

# American Society of Interventional Pain Physicians®

## "The Voice of Interventional Pain Management"

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March 13, 2018

**Chairman Kevin Brady**

Committee on Ways and Means

**Ranking Member Richard Neal**

Committee on Ways and Means

**Chairman Peter Roskam**

Committee on Ways and Means, Subcommittee on Health

**Ranking Member Sander Levin**

Committee on Ways and Means, Subcommittee on Health

RE: Response to Your Letter on Addressing the Opioid Crisis

Honorable Chairmen and Ranking Members of the Committee on Ways and Means:

Thank you for your February 27<sup>th</sup> letter requesting a response from the American Society of Interventional Pain Physicians to multiple questions related to Overprescribing/Data Tracking; Communication and Education; and Treatment.

The American Society of Interventional Pain Physicians (ASIPP) is a not-for-profit professional organization formed in 1998, now comprised of more than 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. As an organization, ASIPP began issuing warnings and preventive measures in early 2000 with its proposal of a national program ... the National All Schedules Prescription Electronic Reporting Act (NASPER), which was signed into law as a state run prescription drug monitoring program in 2005.

**At the least, NASPER must be fully funded by immediate appropriation of pending authorization of \$24 million.**

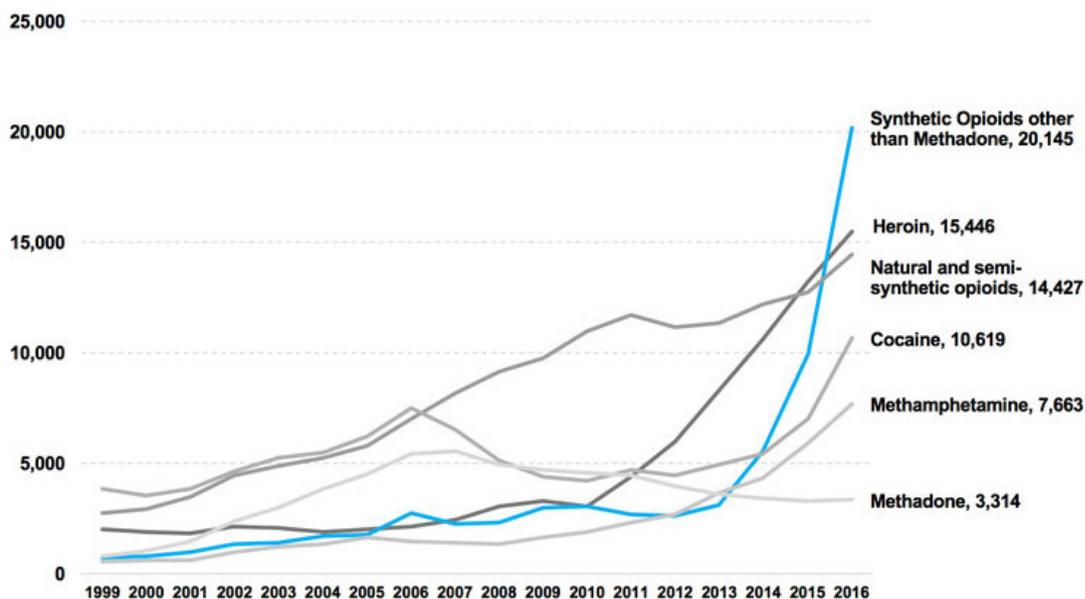
Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.<sup>1</sup>

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<sup>1</sup> The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09.  
[www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf](http://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 discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain.<sup>2</sup>

As you stated, opioid deaths continue to increase at a dramatic pace despite reductions in opioid prescriptions since 2010. Even though opioid prescriptions are still explosive with the amount of opioids prescribed continuing at 3 times higher than 1999, there is a reduction in opioid usage. Of the escalating drug overdoses of 64,000 deaths in 2016, the largest increase occurred in those related to illicitly manufactured fentanyl, which increased over 500% just in the past 4 years and accounts for more than 20,000 overdose deaths in 2016 versus less than 10,000 deaths in 2015. This difference is enough to account for nearly all increases in drug overdose deaths from 2015 to 2016.<sup>3,4</sup> Consequently, while fentanyl contributed to 20,000 deaths, heroin use, which continues to escalate since 2000 has contributed to over 15,000 deaths, whereas prescription drugs continue to be less than 15,000 deaths (Figs. 1-4).<sup>5,6</sup>



**Fig. 1.** Drugs involved in US overdose deaths, 2000 to 2016.

**Source:** CDC WONDER

<sup>2</sup> 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>

<sup>3</sup> Dowell D, Noonan RK, Houry D. Underlying Factors in Drug Overdose Deaths. *JAMA* 2017; 318:2295-2296.

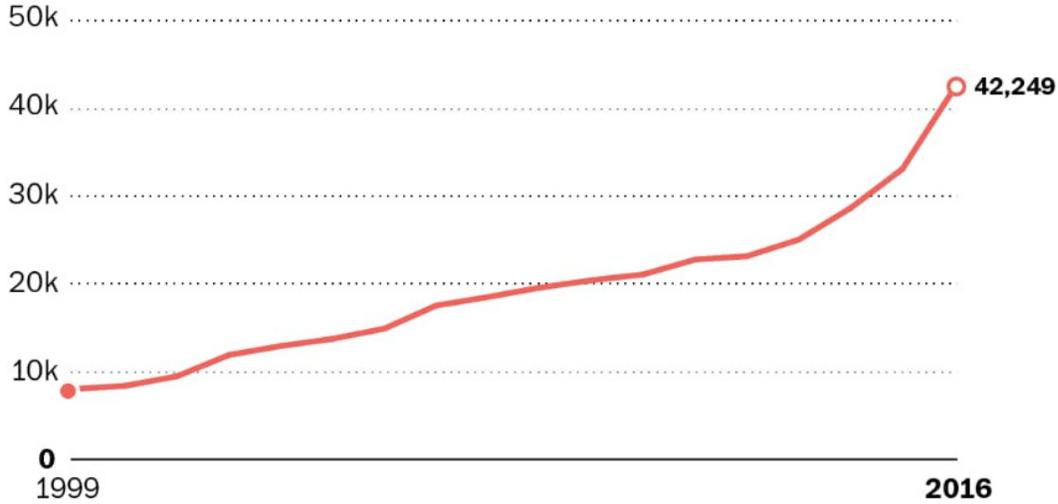
<sup>4</sup> US Centers for Disease Control and Prevention. Provisional counts of drug overdose deaths as of August 6, 2017. [https://www.cdc.gov/nchs/data/health\\_policy/monthly-drug-overdose-death-estimates.pdf](https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf).

<sup>5</sup> Guy GP, Zhang K, Bohm MK, et al. Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015. *MMWR Morb Mortal Wkly Rep* 2017; 66:697-704.

<sup>6</sup> Ingraham C. CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase.' *The Washington Post*, December 21, 2017. [https://www.washingtonpost.com/news/wnk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm\\_term=.f3f893febb8b](https://www.washingtonpost.com/news/wnk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b)

# Opioid deaths surge in 2016

Number of opioid overdose deaths, 1999 to 2016



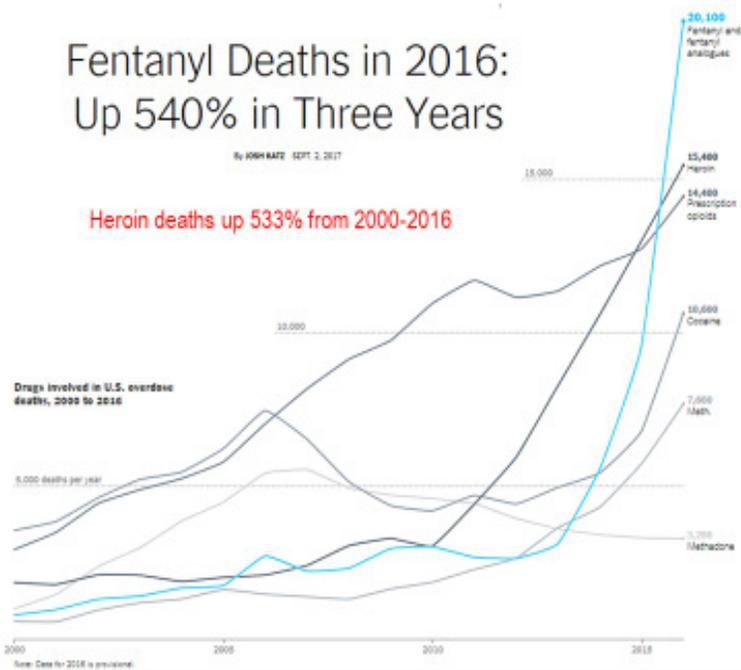
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Source: CDC

**Fig. 2.** Opioid deaths surge in 2016. Number of opioid overdose deaths by category, 1999 to 2016.

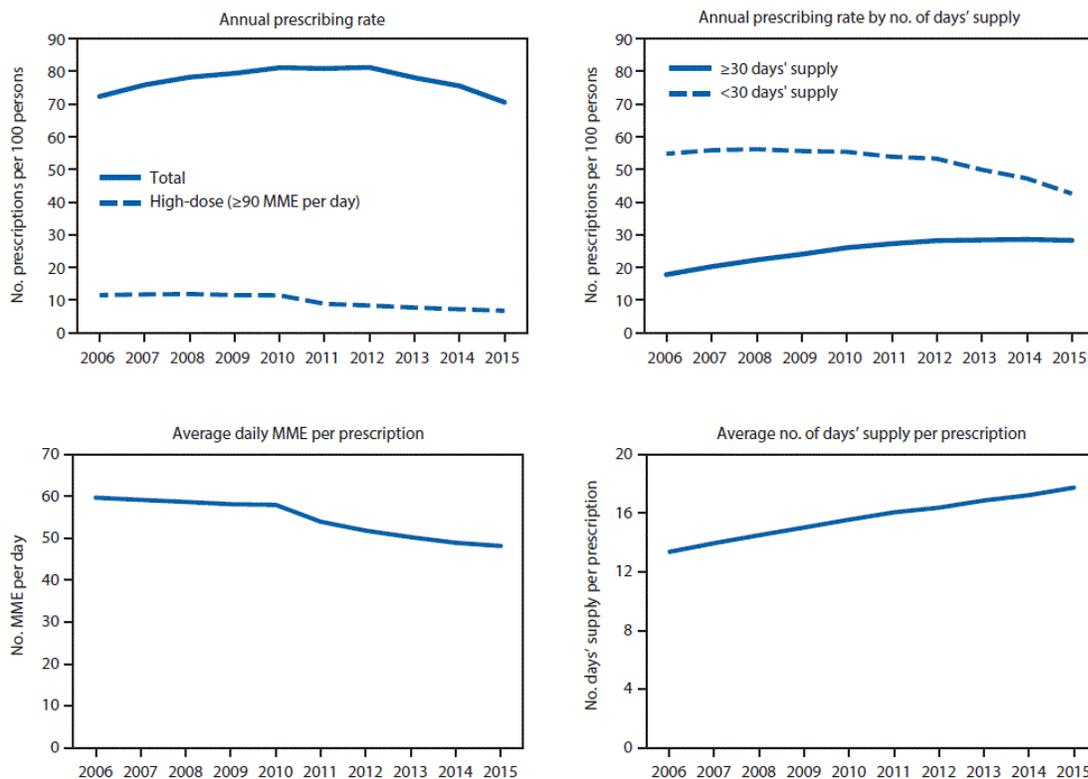
**Source:** Ingraham C. CDC releases grim new opioid overdose figures: ‘We’re talking about more than an exponential increase.’ *The Washington Post*, December 21, 2017.<sup>6</sup>

[https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm\\_term=.f3f893febb8b](https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b)



**Fig. 3.** *Quantification of drug deaths.*

Source: <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>



**Fig. 4.** Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.

**Source:** Guy Jr GP, et al. Vital Signs: Changes in opioid prescribing in the United States, 2006-2015. *MMWR Morb Mortal Wkly Rep* 2017;66:697-704.

Overall deaths due to prescription drugs, excluding methadone, only made up 14%. Consequently, it is not just a prescription overdose epidemic, but rather a fentanyl and heroin epidemic.

Following is a response to your specific questions:

## OVERPRESCRIBING/DATA TRACKING

### 1. Perverse Incentives in Medicare

Multiple incentives in fee-for-service Medicare, and specifically Medicare Advantage, include excessive copays and deductibles amounting up to \$6,000 per person based on new regulations and lack of information to the enrollees prior to the enrollment. This prevents enrollees from receiving appropriate care including nonopioid techniques with physical therapy, nonopioid drug therapy, and interventional techniques. It also makes it difficult for them to obtain coverage with interventional techniques with a payment of as high as \$300 if the procedures are performed in an ambulatory surgery setting or hospital setting.

Medicare Advantage Plans also encourage the prescription of opioids and simple visits by noncoverage of multiple interventional techniques including percutaneous adhesiolysis. They maintain if there is no LCD, then they will not cover any procedure. However, even on the procedures they do cover, they often pay less than 80% of the Medicare payment which provides a reverse incentive (Attachment A).

Many of the procedures that have significant evidence are not covered by Medicare Advantage just because of the lack of an LCD by FFS Medicare.

Fee-for-service Medicare also provides or exacerbates reverse incentives in Medicare by not providing LCDs for all the required procedures, which further leads to noncoverage by others and creates a donut hole with patients being unable to afford payments for nonopioid drug therapy.

As an example, Noridian's current noncoverage policy follows several inappropriate policies regarding interventional technique, all of which have results in inappropriate use of interventional techniques. These onerous policies of interventional techniques, only have exacerbated inappropriate use of interventional techniques. The noncoverage policies are in contrast to the description in the Integrity Manual, which lacks authority for them to provide noncoverage which should only be based on evidence and issued from coverage analysis group with advice from MedCAC.

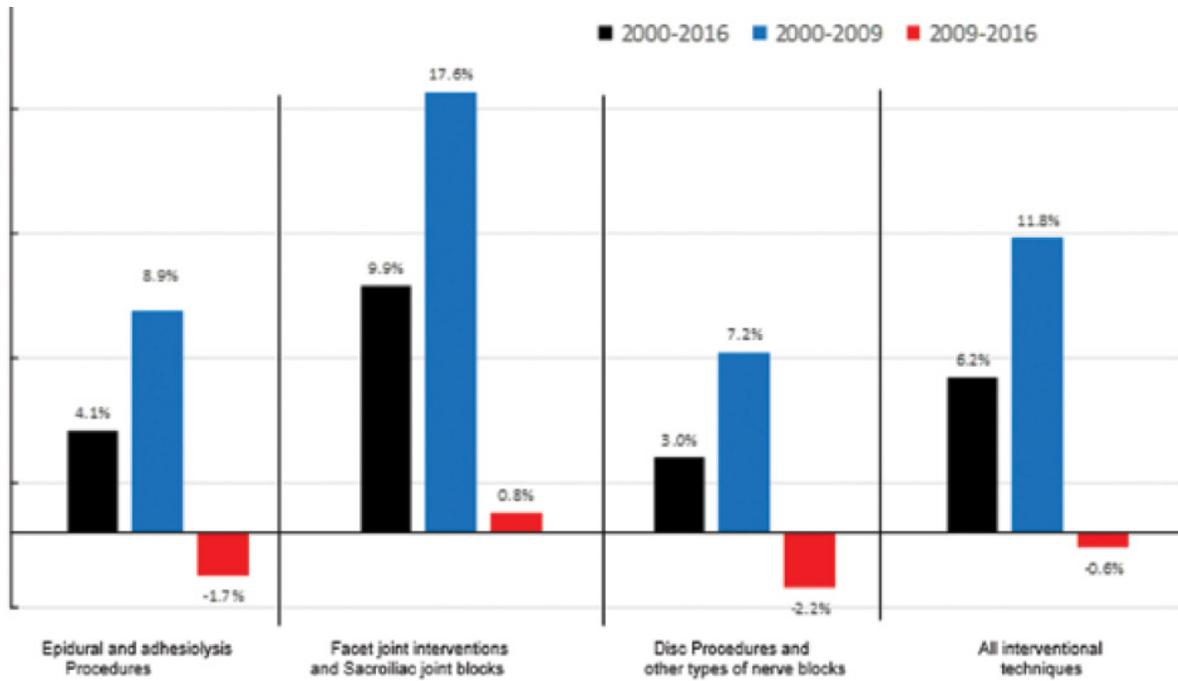
Medicare, including Medicare Advantage plans, Medicaid, and private insurers must provide easier access to, and low or no copayments for, nonopioid techniques including physical therapy and interventional techniques, which could potentially reduce the medication use and improve patient's functions and outcomes.<sup>7</sup>

- Ironically, as reimbursement of interventional techniques has decreased with decreasing utilization since 2010, opioid deaths have been escalating.<sup>8</sup>
- Evidence shows a direct relationship between the decline in utilization of interventional techniques and increase in the number of opioid deaths since 2010 (Figs. 5 and 6).

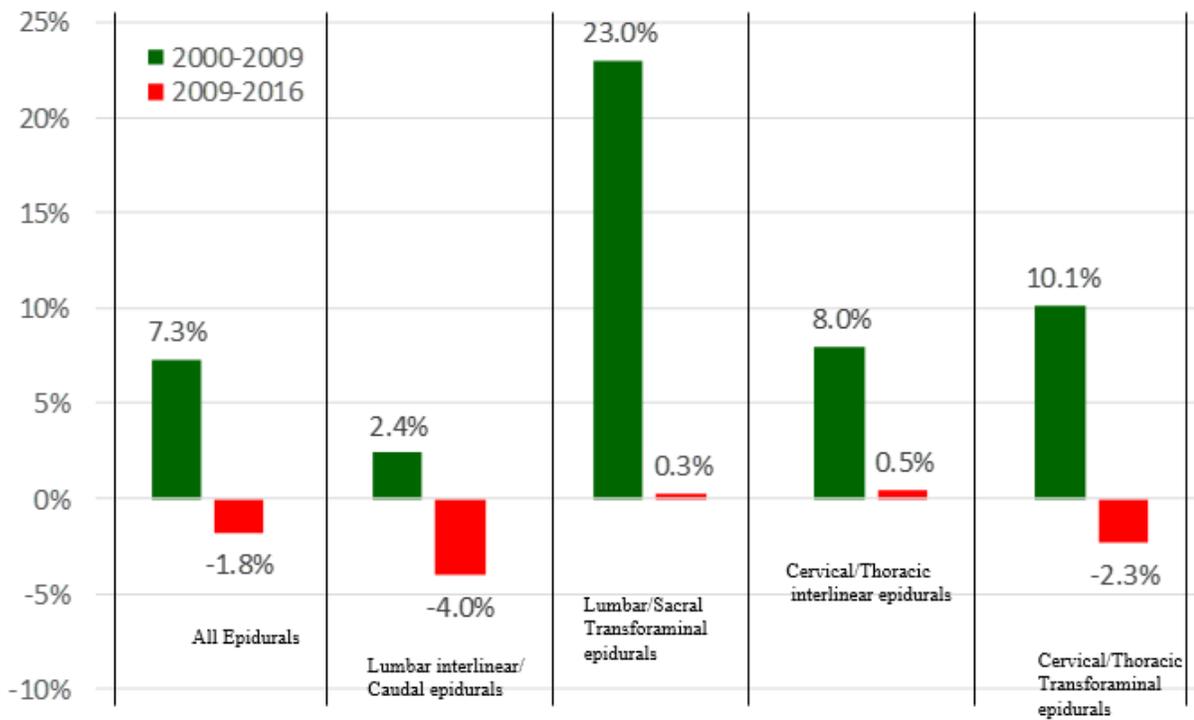
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<sup>7</sup> Manchikanti L, Kaye AM, Knezevic NN, et al. Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2017; 20:S3-S92.

<sup>8</sup> Manchikanti L, Soin A, Mann DP, et al. Reversal of growth of utilization of interventional techniques in managing chronic pain in Medicare population post Affordable Care Act. *Pain Physician* 2017; 20:551-567.



**Fig 5.** Comparative analysis of epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.



**Fig 6.** Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.

Medicare Advantage Plans also incentivize physicians with risk capitation programs which compel physicians to treat patients based on monthly payments versus fee for service. Overall, nonopioid pain medications tend to cost substantially more than short-acting opioid medications, such as oxycodone and hydrocodone. All nonopioid treatments including physical therapy and interventional procedures and behavioral therapies increase the costs.

There is also perverse incentivization of payments in Medicare by reducing the prices for epidural injections performed in all settings initially for physician payments and subsequently for facility payments moving on to other procedures or not performing the procedures because of loss of revenue. As an example, Medicare has reduced payments by 16% to 25% for multiple procedures performed in ambulatory surgery centers in 2017 which has caused substantial difficulties. This reduction is not based on any type of evidence.

Since pain is largely subjective, the perception that it can be easily controlled with opioids is pervasive among primary care physicians. In fact, within Medicare Advantage programs, physicians are incentivized NOT to refer to pain specialists due to their capitation. They will typically treat these patients as long as possible to save money and refer them only when the patient's pain is "no longer controlled" and patients are often dependent on opioids.

Consequently, pain physicians inherit a complex, physically dependent patient who expects to continue opioid therapy, making it much more difficult to reduce opioid usage.

## **2. Second-Fill Limits**

Many states have passed legislation limiting opioid prescriptions for acute pain. These vary from 3 to 7 days depending upon the state. There is usually some ability for the prescribing physician to modify the prescription for certain conditions. Generally speaking, some states limit the prescribing of opioids to 3-7 days requiring an *additional* evaluation for each subsequent prescription. This puts undue pressure on certain patients who may require extended prescriptions for surgeries, trauma, or extended therapy for both. It is recommended that second fill limits should be defined by condition, rather than a blanket limitation for all acute pain, and that this be determined by the treating physician.

## **3. Tools to Prevent Opioid Abuse**

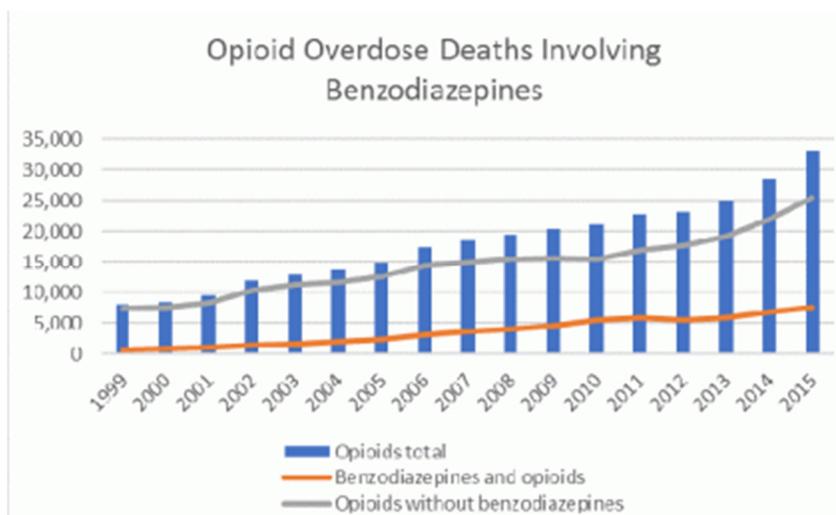
Screening tools exist to risk stratify patients receiving opioid for chronic pain. Most are relatively straightforward and require administration to each patient. There is currently no reimbursement via the Medicare fee schedule to compensate providers for their time to administer and interpret these tools. Examples include the Opioid Risk Tool (ORT), Screener for Opioid Abuse in Pain Patients Revised (SOAPP-R) and the Diagnosis, Intractability, Risk, Efficacy (DIRE) tool.

## **4. Medication Therapy Management (MTM)**

Medication Therapy Management (MTM), while not part of a prescription drug benefit, is a Medicare designed program which involves a pharmacist or other health care specialist reviewing a patient's medication list, often in a one on one setting to determine medication efficacy, side effects, medications interactions, and possible cost reductions. This type of program would be ideal for patients who are risk for substance use disorders (SUD), since many of these patients are the recipients of polypharmacy (taking multiple medications), which could have significant implications. Patients are often prescribed sedatives along with opioids which increases their

overdose risk significantly. Drug to drug interactions particularly with any psychoactive drug and opioids could have serious adverse effects. Geriatric patients commonly are prescribed many different medications, which can interact with sedatives and opioids.

The FDA and other authorities have expended significant amounts of energy and funding in issuing a Black Box warning to providers about combined use of benzodiazepines and opioids. It is a well-known fact for a long time that benzodiazepines are extremely risky, specifically in combination with opioids (Fig.7). However, similar to many Black Box warnings, this has resulted in increased expenses to patients, insurers with many difficulties for patients, sometimes leading to lack of access to benzodiazepines when they are medically needed. Benzodiazepines are rarely needed; however, there are certain settings where occasional or regular use of benzodiazepines is recommended. These conditions include presence of overwhelming anxiety beyond depression, failure to respond to antidepressant therapy, failure to respond to or inability to afford, or lack of availability of psychological interventions, failure to respond to other anti-anxiety medications. In these settings, patients are going to different physicians, which results in numerous visits to these physicians often who are not psychiatrists and also results in repeated drug testing, which only increases the costs. Some patients have disrupted their families and their lives due to these circumstances, leading providers not to provide combination. However, the bottom line remains to be the same. Patients often obtain both drugs, only from 2 different providers.



**Source:** Centers for Disease Control and Prevention (CDC). Multiple Cause of Death, 1999-2015.

**Fig. 7.** *Opioid overdose deaths involving benzodiazepines.*

This situation must be modified with encouraging pain physicians to provide careful benzodiazepine therapy and make available psychological interventions more accessible to avoid such situations for medically necessary patients.

## 5. Electronic Prior Authorization

Any facilitation in prior authorization would be a benefit to both physicians and patients. The current prior authorization (PA) process in the Medicare Advantage plans is intolerable, in that it could take up to 2 weeks to get a PA for a medication. For a patient who has chronic pain, this often compels the physician to prescribe an opioid while awaiting the PA, further promoting the potential for opioid misuse and abuse.

## 6. Prescription Drug Monitoring Programs (PDMPs)

These are vital tools for pain specialist in preventing doctor shopping and identifying potential abusers. ASIPP supports the National All Schedule Prescription Electronic Registry (NASPER) which would coordinate all state PDMP and provide data sharing. Currently, there are a few states that share data. In addition, the Veterans Administration should be included in the data sharing of PDMPs, which they often are not.

**At the least, NASPER must be fully funded by immediate appropriation of pending authorization of \$24 million.**

## COMMUNICATION AND EDUCATION

In the testimony in front of the Ways and Means Committee, ASIPP has provided multiple aspects of education in their 3-tier approach. These include:

1. An aggressive public education campaign with explicit teaching on the dangers of the use of illicit drugs, specifically heroin and fentanyl.
2. A public education campaign relating to the adverse consequences of opioid abuse in general with emphasis on the adverse consequences in combination with benzodiazepines.
  - A recent survey published in the *New England Journal of Medicine* shows that the public blame the opioid crisis on physicians, pharmacists, and pharmaceutical companies without putting much responsibility on patients. Forty-six percent of the public puts the blame on doctors who inappropriately prescribe medication (33%) and 13% put the blame on pharmaceutical companies that sell prescription medication but only 28% blame people who sell prescription pain killers illegally and 10% put the blame on people who take prescription pain killers.<sup>9</sup>
  - In addition, the public believes that public education and awareness programs are effective in a large proportion of patients.
3. Mandatory physician education for all prescribers of any amount of opioids or benzodiazepines with a mandated requirement of 4 hours of continuing education per year.
4. Mandatory patient education associated with the first prescription of any amount of opioid.

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<sup>9</sup> Blendon RJ, Benson JM. The public and the opioid-abuse epidemic. *N Engl J Med* 2018; 378:407-411.

## 1. Beneficiary Notification

Patients could be educated via print or online information on the effects of long term opioid use and alternative pain management treatment options. This is already available via several EMR platforms. Integrating these modules would be of benefit, with options such as Interventional Pain Medicine (IPM), which relies on procedures to treat pain rather than pharmacologic therapies.

## 2. Prescriber Notification and Education

Several states have passed legislation requiring licensed physicians to have education in safe opioid prescribing. ASIPP pioneered such education with our Controlled Substance Management Course which is a core requirement for certification from the American Board of Interventional Pain Physicians. This course could be modified to an enduring online activity and accessed by any physician. Medicare should consider mandatory controlled substance education for DEA licensed physicians.

Many health plans employ pharmacy benefit managers who routinely monitor prescriptions, especially multiple prescriptions from multiple providers. These plans also monitor maximum morphine equivalent dosing (MME) and will notify physicians if they are approaching or exceeding these limits.

## TREATMENT

### 1. Opioid Treatment Programs (OTP) and Medication Assisted Treatment (MAT)

The key question regarding referral to an OTP is the diagnosis of Opioid Use Disorder (OUD). Provider education is essential in diagnosing OUD especially in the chronic pain population. Unfortunately, OTP's are limited in number and MAT is a viable alternative. The Drug Addiction Treatment Act (DATA) of 2000 facilitated the treatment of OUD by allowing certain qualified physicians to obtain a waiver from the DEA to prescribe certain Schedule 3 medications (buprenorphine) to treat OUD. There are approximately 36,000 waived physicians in the US but only a fraction actually treat OUD. In addition, there is no current mechanism in the Medicare Fee Schedule to provide payment for such services. Certain codes exist within CPT such as H0033 Oral medication administration, direct observation but are NOT reimbursed by Medicare.

It is essential that Medicare pay physicians for these services, which are specialized and distinct from routine evaluation and management. In addition, Medicare MUST eliminate the prior authorizations for MAT with buprenorphine, as is being proposed in current Florida legislation. The "fast tracking" of MAT is essential to saving lives and preventing opioid overdoses. The physicians exist, the coding exists, the desire exists; the incentive and reimbursement do not.

Consequently, expand low threshold access to buprenorphine for opioid disorders.<sup>3,10,11</sup> It has been shown that a substantial proportion of patients who would benefit from buprenorphine treatment will receive this only if it becomes more attractive and more accessible than either prescription or illicit opioids.<sup>9</sup>

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<sup>10</sup> Kolodny A. Ten steps the federal government should take now to reverse the opioid addiction epidemic. *JAMA* 2017; 318:1537-1538.

<sup>11</sup> Auriacombe M, Fatséas M, Dubernet J, et al. French field experience with buprenorphine. *Am J Addict* 2004; 13:S17-S28.

- Opioid overdose deaths have been shown to decrease 79% over a period of 6 years after widespread prescribing of buprenorphine in France.<sup>10</sup> This will also lead to availability of buprenorphine and its products for chronic pain management.

The authorities must be careful in providing such facilitation as buprenorphine could be the next outbreak in the opioid crisis. We are seeing many people abusing buprenorphine on the street. One of the many reasons for this is a significant proportion of physicians and nurse practitioners providing buprenorphine therapy or nonpracticing physicians who have been in trouble and have issues with their license. This causes significant hardship to the public with direct payments to them instead of insurers covering them.

Remove methadone from formulary for prescribing outside methadone clinics, which is allegedly responsible for over 3,300 deaths per year with only 1% of total prescriptions.

## **2. Reimbursement**

We have discussed this extensively above specifically in relation to interventional techniques with high deductibles and copays. In fact, we are seeking for modification of payment system for ambulatory surgery centers for interventional techniques. Modification of the payment systems, modification of LCDs, and reduction or elimination of significant copays for interventional techniques will assist improving the opioid overprescribing situation.

## **3. Alternative options for treatment of pain**

There are many different methods for providing multimodal treatment of pain. These include but are not limited to IPM, physical therapies, acupuncture, behavior therapies, etc. Unfortunately, these modalities have been marginalized by payers and Medicare due to perceived costs. The never-ending plethora of PA and subsequent rejections only force more patients to cheaper alternatives, such as opioids.

IPM used appropriately via evidence-based guidelines is an integral part of multimodal pain treatment. The literature supports the use of IPM as well as other modalities, but payers routinely deny these therapies based on costs. They must be reevaluated and reinstated as part of multimodal pain therapy. This will reduce reliance on opioids and symptomatic pain control.

Thank you again for requesting ASIPP to provide input. If you have any further questions, please feel free to contact us.

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