

PCSS-B Training

An Educational Resource for Those Treating
Patients with Opioid Dependence

PCSS Guidance

Topic: Drug Enforcement Administration requirements for prescribers and dispensers of buprenorphine and buprenorphine/naloxone

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Guideline and Federal Document Coverage:

Additional information on this topic is available at: **TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction**, Chapter 6, pp 79-85; Appendix F p 135; Appendix B and C p. 101-119. Laura McNicholas, Consensus Panel Chair M.D. Ph.D. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment
<http://www.kap.samhsa.gov/products/manuals/index.htm>

DEA Requirements for DATA-Waived Physicians Who Treat Narcotic Addiction Using Buprenorphine:

http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

SAMHSA/CSAT Information on Record Keeping:

<http://www.buprenorphine.samhsa.gov/faq.html#A9>

Clinical Questions:

1. What regulations govern Drug Enforcement Administration (DEA) review of practices prescribing and/or dispensing buprenorphine or buprenorphine/naloxone?
2. What paperwork should be maintained?
3. How should medication be stored?
4. What has been the experience of providers who have undergone DEA visits?

Regulations:

Congress passed the Drug Addiction Treatment Act (DATA) on October 17, 2000. This act permits qualified practitioners to administer or dispense Schedule III, IV, or V narcotic medications, that have been approved for the maintenance and detoxification treatment of a narcotic dependent person. Thus far the Food and Drug Administration has only approved the use of buprenorphine mono and buprenorphine/naloxone tablets for this purpose. The DEA is authorized by the Controlled Substances Act (21 U.S.C. 822 (f) 880 and 21 CFR 1316.03 to enter controlled premises (registered locations) and conduct periodic inspections to ensure compliance with recordkeeping, security and other requirements of the Controlled Substances Act.

Paperwork:

Physicians prescribing buprenorphine and buprenorphine/naloxone should maintain records on every patient in treatment with documentation consistent with the recommendations of the DEA and Federation of State Medical Boards (TIP 40 Appendix F). Assessment Forms such as those available in TIP 40 Appendix B and C may also be included in patient

records. All records must be kept for at least 2 years, and be available for inspection by the DEA and copying by officers and employees of the U.S. authorized by the Attorney General. It is not necessary for physicians to produce copies of their certification letters from CSAT.

Patients: Waivered physicians may treat up to 30 patients at any one time during the first year, and thereafter may submit a second notification to CSAT to increase their patient limit to 100. Notification forms are available at:

<http://www.buprenorphine.samhsa.gov/howto.html>.

The physicians' DEA certificate of registration indicates the patient limit to which they must adhere. The physicians should have a method to keep track of the number of patients for whom they are actively prescribing buprenorphine and/or buprenorphine/naloxone.

Prescriptions: Prescriptions for buprenorphine and/or buprenorphine/naloxone must include full identification of the patient's name, address, and drug name, strength, dosage form, quantity and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day when issued [See 21 CFR 1306.05(a)]. Both the physician's regular DEA registration number and the physicians' DATA 2000 identification number (which begins with the prefix X) must be included on the prescription [See 21 CFR 1301.28 (d)(3)].

Storage:

For those physicians dispensing medication directly from their office, CFR 1301.75 stipulates that buprenorphine/naloxone and buprenorphine should be stored in a securely locked, substantially constructed cabinet. The physician must notify the local DEA office, in writing, of the theft or significant loss of any buprenorphine or buprenorphine/naloxone, within one business day.

Dispensing:

For those physicians dispensing medication directly from their office, CFR 1301.75 stipulates that buprenorphine and/or buprenorphine/naloxone should be stored in a securely locked, substantially constructed cabinet and the physician must keep a record of the amount received and dispensed (21 CFR 1304.22) and a physical inventory of all stocks on hand pursuant to CFR 1304.11. The individual practitioner must also include the identification number on all records when dispensing and on all prescriptions when prescribing these narcotic drugs. (21 CFR 1301.28 (d)(3)). The physician must notify the local DEA office, in writing, of the theft or significant loss of any buprenorphine or buprenorphine/naloxone, within one business day.

Information based on past DEA inspections:

DEA inspections usually last 1-2 hours. The physician has the right to refuse consent for the inspection. If the physician refuses consent for the inspection, DEA can obtain an Administrative Inspection Warrant which will allow the investigators to gain entry without consent. Anything of an incriminating nature may be seized and used against the physician in an administrative, civil and/or criminal prosecution.

Information based on past DEA investigations:

As of 9/10/2009, there had been 593 investigations out of 17,139 waivered physicians (3.4%). In these 593 investigations, no problems were cited in 62% of prescribers. Of the 17% in which problems were cited, 54 physicians received verbal warnings related to record

keeping and dispensing violations, 34 received letters of admonition addressing record keeping, security violations, or dispensing violations, 10 surrendered their registration for cause, there were 2 Show Cause proceedings, 1 revocation of registration and 1 resulted in a civil action. 14% had not prescribed buprenorphine products.

References:

TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Chapter 6, pp 79-85; Appendix F p 135; Appendix B and C p. 101-119. Laura McNicholas, Consensus Panel Chair M.D. Ph.D. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment <http://www.kap.samhsa.gov/products/manuals/index.htm>

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PCSS Guidances use the following levels of evidence*:

High = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low = Any estimate of effect is very uncertain.

Type of evidence:

Randomized trial = **high**

Observational study = **low**

Any other evidence = **very low**

* Grading quality of evidence and strength of recommendations

British Medical Journal, 2004;328;1490-