OPIOID SERIES

A LinkedIn Series by PRMS

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Within the past three months, at least three reports on the US opioid crisis have been issued that are worth noting:

1. **From the CDC – Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015**. Key points include the following:
   - The amount of opioids prescribed in the US peaked in 2010 and then decreased each year through 2015. Despite reductions, the amount of opioids prescribed remains approximately three times as high as in 1999.
   - Opioid prescribing varied substantially across the country, with average per capita amounts prescribed in the top-prescribing counties approximately six times the amounts prescribed in the lowest prescribing counties in 2015.
   - Higher amounts of opioids were prescribed in counties with a larger percentage of non-Hispanic whites; a higher prevalence of diabetes and arthritis; micropolitan counties; and counties with higher rates of unemployment and Medicaid enrollment.
   - Prescribers can follow the CDC’s Guideline for Prescribing Opioids for Chronic Pain.

2. **From the Journal of the American Board of Family Medicine – Prescription Opioid Use among Adults with Mental Health Disorders in the United States**. Key points include the following:
   - Studies have suggested that adults with mental health disorders are more likely to be prescribed opioids and remain on them long-term.
   - The 16% of Americans who have mental health disorders receive over half (51.4%) of all opioids prescribed in the US – 60 million of the 115 million prescriptions.
   - Of the adults with mental health disorders, 18.7% were opioid users, compared to only 5% of those without mental health disorders.

3. **From the HHS Office of Inspector General – Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing**. Key points include the following:
   - One in three Medicare Part D beneficiaries received a prescription opioid in 2016.
   - About 500,000 beneficiaries received high amounts of opioids.
   - Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping.
   - About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk.

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i [https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm](https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm)
ii [http://jabfm.org/content/30/4/407](http://jabfm.org/content/30/4/407)
iii [https://www.oig.hhs.gov/oei/reports/oei-02-17-00250.asp](https://www.oig.hhs.gov/oei/reports/oei-02-17-00250.asp)
In Part 1, I covered recent statistics evidencing part of the current opioid crisis. In response, the government has swiftly taken a variety of actions including criminal enforcement.

The Department of Justice (DOJ) has been very active recently. In less than a three-week span, the following occurred:

- **July 13th**: The DOJ reported the largest healthcare fraud enforcement action in DOJ history, in which 412 defendants (115 physicians) were charged in 41 federal districts. This “national takedown” involved more than 1,000 state and federal law enforcement agents arresting those who allegedly participated in healthcare fraud schemes involving $1.3 billion in false billings. And more than 120 defendants, including over 50 physicians, were charged for their role in prescribing and distributing opioids and other dangerous narcotics, specifically noted by the DOJ to be a focus.

- **August 2nd**: The US Attorney General announced a new Opioid Fraud and Abuse Detection Unit, which will, in part, use data to identify and prosecute individuals who are contributing to the prescription opioid epidemic. Per the Attorney General, “This sort of data analytics team can tell us important information about prescription opioids – like which physicians are writing opioid prescriptions at a rate that exceeds their peers; how many of a doctor’s patients died within 60 days of an opioid prescription; the average age of the patients receiving the prescriptions”.

- **August 3rd**: The DOJ reported the arrest of 12 defendants from seven medical clinics who had allegedly diverted at least 2 million prescription pills, including opioids, to the black market. As part of the scheme, the defendants would pay physicians to “sit at home” while thousands of narcotics were prescribed in that doctor’s name, and Medicare was billed more than $500,000 for purported care that was never provided. This scam is particularly scary because those doctors who did the right thing by refusing to participate were also pulled in. Per the DOJ, the defendants also allegedly stole the identities of doctors who refused to participate in the scheme. When the doctor who was offered to sit at home making $20,000 a month doing nothing refused, they created prescription pads in the doctor’s name and allegedly sold fraudulent prescriptions for oxycodone without the doctor’s knowledge or consent.

The Centers for Medicare and Medicaid Services (CMS) is also taking steps to increase oversight of prescriber behaviors. As indicated in Part 1, the government is concerned about opioids prescribed to Medicare beneficiaries. As part of this focus, CMS has enacted the following initiatives, as described in its Opioid Misuse Strategy, to identify high prescribers for additional scrutiny:

- **Medicare Part D Opioid Prescriber Summary File** – Presents information on individual prescribers’ rates of prescriptions

- **National Benefit Integrity Medicare Drug Investigation Contractor** – Consists of several projects, including:
  - Prescriber Risk Assessment – provides a peer comparison of Schedule II controlled substance prescribing practices
  - Pill Mill Doctor Project – identifies prescribers with a high risk of fraud, waste, and abuse in prescribing controlled substances
  - Overutilization Monitoring System – Identifies inappropriate prescribers of controlled substances

There has also been action taken at the state level, such as:

- Creating opioid response plans, typically through the state Attorney General’s office.

- Requiring prescribers have specific opioid training. For example, New York requires the completion of three hours of training in pain management, palliative care, and addiction. This requirement applies all prescribers with an active New York license and a DEA registration (in any state), including those who do not treat for addiction or pain, those who are not currently practicing in New York, and those who do not prescribe controlled substances.

- Promulgating new or updating existing guidelines for prescribing opioids.

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As reviewed in my prior posts, scrutiny of controlled substance prescribing has increased. There are three proven strategies to manage the risks associated with any clinical activity, including prescribing opioids, and we call them the 3 Cs:

1) Collecting information
2) Communicating
3) Carefully documenting

COLLECTING INFORMATION

About the Patient: Perform, and document, a complete initial patient evaluation, including medication history. Also, review your state’s Prescription Monitoring Program (PMP) prior to prescribing. If the report shows prescriptions not reported by the patient, address the issue clinically with the patient.

About the Medications: Stay up-to-date with the medications you prescribe.

About Treatment / Standard of Care: Stay current with and follow federal and state statutes and regulations, guidance from regulatory agencies such as state licensing boards, guidance from professional associations, journal articles, etc. For example, In the August issue of Current Psychiatry, there’s a nice clinical summary by Patkar and Weisler titled “Opioid Abuse and Overdose: Keep Your Patients Safe.” Also, complete appropriate CME courses related to prescribing controlled substances. Note that more and more states are requiring licensees to complete opioid-related CME.

About Abuse and Diversion: Recognize the drug abuser. The DEA notes that common characteristics include unusual knowledge of controlled substances and/or textbook symptoms, requests for specific medication(s), reluctance to try medications other than those requested, no regular physician, etc. And common modus operandi include traveling through town, visiting friends or relatives, stating that certain medications do not work, lost or stolen prescription, pressures by eliciting sympathy or guilt, etc.

About Enforcement: The government is likely to focus its attention on those who seem to prescribe inappropriately - prescribing in large quantities (which could include those who specialize in pain management), prescribing without checking the PMP (when the PMP would have revealed doctor shopping), and prescribing for patients who fatally overdose on the medication. The government has specifically stated a focus on the inappropriate prescribing of opioids to Medicare beneficiaries based on extensive prescription data collected.

COMMUNICATING

With the Patient: Medications should be monitoring on an on-going basis to ensure appropriateness and efficacy. During informed consent discussions, prescribers may want to review office policies related to prescribing (only one prescriber, only one pharmacy, no replacement of lost or stolen prescriptions, etc.) Treatment agreements may be required by the state, and should be considered for use, even if not technically required. Things to cover in a treatment agreement include reasons for termination, random urine screens, proper storage of medications, etc.

With Others: Ensure communication between all involved in the patient’s care, including covering physician, other treaters, etc. Also, communicate with family members as authorized by the patient. In emergency situations, remember that safety of the patient or others is an exception to confidentiality, so no authorization is required. Also, remember that you can listen to what third parties want to tell you without breaching patient confidentiality, so long as you do not disclose any information, including confirmation that the person is a patient.

CAREFULLY DOCUMENTING

Document your treatment decision-making process – what actions you took and why, as well as what actions you considered, but rejected, and why. Documentation allows your work to be understood – by subsequent treaters, by expert witnesses in litigation, and even by you in the event of litigation years after treatment.

For more information and more detailed risk management advice, contact your risk managers.

i http://www.mdedge.com/currentpsychiatry
iii https://www.oig.hhs.gov/oei/reports/oei-02-17-00250.asp
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