

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

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February 22, 2018

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Energy and Commerce Committee

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Ways and Means Committee

Chairman Peter Roskam

Subcommittee on Health, Ways and Means Committee

Ranking Member Sander Levin

Subcommittee on Health, Ways and Means Committee

U.S. House of Representatives

RE: Addressing the Opioid Crisis

Honorable Committee Chairs and Ranking Members:

As President Trump officially declared opioid crisis a national public health emergency and congress continues to work on it, we propose a 3-tier solution for control of opioid epidemic. Understanding that underlying causes of crisis are many, but high rates of overdose deaths seem to be driven at least partially by high prescription rates; however, heroin and fentanyl deaths have been on the rise, even though, legal opioids still act as a gateway to these drugs along with other substances such as marijuana, overprescription often continues to lead to an increased likelihood of addiction. Following are our 3-tier solutions:

Tier 1 includes the following:

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.
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.

Tier 2 includes the following:

5. 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.
6. Expand low-threshold access to buprenorphine for opioid use disorder. 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.
7. Establishment of enhanced prescription drug monitoring program (PDMP) with National All Schedules Prescription Electronic Reporting Act (NASPER) program, with each state with a mandated capacity to be able to interact with at least all bordering states.
8. Mandated review of PDMP data by all providers, prior to all prescriptions.

Tier 3 includes the following:

9. Buprenorphine must be available for chronic pain management in addition to medication-assisted treatment, with a change of controlled substance scheduling to a Schedule II drug.
10. Remove methadone from formulary, which is responsible for over 3,000 deaths per year with only 1% of total prescriptions.

BACKGROUND

The American Society of Interventional Pain Physicians is a not-for-profit professional organization founded in 1998 now comprising of 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. ASIPP is comprised of 50 affiliated state societies, and the Puerto Rico Society of Interventional Pain Physicians. As an organization, ASIPP began issuing warnings and offering preventive measures in early 2000 with its proposal of a national program --- the National All Schedules Prescription Electronic Reporting Act (NASPER), which eventually was signed into law as a state-run prescription drug monitoring program in 2005. As you know, I am happy to state that all 50 states now have PDMPs. In fact, mandatory provider review of prescription drug monitoring programs and pain clinic laws have shown to reduce the amounts of opioids prescribed by 8% and prescription opioid overdose death rates by 12%. In addition, it has also been shown that relatively large reductions in heroin overdose death rates after implementation of mandatory prescription drug monitoring programs and pain clinic laws as of 2015.¹ ASIPP also offers extensive educational efforts for pain physicians including a variety of review courses and competency examinations.

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

¹ Dowell D, Zhang K, Noonan RK, Hockenberry JM. Mandatory provider review and pain clinic laws reduce the amounts of opioids prescribed and overdose death rates. *Health Aff (Millwood)* 2016; 35:1876-1883.

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.²

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.³

OPIOID EPIDEMIC

Unfortunately, opioid deaths continue to increase at a dramatic pace despite reductions in opioid prescriptions since 2010.⁴ No doubt opioid prescriptions are still explosive with the amount of opioids prescribed in the United States continuing to be 3 times higher than in 1999, the year ASIPP developed our idea of the National All Schedules Prescription Electronic Reporting Act (NASPER). Yet, in 2017, the national opioid epidemic continues to show escalation. Drug overdoses accounted for 64,000 deaths in 2016, with over 42,000 of opioid deaths, a 20% increase from 2015 from over 52,000. Increases are greatest for overdoses related to the category including illicitly manufactured fentanyl, which more than doubled, accounting 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.^{5,6} Consequently, while fentanyl contributed to 20,000 deaths, heroin contributed to 15,000 deaths, whereas prescription drugs contributed to less than 15,000 deaths (Figs. 1-3).^{4,7} Deaths due to heroin were up nearly 20% and deaths from other opioids such as hydrocodone and oxycodone were up 14%. Deaths due to methadone declined; however, they still constitute an extremely high percentage with over 3,000 deaths, which is only 1% of prescriptions. As we all realize, things might very well be worse than what is shown in the data. The present problem of overdose deaths is mainly due to illicit fentanyl and heroin use with contributions from prescription opioids. As you may know, Fentanyl is approximately 50 times as potent as heroin. This provides strong economic incentives for drug dealers to mix fentanyl with heroin and other drugs because smaller volumes can provide equally powerful effects at lower costs and easier transport.⁵ Ironically, the majority of people who use heroin are not seeking fentanyl and essentially try to avoid it.⁸ However, technology has improved so much that it is difficult to identify fentanyl, particularly in white powder form, and heroin is typically sold more in states, east of Mississippi river.⁹

² The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf

³ 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>

⁴ 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.

⁵ Dowell D, Noonan RK, Houry D. Underlying Factors in Drug Overdose Deaths. *JAMA* 2017; 318:2295-2296.

⁶ 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.

⁷ 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/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.f3f893febb8b

⁸ Carroll JJ, Marshall BDL, Rich JD, Green TC. Exposure to fentanyl-contaminated heroin and overdose risk among illicit opioid users in Rhode Island. *Int J Drug Policy* 2017; 46:136-145.

⁹ Gladden RM, Martinez P, Seth P. Fentanyl law enforcement submissions and increases in synthetic opioid-involved overdose deaths. *MMWR Morb Mortal Wkly Rep* 2016; 65:837-843.

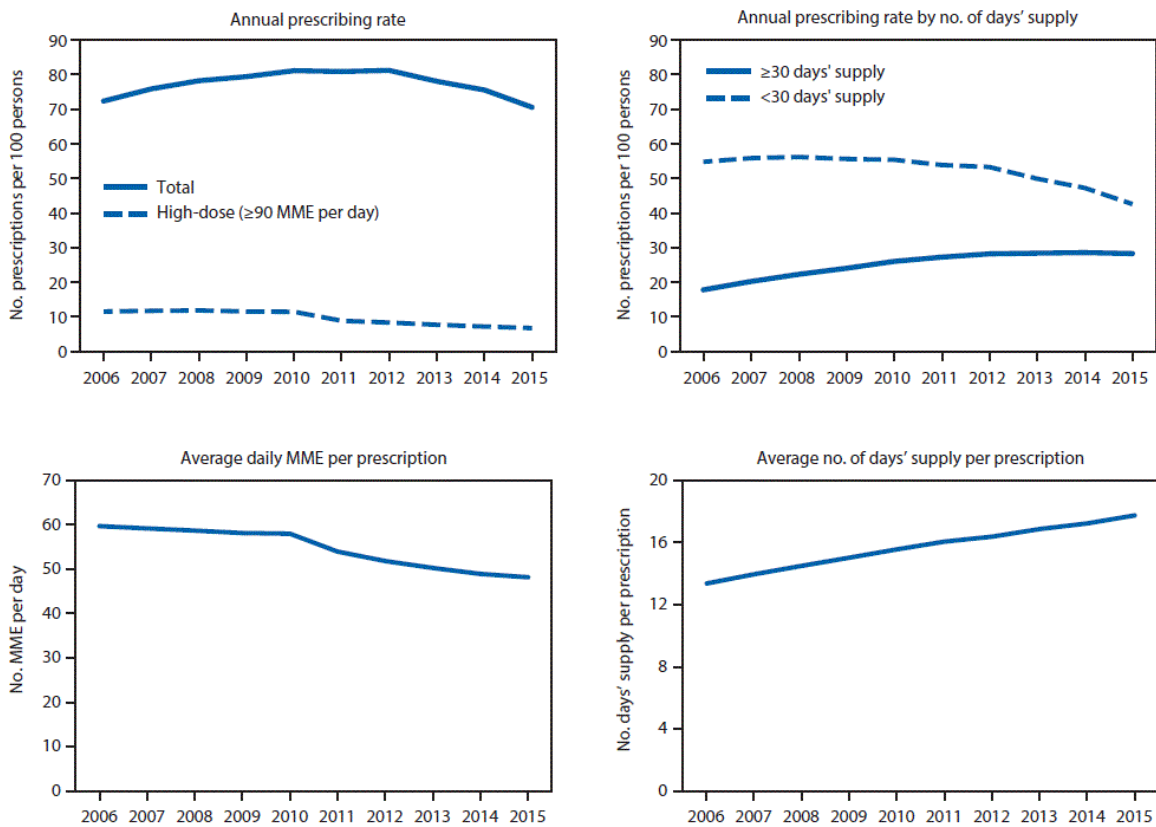
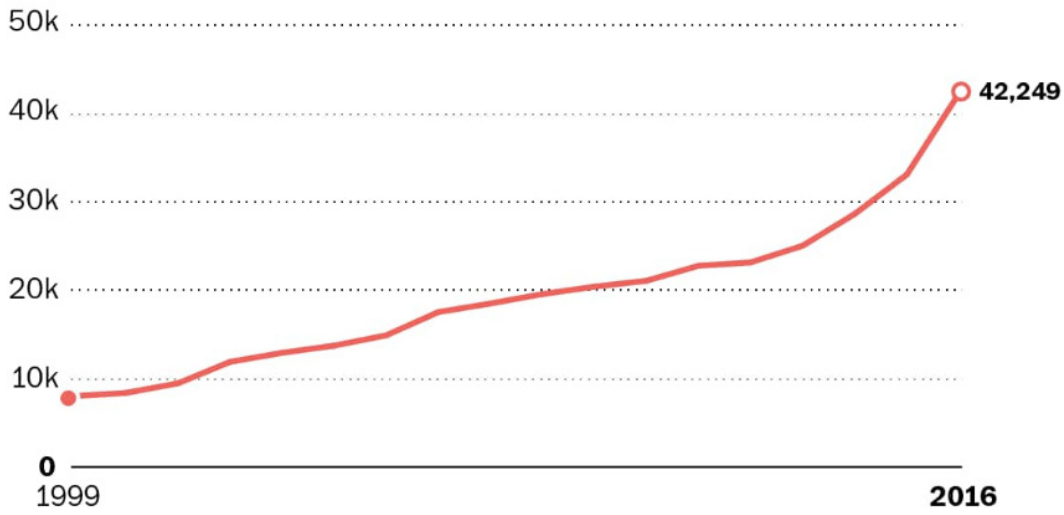


Fig. 1. Annual opioid prescribing rates, by number of days' supply, average daily morphine milligram equivalent (MME) per prescription, and average number of days' supply per prescription — United States, 2006–2015.

Source: Guy Jr GP, et al. Vital Signs: Changes in opioid prescribing in the United States, 2006–2015. *MMWR Morb Mortal Wkly Rep* 2017;66:697–704.⁴

Opioid deaths surge in 2016

Number of opioid overdose deaths, 1999 to 2016



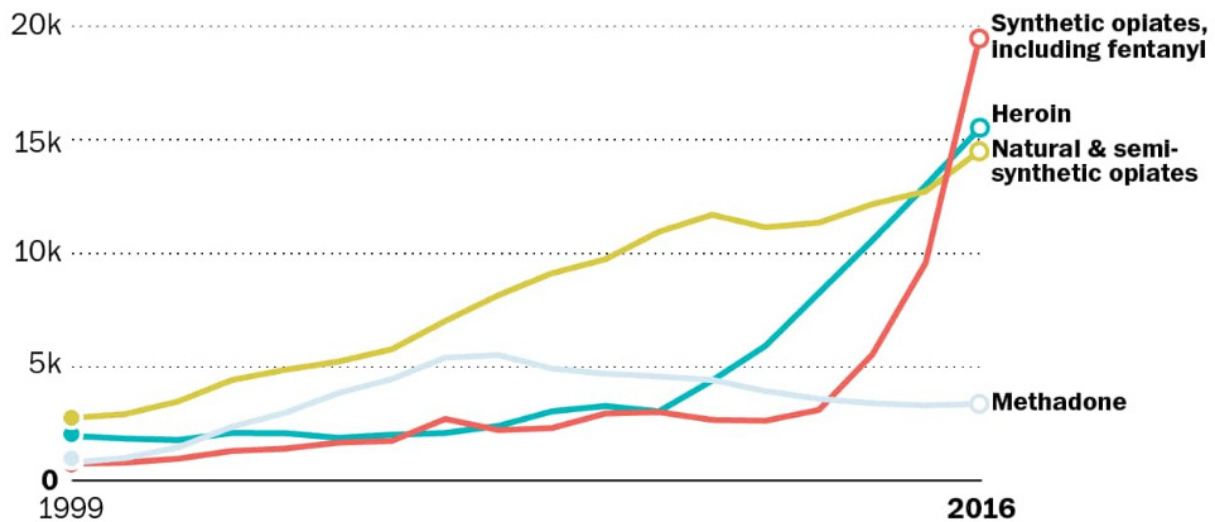
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Source: CDC

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, 2017.⁷

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



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Source: CDC

Fig. 3. 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, 2017.⁷

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

In addition, recent data shows that the number of people presenting for opioid treatment with heroin abuse has increased from 8.7% in 2005 to 33.3% in 2015.¹⁰ There also has been an increase in self-reported fentanyl use among the population entering drug treatment from 9% in 2013 to 15% in 2016, referred to as “unknown fentanyl” products.¹¹ Consequently, the number of prescription opioid admissions is declining and illicit fentanyl and heroin admissions are increasing.

Thus far, the effectiveness of numerous interventions to curb opioid epidemic has been limited, including prescription drug monitoring programs, pain clinic laws, treatment of opioid use disorder, guidelines, and numerous other policies.

¹⁰ Cicero TJ, Ellis MS, Kasper ZA. Increased use of heroin as an initiating opioid of abuse. *Addict Behav* 2017; 74:63-66.

¹¹ Cicero TJ, Ellis MS, Kasper ZA. Increases in self-reported fentanyl use among a population entering drug treatment: The need for systematic surveillance of illicitly manufactured opioids. *Drug Alcohol Depend* 2017; 177:101-103.

A 3-TIER APPROACH TO CURB OPIOID ABUSE AND MAINTAIN ACCESS

As a result of this disturbing trend, we, at ASIPP are suggesting more effective legislative efforts to curb opioid abuse and reduce opioid deaths, while maintaining appropriate access, and the promotion of nonopioid modalities including interventional techniques.¹² Consequently, we, at ASIPP propose a 3-tier approach to achieve these goals.

Tier 1 includes the following:

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.¹³
 - 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.

Tier 2 includes the following:

5. 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.¹²
 - Ironically, as reimbursement of interventional techniques has decreased with decreasing utilization since 2010, opioid deaths have been escalating.¹⁴
 - Evidence shows a direct relationship between the decline in utilization of interventional techniques and increase in the number of opioid deaths since 2010 (Figs. 4 and 5).

¹² 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.

¹³ Blendon RJ, Benson JM. The public and the opioid-abuse epidemic. *N Engl J Med* 2018; 378:407-411.

¹⁴ 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.

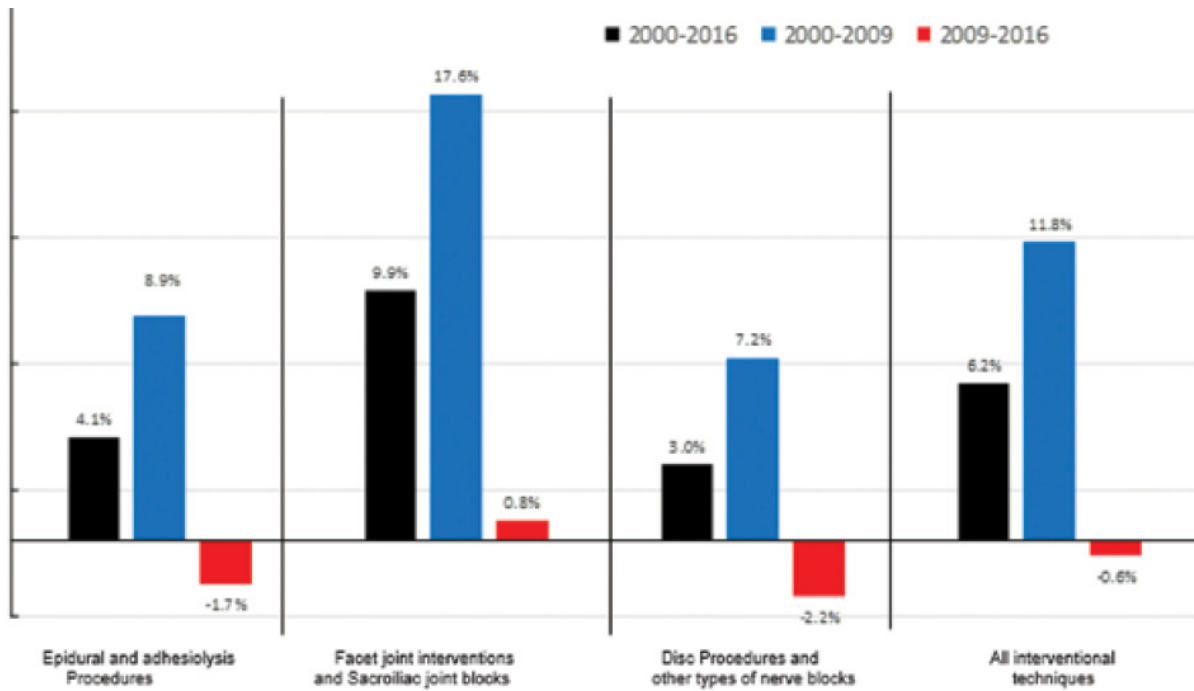


Fig 4. Comparative analysis of epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, and all interventional techniques.

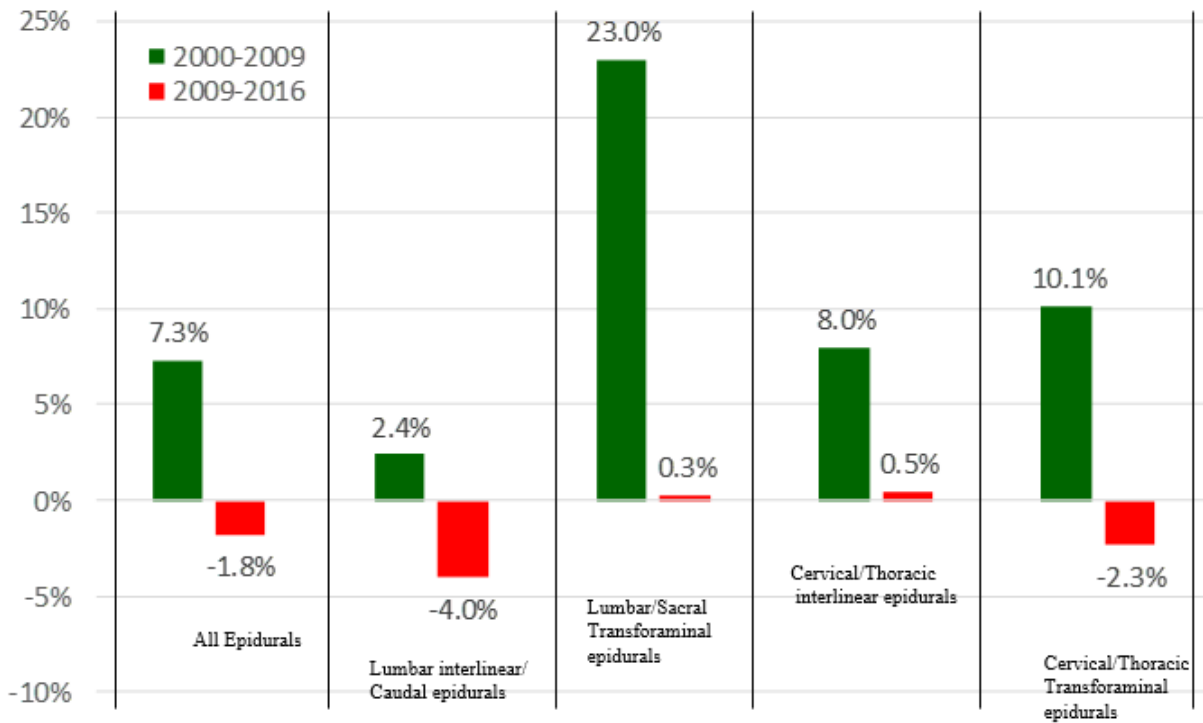


Fig 5. Frequency of utilization of epidural injections episodes from 2000 to 2009 and 2009 to 2016, in Medicare recipients.

6. Expand low-threshold access to buprenorphine for opioid use disorder.^{5,15,16} 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.¹⁵
 - Opioid overdose deaths have been shown to decrease 79% over a period of 6 years after widespread prescribing of buprenorphine in France.¹⁶ This will also lead to availability of buprenorphine and its products for chronic pain management.
 7. Establishment of enhanced prescription drug monitoring program (PDMP) with National All Schedules Prescription Electronic Reporting Act (NASPER) program, with each state with a mandated capacity to be able to interact with at least all bordering states.
 8. Mandated review of PDMP data by all providers, prior to all prescriptions.
- Tier 3 includes the following:
9. Buprenorphine must be available for chronic pain management in addition to medication-assisted treatment, with a change of controlled substance scheduling to a Schedule II drug.
 10. Remove methadone from formulary, which is responsible for over 3,000 deaths per year with only 1% of total prescriptions.

Finally, it is essential to develop treatment paradigms for patients with true somatic causes of pain. Nonopioid techniques have been recommended by IOM and attorney generals of many states. Yet, these have not been adequately considered. In fact, reductions and cuts continue to make difficulties to being able to utilize physical therapy, interventional techniques, and ironically even nonopioid medical therapy options.^{17,18}

Thank you again for providing our organization multiple opportunities to curb the opioid crisis. If you have any further questions, please feel free to contact us.

¹⁵ Kolodny A. Ten steps the federal government should take now to reverse the opioid addiction epidemic. *JAMA* 2017; 318:1537-1538.

¹⁶ Auriacombe M, Fatséas M, Dubernet J, et al. French field experience with buprenorphine. *Am J Addict* 2004; 13:S17-S28.

¹⁷ National Academies of Sciences, Engineering, and Medicine. 2017. *Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use*. Washington, DC: The National Academies Press.
doi: <https://doi.org/10.17226/24781>.

¹⁸ Letter to Marilyn Tavenner, from President and CEO, America's Health Insurance Plans from National Association of Attorneys General RE Prescription opioid epidemic. September 18, 2017.

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