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Drug Enforcement Administration Drug Scheduling

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Definition/Introduction

Drug scheduling became mandated under The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (also known as the Controlled Substances Act). The law addresses controlled substances within Title II. Based upon this law, the United States Drug Enforcement Agency (DEA) maintains a list of controlled medications and illicit substances that are categorized from scheduled I to V. The five categories have their basis on the medication's proper and beneficial medical use and the medication's potential for dependency and abuse. The purpose of the law is to provide government oversight over the manufacturing and distribution of these types of substances. Prescribers and dispensers are required to have a DEA license to supply these drugs. The licensing provides links to users, prescribers, and distributors.[1][2][3]

Issues of Concern

The schedules range from Schedule I to V. Schedule I drugs are considered to have the highest risk of abuse while Schedule V drugs have the lowest potential for abuse. Other factors considered by the DEA include pharmacological effect, evidenced-based knowledge of the drug, risk to public health, trends in the use of the drug, and whether or not the drug has the potential to be made more dangerous with minor chemical modifications.

Schedule I:

- "High abuse potential with no accepted medical use; medications within this schedule may not be prescribed, dispensed, or administered"[1]
- Examples of include marijuana (cannabis), heroin, mescaline (peyote), lysergic acid diethylamide (LSD), methylenedioxymethamphetamine (MDMA), and methaqualone.

Schedule II:

- "High abuse potential with severe psychological or physical dependence; however, these medications have an accepted medical use and may be prescribed, dispensed, or administered"[1]
- Examples include fentanyl, oxycodone, morphine, methylphenidate, hydromorphone, amphetamine, methamphetamine (meth), pentobarbital, and secobarbital.
- schedule II drugs may not receive a refill at the pharmacy

Schedule III:

- "Intermediate abuse potential (i.e., less than Schedule II but more than Schedule IV medications)"[1]

- examples include anabolic steroids, testosterone, and ketamine

Schedule IV:

- "Abuse potential less than Schedule II but more than Schedule V medications"[1]
- examples include diazepam, alprazolam, and tramadol

Schedule V:

- "Medications with the least potential for abuse among the controlled substances." [1]
- examples include pregabalin, Diphenoxylate/atropine, dextromethorphan

See Table 1 for information regarding registration, records, prescriptions, refills, distribution, security, and theft or significant loss of controlled substances.

See Table 2 for information regarding DEA forms 106, 222, 224, and 224a.

Clinical Significance

Medications are routinely added to the list and can be moved from one category to another as our knowledge and understanding of the medications advances. The DEA maintains a current list on its website under the diversion control division heading. Prescribers may prescribe, as allowed by their DEA and state controlled-substance or medical license, Schedule II through V medications. Not all prescribers are licensed to prescribe all levels of controlled substances as their individual state or DEA licenses limit some, and some are under limitations by their professions, such as advanced practice providers in many states. It is the responsibility of the provider and the dispensing pharmacist to be aware of each medication's category and ensure that only properly licensed individuals are prescribing the medications. It is essential to understand the DEA controlled-substance scheduling both to ensure adequate caution when prescribing medications with high abuse potential and also to ensure against prescribing outside of one's authority.[4][5]

The Controlled Substances Act has great potential to improve patient safety by providing federal oversight for drugs with a high potential for abuse. Providers of scheduled substances (physicians, dentists, podiatrists, advanced practitioners) may have links to the distribution of these substances. They are required to have a DEA license and record prescription of scheduled drugs. This licensing prevents overprescribing and obligates providers to be wary of potential drug-seeking patients. The dispenser must also be aware of a patient's medication history and be mindful of the potential for polypharmacy if a patient seeks multiple providers. The current opioid epidemic is a time where federal oversight and interdisciplinary coordination have the potential to reduce harm to patients prescribed scheduled drugs drastically. It will, however, take further time and evaluation to know if drug scheduling actually reduces abuse, addiction, and overdose.[6][7][8][9][10]

Nursing, Allied Health, and Interprofessional Team Interventions

The healthcare team, e.g., physicians, nurses, pharmacists, etc., need to work together to address the proper medical use of controlled substances, e.g., pain control pharmacotherapy. The healthcare team should schedule their patients for routine follow-up visits that include a history and physical exam to monitor for adverse drug effects and drug misuse. Monitoring for signs of drug misuse is a very important responsibility for the healthcare team because of the epidemic rates of drug misuse worldwide, e.g., the USA, which leads to death because of respiratory depression as in the case of opioid analgesic overdose (e.g., oxycodone, fentanyl). Methods for monitoring drug abuse as well as drug diversion include the following examples: assessment surveys, state prescription drug monitoring programs, urine screening, adherence check-lists, motivational counseling, and dosage form counting, e.g., tablet counting. (Level 5)

Review Questions

- [Access free multiple choice questions on this topic.](#)
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Figures

Table 1. Controlled Substances Act Requirements Summary

	Schedule II	Schedule III and IV	Schedule V
Registration	Required	Required	Required
Receiving Records	Order Forms (DEA Form-222)	Invoices, Readily Retrievable	Invoices, Readily Retrievable
Prescriptions	Written Prescription (See exceptions*)	Written, Oral, or Fax	Written, Oral, Fax, or Over The Counter**
Refills	No	No more than 5 within 6 months	As authorized when prescription is issued
Distribution Between Registrants	Order Forms (DEA Form-222)	Invoices	Invoices
Security	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage	Locked Cabinet or Other Secure Storage
Theft or Significant Loss	Report and complete DEA Form 106	Report and complete DEA Form 106	Report and complete DEA Form 106

Note: *All records* must be maintained for 2 years, unless a state requires a longer period.

* **Emergency prescriptions** require a signed follow-up prescription. **Exceptions:** A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, Hospice patients, or compounded IV narcotic medications.

** Where authorized by state controlled substances authority.

Controlled Substances Act Summary Table. Adapted from Department of Justice website

<https://www.deadiversion.usdoj.gov/>

Table 2. DEA forms

DEA Form number	Title of Form	Description
106	Report of Theft or Loss of Controlled Substances	In the case of theft or significant loss of controlled substances, the pharmacy must contact local police and directly notify the DEA within one business day. DEA form 106 provides documentation of the circumstances of the loss.
222	U.S. Official Order Form for Controlled Substances	This form is required for ordering, transfer and disposal of schedule II substances.
224	Application for Registration	Pharmacies and certain practitioners must apply for a DEA registration via DEA form 224. The registration allows possession and handling of controlled substances as specified by the registration.
224a	Renewal Application for DEA Registration	DEA registration must be renewed every 3 years.

DEA forms can be found at www.DEAdiversion.usdoj.gov

DEA forms. Adapted from <https://www.dea diversion.usdoj.gov/>, the website is work of the U.S. Government and is not subject to copyright protection in the United States.

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High-Volume Prescribers Do Not Drive Medicare Prescriptions of Schedule II Opioids

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To the Editor

Researchers have suggested that the opioid overdose epidemic¹ is primarily driven by small groups of prolific prescribers and “corrupt pill mills.”^{2,3} For example, the California Workers’ Compensation Institute found that 1% of prescribers accounted for one-third of schedule II opioid prescriptions and 10% accounted for 80% of prescriptions.⁴ This propagates a message that opioid overprescribing is a problem of a small group of high-volume prescribers, while general use is likely safe and effective. Medicare data provide the opportunity to address whether such prescribing patterns occur across a national population.

Methods

We examined individual prescriber data from the 2013 Medicare Part D (prescription drug coverage) claims dataset created by the Centers for Medicare and Medicaid Services.⁵ Part

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Author Contributions: Dr. Chen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Chen, Humphreys, Lembke

Acquisition of data: Chen, Shah

Analysis and interpretation of data: Chen

Drafting of the manuscript: Chen

Critical revision of the manuscript for important intellectual content: All authors

Statistical analyses: Chen

Administrative, technical, or material support: Shah

Study supervision: Humphreys, Lembke

Content is solely the responsibility of the authors and does not necessarily represent the official views of the VA or Stanford Healthcare.

Promotional Image: Figure 2

Tweet: Opioid Prescribing Distribution in Medicare: Not just a few bad apples.

D covers ~68% of the ~50 million people on Medicare, the federal insurance program for Americans who have certain disabilities or are 65 or older.

For each prescriber National Provider Identifier (NPI) number (N=808,020), the data identify each drug prescribed, total number of claims, and total costs. Each NPI includes location and specialty of practice. The data represent 1,188,393,892 claims for \$80,941,763,731. We focused on schedule II opioid prescriptions containing hydrocodone, oxycodone, fentanyl, morphine, methadone, hydromorphone, oxymorphone, meperidine, codeine, opium, or levorphanol.

We calculated the cumulative claims for schedule II opioids from the top individual prescribers (sorted by number of claims) relative to the total claims for all prescribers. For comparisons, we repeated this for prescription *costs*, for all drugs, and for each state.

Results

Figure 1 reports which provider specialties account for the most opioid drug claims. Figure 2 reports the concentration of drug claims amongst the most prolific individual prescribers. Respective California Workers' Compensation data⁴ are included. Notably, the top 10% of Medicare prescribers account for a smaller proportion of opioid claims (56.7%) than for all Medicare prescriptions and for the California Workers' Compensation prescribers. Minimal regional variation is observed across provider states, with per state values ranging from 56.6% to 57.7%. Excluding hydrocodone (schedule III prior to 2014) yields similar trends with the same top three prescribing specialties and 57.9% of claims from the top 10% of prescribers.

Comment

The data studied represent a comprehensive national population of Medicare Part D prescribers, but do not necessarily reflect providers' complete practices, patient factors (e.g., comorbidities and prescription indications), or medication dosing to inform morphine equivalents. With those cautions, two important findings are evident.

Opioid prescriptions are concentrated in specialty services in Pain, Anesthesia, and Physical Medicine and Rehabilitation (PM&R). By sheer volume however, total prescriptions are dominated by general practitioners (Family Practice, Internal Medicine, Nurse Practitioners, and Physician Assistants).

Contrary to the California Worker's Compensation data showing a small subset of prescribers accounting for a disproportionately large percentage of opioid prescribing, Medicare opioid prescribing is distributed across many prescribers and is, if anything, less skewed than all drug prescribing. The trends hold up across state lines, with negligible geographic variability. Figure 2 does show greater skewing for total drug *costs* of Medicare opioid claims, with 78% accounted for by 10% of prescribers. This could be selection of more expensive formulations or higher doses prescribed.

The distribution of any social phenomena has some degree of skewing similar to an “80/20 rule” (e.g., 20% of the population controls 80% of the wealth).⁶ As of 2013 however, these data argue that opioid prescribing is no more skewed than other prescriptions, reflecting a widespread practice relatively indifferent to individual doctors, specialty or region. High-volume prescribers are not responsible for the high national volume of opioid prescriptions. Efforts to curtail national opioid overprescribing must address a broad swath of prescribers to be effective.

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Schedule II Opioid Claims By Provider Specialty

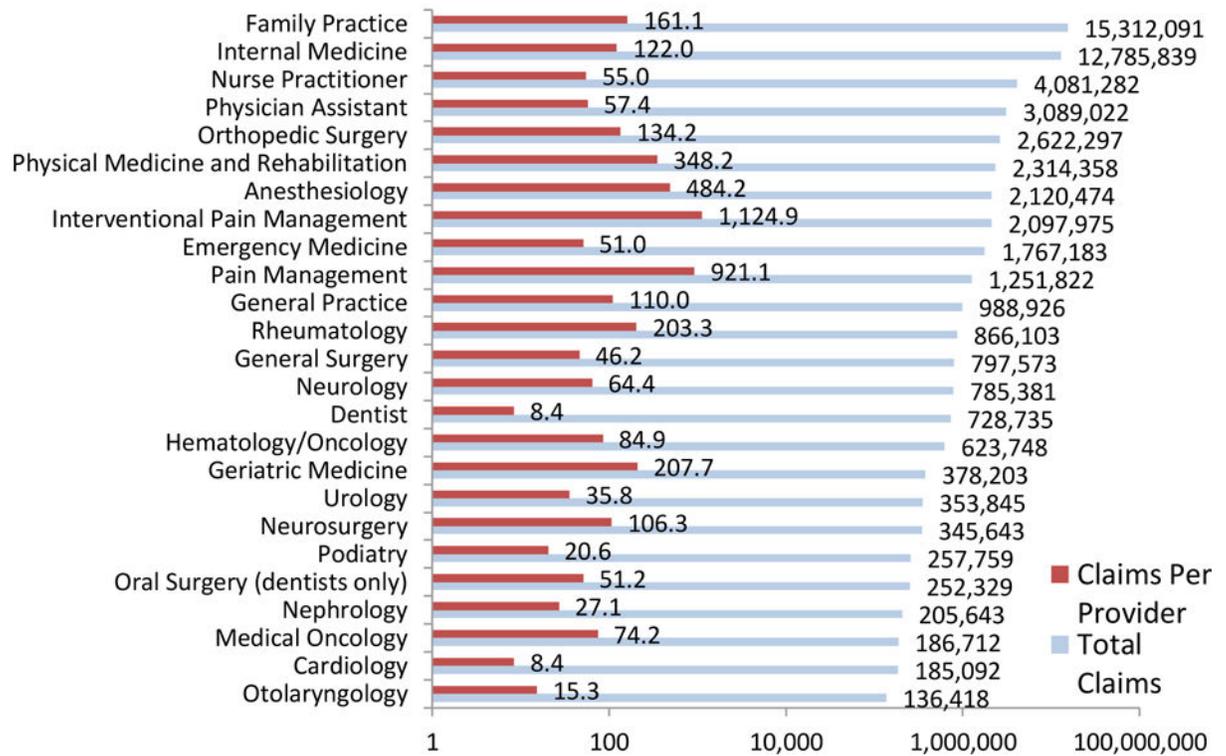


Figure 1.

Top 25 provider specialties by total Medicare Part D claims for schedule II opioids in 2013.

Values reported on logarithmic scale.

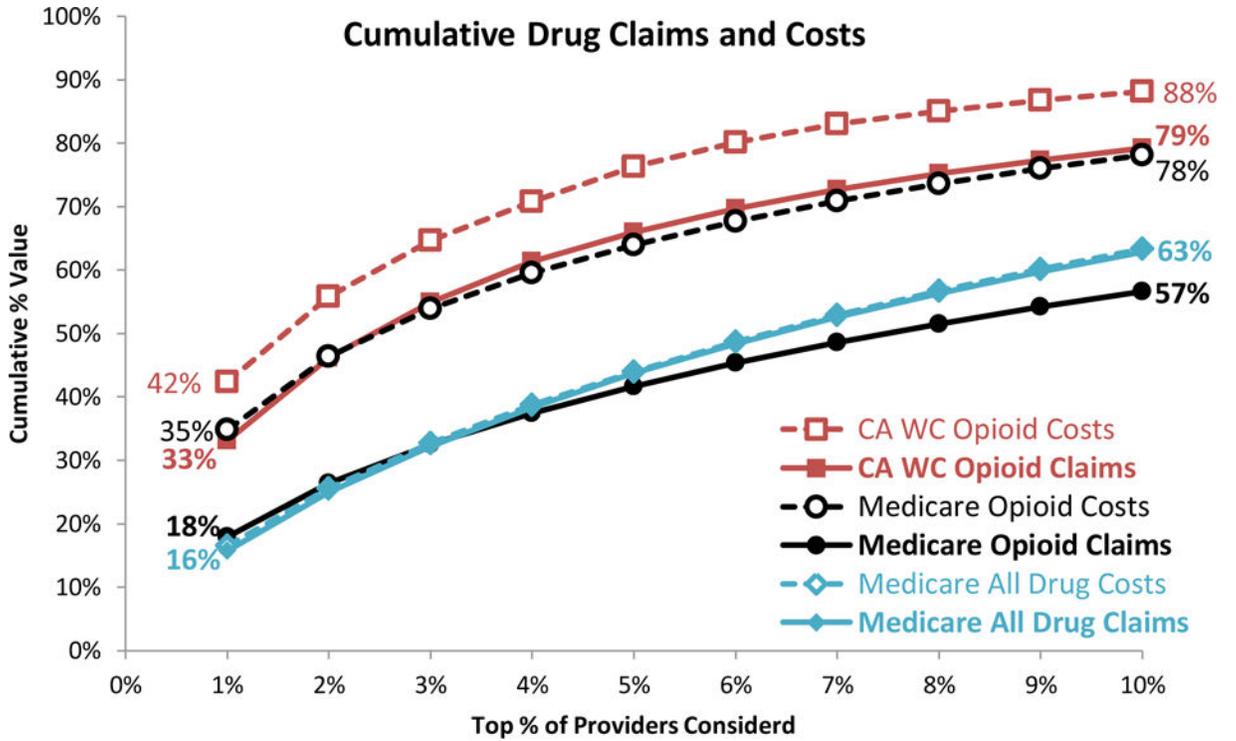


Figure 2. Cumulative percent claims and costs for the top ten percent of prescribers for different populations. For example, 1% of California workers’ compensation (CA WC) providers incur 42% of their schedule II opioid costs. Note: The Medicare All Drug Claims curve overlaps and obscures the respective Costs curve.