

## Prescribing Controlled Substances

What a Practice Needs to Know  
From a DEA Perspective



May 12, 2022

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### Key Topics

- COVID-19 FAQ
- Understanding prescription drug abuse and non-compliance
- Recognizing aberrant patient behaviors and how these behaviors may be symptomatic of non-compliance



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### Key Topics

- Methods for detecting non-compliant patient behavior
- Monitoring patient adherence to a prescription regimen
- Key government initiatives aimed at prescription abuse and specific duties of DEA



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### Closed System of Distribution



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### What Is Your Responsibility?

#### There is a responsibility to:

- Help ensure patients are using medications properly.
- If aberrant behavior is observed, noted in testing or disclosed via a complaint to the practice ...
  - Do not ignore it.



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### Two Dimensions Of The Problem

- I. Illicit use or abuse of prescription medications
- II. Non-compliance with prescription regimens



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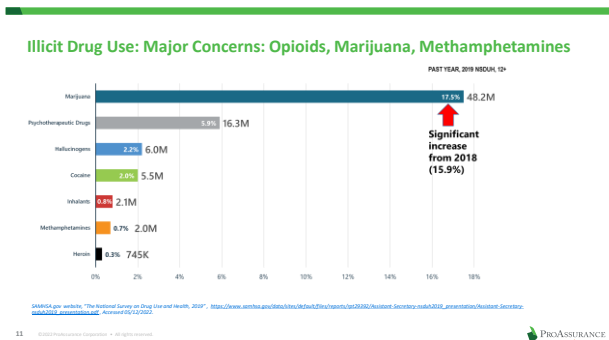
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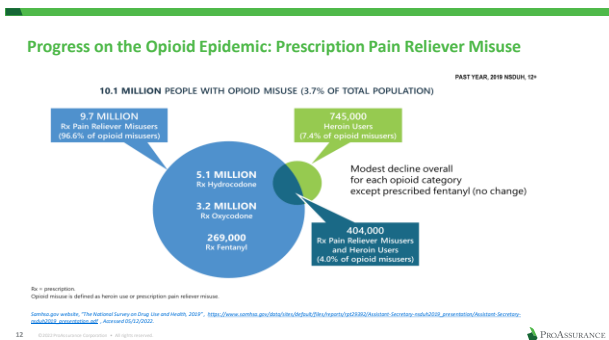
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### Prescription Drug Abuser: Some Common Characteristics

- Unusual behavior in the waiting room
- Assertive personality
  - Often demanding immediate action
- Unusual appearance
  - Extremes of slovenliness or being overdressed
- Unusual knowledge of controlled substances
- Recites medical history with textbook symptoms
- Evasive or vague answers to questions regarding medical history



Interviews with NADOD President John Burke and Richard Tucker's experience and training  
National Institute on Drug Abuse website: <https://nida.nih.gov/indicated-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction>. Accessed 05/25/2022.

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### Prescription Drug Abuser: Some Common Characteristics

- Reluctant or unwilling to provide reference information
  - Often has no regular doctor or health insurance
- May request a specific medication and may be reluctant to try a different drug
- May appear to have no interest in diagnosis
  - Fails to keep appointments for further diagnostic tests; refuses to see another practitioner for consultation



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### Recognizing The Physical Signs Of Prescription Drug Abuse

- Abusers of prescription drugs may use or ingest prescription medication in the same manner as abusers of illicit drugs, yielding the same signs of illicit use.
- Signs of illicit use:
  - Inflammation in nasal cavity
  - Gum disease and infection
- Signs of subcutaneous use
  - Between toes
  - Under tongue
  - Behind knees
  - Genitalia
  - Arms



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### Other Evidence Of Possible Prescription Drug Abuse

- Information gained from the urine testing
- Information received from sources other than the patient:
  - Other practices or pharmacies
  - Friends or family
  - Anonymous sources



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### DEA's Role in Prescribing Controlled Substances

- DEA's role under the Controlled Substances Act (CSA) is to ensure that controlled substances are prescribed, administered, and dispensed only for **legitimate medical purposes** by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations.
- Each State also has its own laws (administered by State agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by State-licensed practitioners acting in the usual course of professional practice.

DEA website, Diversion Control Division, [https://www.deadiversion.usdoj.gov/prag\\_disrupt/index.html](https://www.deadiversion.usdoj.gov/prag_disrupt/index.html) . Accessed 05/25/2022.

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### Legitimate Medical Purpose Usual Course of Professional Practice

"This requirement has been construed by the courts to mean that the Rx must be issued "in accordance with a standard of medical practice generally recognized and accepted in the United States....."

DEA website, [https://www.deadiversion.usdoj.gov/prag\\_disrupt/index.html](https://www.deadiversion.usdoj.gov/prag_disrupt/index.html) . Accessed 05/25/2022.

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## Non-compliance With Prescription Regimens

Not all non-compliant patients are abusers



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### Possible Non-Compliance Scenarios

- Is the patient taking drugs as prescribed?
- Is the patient sharing his or her medications with others?
- Does the patient take a smaller than prescribed dose?
- Is the patient hoarding medication?



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### Monitoring For Abuse And Non-Compliance

- Practices should periodically assess all patients using controlled substances for a prolonged period of time.
- Assessment approaches can include:
  - Assessment of patient progress toward achieving therapeutic goals
  - Presence of adverse events
  - When indicated because a patient is high risk or is known to have engaged in aberrant behavior, results of urine drug testing



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### Monitoring For Abuse And Non-Compliance

- Adherence to prescribed therapies
- Standardized screening tools to assess for:
  - Aberrant drug-related behaviors
  - Substance abuse
  - Psychological issues



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### Suggested Patient Assessment Questions

- Has the patient ever sought treatment for drug abuse?
- Is the patient seeing more than one physician?
- Is the patient comfortable with a detailed pain management agreement if they are using controlled substances for a prolonged period of time?



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### Suggested Patient Assessment Questions

- Is the patient comfortable with periodic urine drug testing?
- Is the patient using illicit drug(s)?
  - Does the patient have physical signs of drug abuse?
  - *The initial interview can set the tone for further discussion and use of risk management tools.*



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### Risk Assessment: An Ongoing Process

- Be aware of pill counts
- Consider caregivers, friends and family for potential of diverting or misusing medications
- Have a medication agreement with the patient that includes expectations of the treatment plan
- Use of a prescription monitoring solution, as a tool to assist the physician, in assessment of patient adherence to prescribed regimens



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### The More You Know, The Better

- Physicians should know the following:
  - Whether patients are likely to be taking their medications in a manner consistent with the dose and frequency prescribed?
  - Is a patient taking illicit drugs?
  - Is a pain medication present at high concentrations, which could indicate abuse?
    - Can those levels be shown in a prescription monitoring report?
  - Is the prescribed medication not present?
    - Could indicate non-compliance or possible diversion.



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### Advice for a Practice During a Visit From DEA

- Since inspections may occur at any time during typical business hours, the **registrant must have an action plan** that is reviewed by all authorized personnel on how to immediately retrieve the necessary documentation required for a DEA inspection.
- Review the DEA Diversion Inspectors' credentials and obtain their contact information.
- Inquire the reason for the inspection.



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## Advice for a Practice During a Visit From DEA

- Have all documentation readily available.
- Take notes of all recommendations and observations made by the DEA Diversion Investigators.
- Obtain a location in the office to allow the investigators to review records and policies.
- Ask any questions you may have regarding their findings so corrective actions can be implemented.
- ***Be polite and cordial. Do not argue or debate with the investigators.***



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## What About Patient Charts ?

- Your patient files and charts should be complete and accurate, clearly legible, fully articulate and document each patient medical history, your thorough physical examination conducted, medical diagnosis and justification for writing any controlled substance prescription being issued to a patient for a legitimate medical purpose as well as any authorization for refills.
- The files and charts should be absent of red flags that will require further investigation by DEA.

DEA website, Division of Drug Control, <https://search.deadiversion.usdoj.gov/basis/search/DrugXSL.nsf/print-static-usdoj?openpage&order=5000&prose=5000&trunc=5000&view=5000&doc=2&order=1&start=0&query=patient-chart&submit=Search>, Accessed 05/12/2022

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## What About Patient Charts?

- When appropriate your files and charts should include results of blood work, electronic imaging such as: x-rays, scans and/or MRI testing, additional physician consults and opinions and your follow-up with the patient. Some doctors have included the results of random urinalysis drug testing for patients who regularly receive controlled substance prescriptions to help assure they are legitimately using the medication and not diverting the drugs.

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## The Part Fentanyl Plays in Overdose Deaths

Sharp increases in opioid overdose deaths since 2013 are partly explained by the introduction of illicitly manufactured fentanyl into the heroin market. Outbreaks related to fentanyl analogs also have occurred. One fentanyl analog, Carfentanil, is estimated to be 10,000 times more potent than morphine. Fentanyl analogs are not routinely detected because specialized toxicology testing is required.



O'Donnell JK, Halpin J, Mattson CL, Goldberger BA, Gladden RM. Deaths involving Fentanyl, Fentanyl Analogs, and U-47700 — 30 States, July–December 2016. *MMWR Morb Mortal Wkly Rep* 2017;66:1197–1202. DOI: <https://www.cdc.gov/nchs/data/databriefs/db428.pdf>. Accessed 05/12/2022.

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## The Part Fentanyl Plays in Overdose Deaths

Illicitly manufactured fentanyl is now a major driver of opioid overdose deaths in multiple states, with a variety of fentanyl analogs increasingly involved, if not solely implicated, in these deaths. This finding raises concern that in the near future, fentanyl analog overdose deaths might mirror the rapidly rising trajectory of fentanyl overdose deaths that began in 2013 and become a major factor in opioid overdose deaths.



O'Donnell JK, Halpin J, Mattson CL, Goldberg BA, Gladden RM. Deaths involving Fentanyl, Fentanyl Analogs, and U-47700 — 30 States, July–December 2016. *MMWR Morb Mortal Wkly Rep* 2017;66:1197–1202. DOI: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6643a1.htm> Accessed 05/12/2022.

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## Novel Psychoactive Substance: Flualprazolam



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### Novel Psychoactive Substance: Tianeptine



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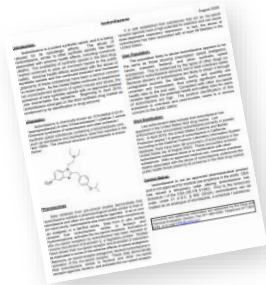
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### Novel Psychoactive Substance: Isotonitizine



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### Resources

- DEA Office of Diversion  
[www.deaofficeofdiversion.org](http://www.deaofficeofdiversion.org)  
Accessed 06/12/2022.
- Office of National Drug Control Policy  
[www.oncdp.gov](http://www.oncdp.gov)  
Accessed 06/12/2022.



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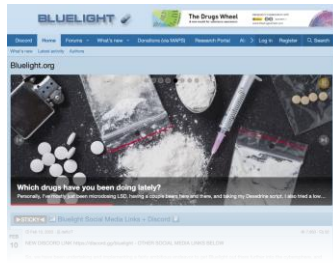
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### Illicit Use Peer Review Websites

- Peer Reports on the use of various opiates
- Non-scientific data on uses of various opiates
- Data from the "user" perspective

[www.bluelight.org/vb/content/?\\_A=content/52/12/2022](http://www.bluelight.org/vb/content/?_A=content/52/12/2022)



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### Illicit Use Peer Review Websites

- Inspired by the principles of crowdsourcing, *StreetRx* is a one-of-a-kind program that identifies and tracks the street value of prescription and illicit drugs. *StreetRx* gathers user-submitted data to map the street price of a variety of drugs across the country.
- *StreetRx* users can anonymously post, view, and rate submissions, shedding new light onto the often muddy waters of the black market. By providing invaluable information about the preferences of users, health communication specialists can adapt the outreach efforts to the local needs of their community.

[https://streetrx.com/\\_A=content/16/12/2022](https://streetrx.com/_A=content/16/12/2022)

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### Protecting Prescribers and Appropriately Treating Patients

- This program is NOT intended to discourage the prescribing or dispensing of appropriate medication for legitimate medical purposes.
- **Physicians and other authorized prescribers should not allow those who divert or misuse prescription drugs to influence the legitimate prescribing and dispensing of controlled substances.**



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### Summary

- Prescription drug abuse and non-compliance should be a critical concern for all practices.
- Be aware of aberrant patient behaviors.
- Monitoring for non-compliance and controlled substance abuse is a continuous, ongoing process—increasingly required by authorities.
- Ensuring adherence to a prescription regimen is crucial for protecting patient safety and society at large.



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### Risk Management Considerations



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### Drug Overdose Deaths 1999-2020

- 71% of overdose deaths involve opioids
  - Synthetic opioids main driver
- Geographic shift
  - Types of drugs involved
  - No significant decrease from 2018-2019



National Center for Health Statistics, National Vital Statistics System, Mortality, [https://www.cdc.gov/nchs/data/ndohr/08428\\_indexes.pdf#5](https://www.cdc.gov/nchs/data/ndohr/08428_indexes.pdf#5), Accessed 05/03/2022.

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### Case Study

- Autopsy toxicology results
  - Positive for benzodiazepines, carisoprodol, and opiates
- Family medicine physician never checked drug monitoring database or collaborated with pain management
- No toxicology screen
- No investigation into circumstances of patient's discharge from pain management

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### Case Study

- Plaintiff's expert testified physician breached the standard of care with the following allegations:
  - Prescription of medications in quantity, doses, and classifications that function to depress CNS
  - Failure to monitor pain medications prescribed
  - Failure to refer to other specialties (i.e., neurology, psychiatry)
  - Case settled

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### Treatment Plan

- Thorough and updated H&P, including the following:
  - Nature & intensity of pain
  - Current/past diagnostic studies & treatments
  - Underlying coexisting diseases
  - Effect of pain on physical/psychological functioning
  - Screening for substance abuse/depression/suicide

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### Ongoing Treatment Plan

- Descriptive qualifiers (i.e. aching, sharp, dull, etc.)
  - Identification of pain locations
  - Pain scale (numeric, pictorial)
  - Impact qualifiers on ADL
  - Identification of objectives to measure treatment success

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### Treatment Plan for Continuing Treatment

- Documentation
  - Diagnostic studies or consultations planned
  - Urine screen results
  - Informed consent/pain contract
  - Regularly scheduled follow-up appointments
  - Adjustments in drug therapy

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*If I don't have a pain management practice, I am not at risk. . .*

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### Communicate Expectations

- Establish expectations and consequences before prescribing controlled substances
  - No prescriptions from other physicians
  - Refills only at scheduled appointments
    - No replacement prescriptions
    - Medication only used as directed
  - No illicit drug use

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### Communicate Expectations

- Subject patients to random drug screening
- Establish procedure for randomized pill counts
- Obtain acknowledgement that failure to meet expectations results in termination of treatment relationship or treatment with certain medications
- Memorialize expectations in controlled substance agreement

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*How does one establish prescribing boundaries with patients?*

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### Resources

- DEA website, Diversion Control Division, COVID-19 Information Page, <https://www.deadiversion.usdoj.gov/coronavirus.html>, Accessed 05/12/2022.
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- SAMHSA.gov website, "The National Survey on Drug Use and Health, 2017", [https://www.samhsa.gov/data/sites/default/files/reports/rpt29292/Assistant-Secretary-nsduh2017\\_presentation/Assistant-Secretary-nsduh2017\\_presentation.pdf](https://www.samhsa.gov/data/sites/default/files/reports/rpt29292/Assistant-Secretary-nsduh2017_presentation/Assistant-Secretary-nsduh2017_presentation.pdf), Accessed 05/25/2022.
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- CDC website, National Center for Health Statistics, National Vital Statistics System, Mortality, <https://www.cdc.gov/nchs/data/databriefs/db428.pdf>, Accessed 05/25/2022.

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### Resources

- O'Donnell JK, Halpin J, Mattson CL, Goldberger BA, Gladden RM. Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016. MMWR Morb Mortal Wkly Rep 2017;66:1197–1202. DOI: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6643e1.htm>, Accessed 05/12/2022.
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