

---

# Viewing Recent Opioid Regulations In Context

---

By Crystal Pike, Kenneth Weinstein, Pavel Darling and Paul E. Greenberg; Analysis Group, Inc.

Law360, New York (April 1, 2016, 11:13 AM ET)



Crystal Pike



Kenneth Weinstein



Pavel Darling



Paul E. Greenberg

---

On March 18, 2016, the U.S. Centers for Disease Control published a guideline regarding the prescribing of opioids for chronic pain. On March 22, the U.S. Food and Drug Administration announced a “black box” warning for immediate-release opioids<sup>1</sup>. These developments are the latest in a series of policy initiatives by federal and state agencies aimed at curbing opioid misuse and abuse. Other government agencies have also grappled with the twin objectives of maintaining access to opioids for those with a legitimate medical need while restricting inappropriate use. For example, several states have implemented state-specific regulations and/or prescription drug monitoring programs<sup>2</sup>, while the Drug Enforcement Agency has reclassified hydrocodone combination products from Schedule III to Schedule II and increased its enforcement efforts. In addition, pharmaceutical companies have introduced abuse-deterrent formulations and the American Medical Association (AMA) has initiated a task force to put forward updated guidelines and training programs designed to prevent or limit abuse<sup>3</sup>. Viewed in this context, the new CDC guideline and FDA black box warnings are the latest in a long series of efforts to address the inappropriate use of opioids.

Prescription opioids include a range of products with a similar mechanism of action that provide pain relief and sedation, but carry the risk of abuse, unintended misuse and dependence. Most are now classified as Schedule II by the DEA, the highest schedule for legal drugs (see table for complete description of schedules I-V). Within the opioid class, oxycodone and hydrocodone, both semisynthetic products, are by far the most widely used, accounting for approximately 75 percent of all opioid prescriptions.

Based on our review of the medical literature, published government statistics and ongoing analysis of medical claims data for privately insured individuals, we have identified some important facts and trends among oxycodone/hydrocodone patients:

- Estimates show that opioid prescriptions over the past decade have increased by more than 25 percent, from 163 million to 207 million prescriptions<sup>4</sup>; however, in our analysis of privately insured individuals, while the number of prescriptions increased over the past decade, the percentage of adults using opioid analgesics has remained stable<sup>5</sup>. This suggests that the increase in prescriptions is in part explained by growth in the general insured population as well as physicians writing more prescriptions per patient over time.
- During this period, many more options have been made available to people suffering from acute and chronic pain, driven by a variety of factors (e.g., new drug approvals, improved and longer-acting formulations, greater access to medications as a result of generic availability and broader insurance coverage).
- The annual economic burden of opioid abuse is staggering, estimated at \$56 billion in 2007<sup>6</sup>. While the percent of adults reporting nonmedical use of these medications has remained stable over the past 10 years, opioid-related deaths have increased substantially over this time (tripling between 2000 and 2015)<sup>7, 8</sup>.

One of the CDC's recent recommendations is based on the belief that dispensing only the necessary number of days supply can mitigate both overuse as well as diversion to the black market. That is why the agency now advises that for acute pain, prescriptions of more than 7-days supply "will rarely be needed." In our experience analyzing patient usage data, 25 percent to 35 percent of oxycodone/hydrocodone prescriptions have 30-days supply and 50 percent to 60 percent have more than 7-days supply. Thus, adopting the more stringent CDC guideline in this context will likely result in a significant reduction in average days supplied per prescription. Of course, it is possible that this will cause some of these patients to fill additional prescriptions given the smaller number of days supply available for each one.

In addition to regulatory concerns with excessive days supply per prescription, policies aimed at reducing opioid abuse often attempt to curb the overall number of pills available in the marketplace. While approximately 25 percent of oxycodone prescriptions and 35 percent of hydrocodone prescriptions have fewer than 30 pills per prescription, 35 percent of oxycodone prescriptions and 25 percent of hydrocodone prescriptions exceed 90 pills. In addition, 80 percent of patients using these opioids are prescribed three plus pills per day. The bottom line is that oxycodone/hydrocodone prescriptions often contain enough pills for patients to take several pills per day during their treatment regimens.

As a result of this dynamic, the CDC guideline also recommends limiting the duration of treatment for chronic pain patients, specifically suggesting that "clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three months or more frequently<sup>9</sup>." While two-thirds of oxycodone/hydrocodone patients in our datasets have only a single

claim per year, more than 20 percent have three or more claims annually. As a result, it will be interesting to see if the CDC's guideline to physicians with respect to assessing the benefits and harms every three months results in a sizable change in the proportion of long-term patients.

Given the changing regulatory landscape with respect to controlled substances, additional research is warranted concerning the impact of these changes on rates of abuse, misuse and overdose as well as on the adequacy of care for patients with legitimate medical need. On the one hand, the CDC's new guideline emphasizes the use of nonopioid therapy to treat chronic pain, which could eventually spur the development of new and effective alternative treatments. On the other hand, heroin use and overdose has increased dramatically during this time period, with some contending that this outcome has been a direct consequence of restricting widespread access to opioids. Assessing the effectiveness of regulatory changes to reduce prescription opioid abuse, while still addressing legitimate patient pain management needs, will require effectively marshaling and analyzing the data that capture the wide range of patient experiences. In addition, further research on the apparent disconnect between the growth in number of prescriptions over time and the stable prevalence rate, as well as the drivers behind differences in quantities supplied per prescription, could help improve policy efforts aimed at reducing abuse/misuse while preserving access for legitimate patient need.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

## Endnotes

- 1 CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Recommendations and Reports, March 18, 2016, 65(1); 1-49. FDA News Release.
- 2 See e.g., Massachusetts legislative act signed on March 14.
- 3 See <http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-task-force>.
- 4 Volkow, Nora D., "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," presented to the Senate Caucus on International Narcotics Control, May 14, 2014.
- 5 OptumHealth Reporting and Insights. This trend is also supported by recent CDC analyses, see, Centers for Disease Control and Prevention, NCHS Data Brief No. 189, February 2015.
- 6 Birnbaum HG, White AG, Schiller M, Waldman T, Cleveland JM, Roland CL. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Med.* 2011;12:657–667. doi: 10.1111/j.1526-4637.2011.01075.x.
- 7 Substance Abuse and Mental Health Services Administration, Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health, September 2015.
- 8 CDC Morbidity and Mortality Weekly Report, Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014, January 1, 2016 / 64(50); 1378-82.
- 9 CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Recommendations and Reports, March 18, 2016, 65(1); 1-49.

All Content © 2003 – 2017, Portfolio Media, Inc.