cuts were spread over time, minimizing influence of sudden fluctuations which were expected to be substantial.
• In 2001, with the addition of 9 replacement codes, CMS has mistakenly denied payments stating that they were new codes. However, once CMS has realized that these were replacement codes, the payments were retroactively applied.

The final issue in reference to methodology requires corrections and appropriate application of site of services.

• As we have discussed there is significant debate on site-of-service differentials since Medicare Payment Advisory Commission (MedPAC) recommendation in 2012.
• Our contention is that these procedures are misvalued based on the overwhelming fact that over 90% of interventional procedures are performed outside the operating room in clinic settings in hospitals. Consequently, the costs by hospitals are not a reflection of costs in ambulatory surgery centers as over 90% of the procedures in ambulatory surgery centers are performed in the operating room with less than 10% performed in a procedure room, which is still much higher than a hospital clinic room.

• We have looked at statewide data from Kentucky. The Cabinet for Health and Family Services, Office of Health Policy, Commonwealth of Kentucky has a mechanism for collection of all types of data. These types of data may be available in other states; however, we do not have access to those.
• Commonwealth of Kentucky collects data of total ambulatory pain procedures, collecting the data of the total pain management in operating rooms. Based on this data, of the total pain management in the operating room of the total of approximately 20,000 pain management procedures performed in the operating room, only 4,138 procedures were performed in hospital operating room.
• This is in contrast to total number of hospital outpatient department pain management procedures of twenty-nine thousand just in Medicare patients. Consequently, these can be translated to 60,000 to 75,000 total procedures performed in Kentucky, of which only 4,138 were performed in the operating rooms with fewer than 10% being performed in the operating rooms.
• In contrast, a significantly higher proportion of procedures are shown to be performed in the operating rooms in surgery centers as the data also shows pain procedures performed outside the operating room in ASC procedure room, which is much superior to a clinic setting established in hospitals.

We contend that the data collection across the nation would show the same types of results.

The costs of performing a procedure in the operating room versus in a clinic is highly variable with approximately at least two-fold increase in an operating room. Exact cost data is difficult for us to obtain; however, CMS can do this.

• As CMS is already collecting with modifiers of onsite and offsite procedures performed, CMS also has ability to collect this data by applying modifiers without major cost increases to the agency or the providers.
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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