

# When Pain Management Services Turn into Compliance Pain



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According to the Centers for Disease Control and Prevention (CDC), approximately 1 in 5 Americans suffer from chronic pain, while about 1 in 14 have suffered from high-impact chronic pain which results in substantial restriction to daily activities.<sup>1</sup>

It is no wonder then that pain management services are prevalent in the health care system and that government enforcement agencies encounter significant fraud, waste, and abuse in this area.

## Opioid Enforcement

Opioids are frequently used to manage pain for many patients. In many cases, they are used appropriately and help patients significantly. However, compliance professionals need to be aware of the enforcement surrounding non-compliance with opioid use. The significant increase in opioid overdose deaths is one of the reasons enforcements are common. Chart 1 shows the significant increase in opioid overdose deaths over the last 20+ years.

Undoubtedly, the rise in deaths is one of the main reasons government agencies have developed organized enforcement efforts and regional strike forces.<sup>3,4,5</sup> One of the areas of focus for these task and strike forces is unlawful subscribing by clinicians.

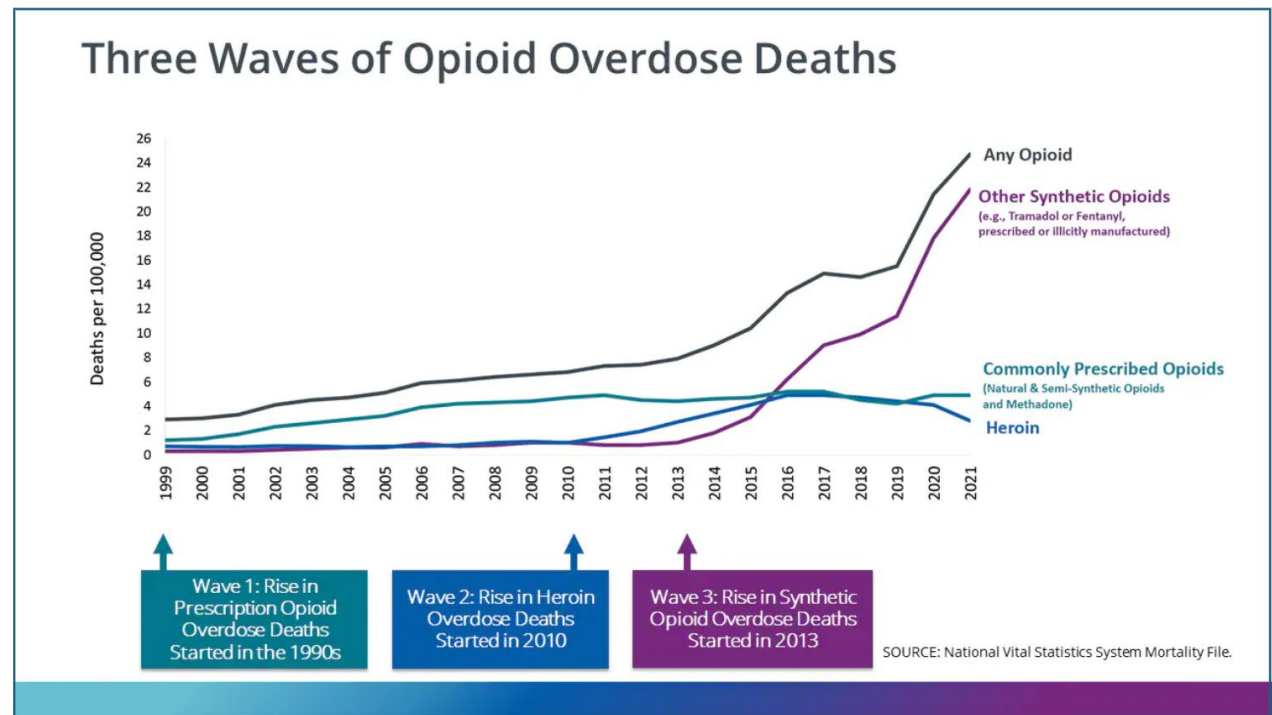
For example, a federal jury in Ohio convicted a pain management physician for unlawfully

distributing opioids from his clinic.<sup>6</sup> Court documents and evidence presented at trial showed the physician ran a pain clinic to which individuals traveled hundreds of miles to obtain prescriptions for opioids and other controlled substances. Patients traveling great distances for opioid prescriptions should raise a red flag as the common availability of appropriately prescribed opioids does not typically require it.

The doctor charged \$750 for an initial visit and \$120 for subsequent monthly visits. The prescriptions issued for opioids and other

controlled substances greatly exceeded recommended dosages and were in dangerous, life-threatening combinations. In a five-year period, the doctor prescribed over 137,000 pills, including opioids, benzodiazepines, and muscle relaxants, to nine individuals.

The jury convicted him of 24 counts of unlawful distribution of a controlled substance, outside the usual course of professional practice, and not for a legitimate medical purpose to nine individuals. He faces a maximum penalty of 20 years in prison for each charge.



[2] <https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html>

Another approach for managing pain, especially back pain, includes various types of spinal injections. These include, for example, facet joint injections, facet joint denervation sessions, lumbar epidural injections, and trigger point injections. The HHS Office of Inspector General (OIG) has been auditing Medicare payments for these types of spinal pain management services.<sup>7</sup> Their work is only partially completed, and they have begun to issue reports outlining their findings.

In an audit focused on facet joint denervation sessions, the OIG concluded that Medicare inappropriately paid physicians nearly \$10 million for the 20-month period included in their review.<sup>8</sup> The inappropriate payments resulted from Medicare paying for sessions that exceeded the coverage limitation. The OIG found that overpayments came from 11 of Medicare's jurisdictions whose Medicare Administrative Contractors (MACs) had a coverage limitation of two facet-joint denervation sessions per beneficiary for each covered spinal region during a 12-month period. In addition, they found overpayments from nine of Medicare's jurisdictions whose MACs had a coverage limitation of four facet joints per denervation and three MACs with a coverage limitation of 10 facet joints per denervation session.

In a different audit, OIG looked at spinal facet-joint injections during a 12-month rolling period.<sup>9</sup> To address inappropriate billing for pain management tied to overuse of spinal facet-joint injections, MACs developed a limitation of coverage that allows physicians to be reimbursed, during a rolling 12-month period, for a maximum of five sessions in which facet-joint injections are delivered to the lumbar region of the spine (lumbar spine) or the cervical and thoracic regions of the spine (cervical/thoracic spine). The OIG evaluated overpayments in this context and found that approximately 22.6% of the total amount reimbursed to physicians during the period did not meet Medicare coverage criteria. The overpayment amount in their \$3.3 million sample was \$748,555.

In a separate report of just one jurisdiction and MAC, the OIG found \$4.2 million in improper Medicare payments for spinal facet-joint injections.<sup>10</sup>

Epidural steroid injections are another type of pain management service for back pain. The OIG performed another review focused solely on these epidural injections.<sup>11</sup> To address inappropriate billing for and overuse of epidural steroid injections, 10 MACs developed coverage limitations, through Local Coverage Determinations (LCDs), for epidural steroid injection sessions. These coverage limitations

allow physicians to be reimbursed for a maximum number of epidural steroid injection sessions in a 6-month or a 12-month period.

The OIG reviewed 303,408 steroid injection sessions from a two-year period where the particular MACs paid physicians \$52.8 million for these sessions. OIG concluded that 80,419 sessions, totaling \$13.8 million exceeded the coverage limitation of the respective MACs.

### **Pain Management Related Services**

There are many other services related to pain management. For example, many pain management clinicians rely on diagnostic studies and laboratory tests as they manage a patient's chronic pain over months and years. Enforcement involving these related services are also well publicized.

A pain management physician in Kentucky agreed to the entry of a \$20 million consent judgement to resolve allegations that he violated the False Claims Act by billing federal health care programs for unnecessary diagnostic tests.<sup>12</sup>

The case was brought to the government's attention by two qui tam, or whistleblower, lawsuits under the False Claims Act. It was alleged the doctor submitted or caused the submission of false claims to federal health



care programs for medically unnecessary balance tests, nerve conduction and electromyography procedures, and qualitative drug screens performed in his pain clinics located in two states.

Urine drug screening has been the focus of multiple enforcement actions by the U.S. Department of Justice. In one example, two pain management physicians in Texas agreed to pay \$3.9 million to resolve allegations that they violated the False Claims Act by knowingly billing Medicare, Medicaid, and TRICARE for medically unnecessary urine drug testing.<sup>13</sup> It was alleged that they ordered excessive and unnecessary urine drug testing for patients without any individualized assessment of clinical need. They allegedly started by making sure all urine drug tests ordered by the physicians in the practice were performed at the practice's in-house laboratory. The United States alleged that the two doctors who drafted the testing protocols that resulted in unnecessary tests were aware that the in-house laboratory was conducting an excessive number of tests on urine samples, and that their practice could not remain profitable without the income generated from unnecessary testing. This information was first brought to the government's attention by former employees who filed whistleblower lawsuits.

All over the country, similar cases involving urine drug testing are being brought to the

attention of the government. Just a few of the many examples of settlements involving urine drug testing include:

- \$2.85 million settlement with Seattle physician<sup>14</sup>
- \$980,000 settlement with a Maryland physician and practice<sup>15</sup>
- \$11.4 million settlement with the owner of pain clinics in California<sup>16</sup>

## Conclusion

Chronic pain affects millions of Americans. Thousands of physicians are appropriately caring for, and helping, these patients. However, pain management services are not without compliance issues. Some of the issues discussed in this paper have included unlawful prescribing of opioids, various spinal injections and procedures, and related services such as diagnostic testing and urine drug screening.

Compliance officers should be aware of these risks and implement appropriate procedures and monitoring to help prevent, detect, and correct non-compliance.

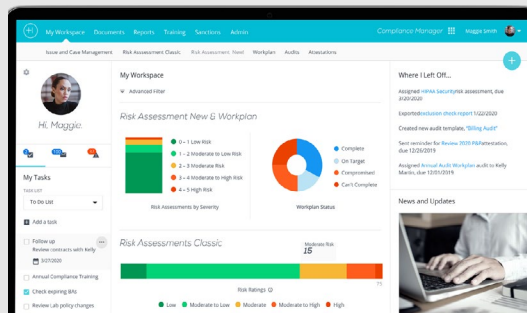
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- [2] <https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html>
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