

Dear DEA

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Introduction

“Dear DEA” is a series of five clinical vignettes intended to address common concerns of clinicians and to demonstrate the cooperation of the Drug Enforcement Administration (DEA) with health professionals. The DEA is available to clarify the federal regulations on legally prescribing controlled substances to patients.

It is essential that prescribing clinicians understand the federal regulations that address administering, prescribing, and dispensing scheduled controlled substances whether they treat patients in a medical office, a hospital, a long-term care facility, or a hospice setting. This information is necessary not only to reduce diversion and misuse of controlled substances but also to protect the clinicians’ abilities to provide care. It may be equally important for clinicians to have sufficient comfort with their knowledge that they do not invariably “err on the side of caution” and thereby provide inadequate care.

The government’s role regarding controlled substances is determined by dual imperatives and the central principle of “balance.” One mandate is to establish a system of controls to prevent misuse and diversion of controlled substances. The second mandate is to ensure the availability of controlled substances for medical and scientific purposes and for these medications to be accessible to all patients who need them [1].

The following vignettes describe situations in which clinician uncertainty had the potential to adversely affect practice. Each case was resolved by prompt and clear information provided by Patricia

M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, DEA, Washington DC.

First Clinical Vignette: Is It Illegal to Postdate Prescriptions?

Dear DEA

I am requesting clarification of the commonly used practice of using the “Do Not Fill Until ___ (a later date)” method for writing prescriptions for a Schedule II controlled substance.

The code of federal regulations section 1306.05 (manner of issuance of prescriptions) states all prescriptions for controlled substances shall be dated as of, and signed on, the date issued. However, in certain instances when one is prescribing a Schedule II controlled substance, especially an opioid, there is a need to divide the quantity of medications in half. Therefore, each prescription will have the same date of issue, as directed in section 1306.05, but one of the prescriptions will have a “Do Not Fill Until ___” date on it so that it can be filled without a return visit to the office. This commonly occurs in clinical practice under the following circumstances:

- 1 A stable pain patient’s visits are every 8 weeks, and the insurance company will pay for only 4 weeks of medicines per prescription.
- 2 A patient has an appointment every 2 weeks, but for clinical reasons the prescriber wants the patient to have only a 1-week supply of medicine.

To the best of my knowledge, the use of the “Do Not Fill Until ___” is not addressed in any regulation. Therefore, I respectfully request the DEA to address this method of prescribing and send me a clarification on official stationary. With your permission, this information would be used in professional educational meetings and posted on appropriate academic web sites.

Reprint requests to: Howard A. Heit, MD, FACP, FASAM, 8316 Arlington Boulevard, Suite 232, Fairfax, VA, 22031. Tel: (703) 698-6151; Fax: (703) 698-6154; E-mail: Howard204@aol.com.

I would like to thank you in advance for attention to this matter.

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Dear Dr. Heit

This is in response to your correspondence regarding the DEA's policy concerning the legality of a practitioner issuing several Schedule II prescriptions on the same date for the same medication for a stable patient or for other clinical reasons.

The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time. If, in keeping with the practitioner's professional medical judgment, multiple prescriptions are issued at a time, each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing. For example, if three prescriptions, each for a 30-day supply, are issued on January 9, 2003, each prescription must be dated January 9, 2003. In addition, the prescription to be filled at later dates must include directions for the dispensing pharmacist such as, "do not dispense before February 9, 2003," and "do not dispense before March 9, 2003." Although Title 21 of the Code of Federal Regulations, Section 1306.12 (21 CFR 1306.12) prohibits the refilling of a prescription for a Schedule II controlled substance, the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice *provided* that it is not in violation of the laws of the state in which the practitioner is licensed.

Although the DEA does not restrict the frequency or quantity of prescriptions, state medical/pharmacy boards or insurance providers may impose some limits on the prescribing or dispensing of controlled substance medications. The practitioner may wish to contact these parties for information regarding any limits they impose on the quantity of medications that may be prescribed or dispensed.

The DEA appreciates your efforts in informing other practitioners of DEA policies on the handling of controlled substances. The above cited regulations and information regarding DEA's

Diversion Control Programs are available on our web site at www.DEADiversion.usdoj.gov.

I hope this information is useful to you.

PATRICIA M. GOOD, CHIEF
*Liaison and Policy Section
 Office of Diversion Control*

Second Clinical Vignette: Can I Prescribe Opioid Analgesia to a Patient in a Methadone Clinic?

Dear DEA

I am requesting clarification on the legality of prescribing opioid analgesia to a pain patient who also receives methadone on a regular schedule from a narcotic treatment program (NTP). The once-a-day dispensing of methadone is adequate to treat his addiction but not his pain syndrome.

The Code of Federal Regulations states I may administer, prescribe, or dispense a Schedule II controlled substance to a person with intractable pain, in which no relief or cure is possible or none has been found after a reasonable effort (21 CFR 1306.07). I know I can treat acute/chronic pain with a Schedule II controlled substance in a recovering narcotic-addicted patient. Federal law or regulations do not restrict the prescribing, dispensing, or administering of a narcotic medication to a narcotic-addicted patient for the purpose of alleviating pain if such prescribing is medically appropriate within standards set by the medical community (21 CFR 1306.07). I understand that my records must document that I am treating pain and *not* the disease of narcotic addiction. However, to administer or dispense directly (but not prescribe) a Schedule II narcotic drug to a narcotic-dependent person for "detoxification" or "maintenance treatment," a physician must have a separate registration with the DEA as an NTP (21 CFR 1306.07).

Specifically, can I prescribe a schedule II controlled substance such as methadone to treat pain in a patient who is also enrolled in an NTP?

I would like to thank you in advance for attention to this matter.

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Dear Dr. Heit

This is in response to your letter regarding pain management and narcotic addiction treatment.

Pain specialists may treat a chronic pain patient currently enrolled in a narcotic treatment program with narcotics: The Controlled Substances Act does not set standards of medical practice. It is the responsibility of individual practitioners to treat patients according to their professional judgment for a legitimate medical purpose in accordance with generally acceptable medical standards.

As you know, state boards of medical examiners establish standards of medical practice and regulate such practice by doctors and other practitioners in their states. Many states have undertaken actions to develop guidelines for pain treatment. A booklet entitled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* is enclosed for your use. You may also wish to contact your state medical authorities or other nationally recognized organizations such as the American Methadone Treatment Association, the American Society of Addiction Medicine, or the American Academy of Pain Medicine.

Although pain specialists may treat a chronic pain patient currently enrolled in a narcotic treatment program, they may only treat the patient's pain. Care of patients fighting substance abuse requires sensitivity to the issue and careful monitoring of outcomes. As a suggestion, you may wish to obtain the patient's permission to coordinate your pain management treatment with his/her narcotic treatment program.

If a practitioner wishes to provide detoxification treatment or maintenance treatment to narcotic-dependent persons with methadone or levo-alpha-acetyl-methadol (LAAM), a separate registration with the DEA as a narcotic treatment program is required. A registration as a narcotic treatment program will allow the practitioner to administer or directly dispense, but not prescribe, narcotic drugs.

I hope this information is useful to you.

PATRICIA M. GOOD, CHIEF
Liaison and Policy Section
Office of Diversion Control

Third Clinical Vignette: Can I Use Methadone to Wean Pain Patients From Opioids?"

Dear DEA

I am writing to request clarification of the regulations regarding the weaning of opioids from

patients who are physically dependent on them. I treat a number of patients who have failed to respond to moderate- to high-dose opioid therapy, and I direct a program in which their current opioid is replaced with another, which is then weaned.

Our hospital pharmacy has declined to provide methadone for this purpose, out of the belief that I am performing "methadone detoxification," which of course requires special registration. The pharmacy also questioned the legality of my practice of weaning these patients by replacing their usual opioid analgesic with a tapering dose of controlled-released morphine.

My understanding has been that the detoxification of patients with the disease of narcotic addiction was legally distinguished from the weaning of opioids in pain patients, but I now need to know this with more certainty.

I would like to thank you in advance for attention to this matter.

EDWARD C. COVINGTON, MD
Director, Chronic Pain Rehabilitation
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Dear Dr. Covington

This is in response to your letter in which you discuss the difference between the weaning of a patient being treated for pain from opioids and the detoxification of a patient being treated for drug addiction. You are correct in your understanding that these are considered distinct activities under the Controlled Substances Act (CSA) of 1970 and its implementing regulations.

The Narcotic Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 amend the CSA to allow for the use of opioid drugs to treat addiction either through maintenance or detoxification under specific criteria. Schedule II opioids approved for addiction treatment are limited to methadone and LAAM and may only be administered or dispensed (not prescribed) by DEA-registered NTPs. Schedules III-V opioids specifically approved by the Food and Drug Administration (FDA) for use in addiction treatment may be prescribed, administered, or dispensed by certified practitioners who have obtained the appropriate waivers from the Center for Substance Abuse Treatment.

The above legal allowances were established to allow for the treatment of addiction with opioid controlled substances. These limitations and requirements in no way impact the ability of a practitioner to utilize opioids for the treatment of pain when acting in the usual course of medical practice. Consequently, when it is necessary to discontinue a pain patient's opioid therapy by tapering or weaning doses, there are no restrictions with respect to the drugs that may be used. This is not considered "detoxification" as it is applied to addiction treatment.

I hope this information is of assistance to you in your continued efforts to promote the effective and responsible treatment of pain.

PATRICIA M. GOOD, CHIEF
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Office of Diversion Control

Fourth Clinical Vignette: Can I Use Suboxone®/Subutex® for Analgesia?

Dear DEA

The FDA approved buprenorphine with or without naloxone for office-based opioid treatment following the Drug Addiction Treatment Act of 2000. Buprenorphine can be prescribed as maintenance therapy or for detoxification for narcotic addiction. The prescriber must be a certified and specially trained physician who has received a waiver from the requirement to register as an NTP from the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration.

The FDA permits the off-label use of approved medications. Therefore, can a clinician prescribe off-label use of buprenorphine with or without naloxone (Suboxone®/Subutex®) for the treatment of pain? In addition, if a clinician uses buprenorphine (Suboxone®/Subutex®) for the treatment of pain, does the prescriber need the special waiver that is required to prescribe buprenorphine for addiction or will DEA registration for Schedule III controlled substances be sufficient?

I would like to thank you in advance for attention to this matter.

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Dear Dr. Heit

This is in response to your correspondence in which you requested the DEA to respond to the following questions: Can a clinician prescribe off-label use of buprenorphine with or without naloxone (Suboxone®/Subutex®) for the treatment of pain? If a clinician uses buprenorphine (Suboxone®/Subutex®) for the treatment of pain, does the prescriber have to have a DEA registration or does he or she need the special waiver that is required to prescribe buprenorphine for addiction?

The buprenorphine products Suboxone® and Subutex® are the two Schedule III narcotic medications currently approved for the treatment of opioid dependence under the federal Drug Addiction Treatment Act of 2000 (DATA). The off-label use of the sublingual formulations of buprenorphine (Suboxone®/Subutex®) for the treatment of pain is not prohibited under DEA requirements. However, off-label use does pose a dilemma for pharmacists. Currently, there is no requirement under the DATA for a qualified practitioner to put the Unique Identification Number (UIN) on a prescription for Suboxone® or Subutex® for maintenance or detoxification treatment.

On June 24, 2003, the DEA published a Notice of Proposed Rulemaking (NPRM) that will require qualified practitioners to include the UIN on all prescriptions written for either Suboxone® or Subutex® for narcotic addiction treatment. This requirement will be the only way to determine whether a prescription for Suboxone® or Subutex® was written for maintenance or detoxification treatment or some other condition. Buprenex®, a Schedule III, injectable formation of buprenorphine, is approved and marketed in the United States as an analgesic and is widely used in the treatment of pain.

If a physician prescribes, dispenses, or administers buprenorphine (Suboxone®/Subutex®) for the treatment of pain or for any other reason, a DEA registration is required because both products are Schedule III controlled substances. The DATA waiver specifically authorizes qualified practitioners to treat narcotic-dependent patients using FDA-approved Schedule III–V narcotic controlled substances for maintenance and detoxification. The DATA waives the requirement for obtaining a separate DEA registration as a narcotic treatment program for physicians using the approved drugs for maintenance and detoxification; however, it does not apply to physicians using

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Suboxone® or Subutex® for the treatment of pain. A physician using Suboxone® or Subutex® for the treatment of pain would be required to register with the DEA as practitioner with Schedule III privileges.

The Narcotic Treatment Act of 1974 and the DATA amend the CSA to allow for the use of opioid drugs to treat addiction either through maintenance or detoxification under specific criteria. Schedule II opioids approved for addiction treatment are limited to methadone and LAAM and may only be administered and dispensed (not prescribed) by DEA-registered NTPs. Schedules III–V opioids specifically approved by the FDA for use in addiction treatment may be prescribed, administered, and dispensed by certified practitioners who have obtained the appropriate waivers from the Center for Substance Abuse Treatment.

The above legal allowances were established to allow for the treatment of addiction with opioid controlled substances. These limitations and requirements in no way impact the ability of a practitioner to utilize opioids for the treatment of pain when acting in the usual course of medical practice. Consequently, when it is necessary to discontinue a pain patient's opioid therapy by tapering or weaning doses, there are no restrictions with respect to the drugs that may be used. This is not considered "detoxification" as it is applied to addiction treatment.

I hope this information is of assistance to you in your continued efforts to promote the effective and responsible treatment of pain.

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Fifth Clinical Vignette: Can I Use a Full μ -Opioid Agonist as a Temporary Substitute for Suboxone®/Subutex® in a Patient who Requires Elective Surgery?

Dear DEA

The Drug Addiction Treatment Act of 2000 allows office-based opioid treatment (OBOT) with buprenorphine with or without naloxone. Buprenorphine can be prescribed by certified and specially trained physicians who have received a waiver from the requirement to register as an NTP from the Center for Substance Abuse and Treatment (CSAT) of the Substance Abuse

and Mental Health Services Administration (SAMHSA).

I am requesting the DEA provide clarification on the legality of prescribing an opioid medication for a patient on buprenorphine treatment for addiction who requires an elective outpatient surgical or dental procedure:

- 1 Are the days before the procedure (pre-acute pain) covered presently under current federal regulations that address treating pain with a secondary diagnosis of addiction in this specific clinical setting?
- 2 Or, would the doctor prescribing a full agonist during this pre-pain period be perceived as maintaining a patient on an opioid, which would be noncompliance with existing federal regulations?

I would like to thank you in advance for attention to this matter.

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Dear Dr. Heit

The questions pertain to patients being treated with buprenorphine for addiction by qualified physicians under the Drug Abuse Treatment Act of 2000 (DATA) and under what circumstance these patients could receive other opioid (full agonist) medications for pain.

The law requires that a prescription for controlled substances be issued by a practitioner acting in the usual course of professional practice and for a legitimate medical need (21 CFR 1306.04). The term "legitimate medical need" is not defined in the law, and the DEA does not set standards as to what constitutes the usual course of professional practice. Those standards are set by the medical community. Federal laws or regulations do not prohibit a physician from prescribing any controlled substance that he/she believes is medically necessary to treat a patient. Each physician must decide whether the prescribing of narcotic drugs is medically appropriate within acceptable medical community standards. As long as a physician prescribes controlled substances for a legitimate medical purpose, he/she has no need

to fear that the DEA will take action against him/her.

Therefore, a patient being treated for narcotic addiction with buprenorphine by a qualified physician, who opts to receive an elective outpatient surgical or dental procedure that will require the prescribing or dispensing of other opioid medications to alleviate acute pain, has demonstrated a legitimate medical need. A practitioner is not prohibited from prescribing any controlled substance that he/she believes is medically necessary to treat this patient's pain.

Regarding the second question, the federal regulations are clear. The administering or dispensing (not prescribing) of a narcotic drug in any schedule to a narcotic-drug-dependent person for detoxification or maintenance treatment requires a separate registration with the DEA as a narcotic treatment program (21 Code of Federal Regulation 1306.07(a)). This aspect of the regulation is being modified to reflect the provisions of DATA that will allow a physician to prescribe or dispense FDA-approved Schedules III–V addiction treatment medications provided they are “qualified” by CSAT and receive a unique identification number assigned by the DEA. In this instance, the requirement of a separate registration as a narcotic treatment program will be waived.

However, prescribing or dispensing opioid medication to a narcotic-addicted patient for the purpose of alleviating pain should be viewed no differently than prescribing or dispensing such medications to any other legitimate pain patients. Confusion occurs when any prescribing or dispensing of controlled substances to a narcotic-drug-dependent person is automatically viewed as detoxification or maintenance treatment.

I trust that this information adequately responds to your concerns.

PATRICIA M. GOOD, CHIEF
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Conclusion

All regulations are written without full knowledge of future situations that may be impacted by them. Those regulations that govern the practice of pain medicine may leave the practitioner with a sense of ambiguity as to what is and is not permissible. In the face of this uncertainty, the cautious clinician may play it safe by doing too little or nothing at all. It is reassuring to know that, while clinical uncertainties persist, the legal uncertainties can be resolved without the need to expose one's patients or one's practice to risk, simply by contacting the DEA. In a very real sense, this constitutes a partnership between enforcement authorities and clinicians in the mutual goal of improving the health of those with chronic pain.

Acknowledgment

We thank David E. Joranson, MSSW, Senior Scientist, Director, and Aaron Gilson, PhD, Assistant Scientist, Assistant Director, at the University of Wisconsin Pain & Policy Studies Group for their assistance in the letters to the DEA.

Reference

- 1 A guide to evaluation: Achieving balance in federal and state pain policy. Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, July 2000.