Buprenorphine and Buprenorphine/Naloxone Sublingual Tablets

Pharmacist Information

(Not VA specific)

THIS IS ONLY AN ABBREVIATED SUMMARY OF PHARMACIST INFORMATION EXCERPTED FROM

- THE FAQ SECTION OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT (CSAT) WEB SITE FOR BUPRENORPHINE (**http://buprenorphine.samhsa.gov/index.html**);
- THE DRAFT VERSION OF THE *CSAT BUPRENORPHINE FACTSHEET FOR PHARMACISTS* (SOON TO BE AVAILABLE ON THE SAME WEB SITE);
- *SUBOXONE AND SUBUTEX INFORMATION FOR PHARMACISTS*; AND
- HANDOUTS AND NOTES FROM THE CSAT'S *BUPRENORPHINE UPDATE FOR PHARMACY REPRESENTATIVES* MEETING ON 7 NOVEMBER 2002.

FOR FURTHER UPDATES AND COMPLETE INFORMATION, PLEASE CHECK SAMHSA'S BUPRENORPHINE WEB SITE (http://buprenorphine.samhsa.gov/index.html) OR CALL CSAT'S TOLL-FREE BUPRENORPHINE INFORMATION CENTER (866-BUP-CSAT).

How will patients obtain doses for induction?

Induction doses of buprenorphine or buprenorphine/naloxone should be given under supervision in the physician's office.

Options for patients to obtain induction doses include:

- **Physician dispenses medication from supply of medication in the office.** An office supply of buprenorphine should be stored in a locked cabinet in a secure room with limited access. A safe is not necessary for small amounts. It is suggested that patient information be made available in the physician's office.
- **Pharmacy dispenses doses, patient returns to physician's office for administration.** The physician may call or fax ahead to the pharmacy to request delivery (if this service is provided), or to ensure the medication will be ready in advance of the patient's arrival. (Recall that the patient is likely to be in mild withdrawal while awaiting the prescription.) Some physicians may send a patient's family member to the pharmacy to pick up the induction dose. The induction phase may take several days to complete; therefore, the patient may be visiting the pharmacy repeatedly at the beginning of treatment.

After the induction phase, buprenorphine/naloxone is the preferred product for take-home doses.

How can a pharmacist verify if a physician has a waiver to prescribe buprenorphine for the treatment of opioid addiction?

The physician's "X" ID number should be written on the prescription. SAMHSA and the Drug Enforcement Administration strongly encourage physicians to include their DATA waiver ID number on prescriptions for opioid addiction treatment medications. CSAT understands that the DEA is planning to issue Federal regulations that will require this ID number on all such prescriptions. This ID number will be a nine-digit alphanumeric sequence corresponding to the physician's regular DEA registration number with the first character replaced with an "X." This waiver ID number is required on VA prescriptions for buprenorphine or buprenorphine/naloxone used in the office-based treatment of opioid dependence. The waiver ID number is not required when buprenorphine or buprenorphine/naloxone is prescribed by an

Opioid Treatment Program physician. The waiver ID number is also not required if a patient is hospitalized for a reason other than opioid dependence, and is started or continued on buprenorphine or buprenorphine/naloxone for opioid dependence as an incidental treatment.

Physician locator page. SAMHSA has placed a Physician Locator page on the buprenorphine SAMHSA Web site that will list physicians in each state who have waivers to prescribe buprenorphine or buprenorphine/naloxone for opioid addiction treatment. A physician listed on the Physician Locator site can be considered to have a valid DATA waiver. Note, however, that the site will not list every physician with a valid waiver; only those who agree to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.

> CSAT and the DEA are required to determine a requesting physician's eligibility to receive the waiver within **45 days** after receipt of a Notification of Intent. DATA 2000 allows a physician to prescribe or dispense approved Schedule III, IV, or V medications for the treatment of an individual patient after submitting a Notification of Intent but before receipt of the ID number, if the requesting physician notifies CSAT of his or her intent to do so.

Call SAMHSA. A pharmacist desiring to verify that a physician who is not listed on the site has a valid DATA waiver can contact SAMHSA at 301-443-0457, or by e-mail at nreuter@samhsa.gov. Pharmacists should convey their DEA registration number with these requests. Pharmacists may also find out if a physician has submitted a Notification of Intent but has not yet received the ID number by calling the SAMHSA number or e-mailing nreuter@samhsa.gov.

Check physician's waiver approval letter. A pharmacist may request from the physician a copy of the letter indicating that CSAT had approved the physician's waiver.

[Note: The process for finding out which physicians have applied for the waiver was still being sorted out at the time of the CSAT meeting for pharmacy representatives on 7 November 2002. There was concern that it was easy for any physician to write an "X" before their DEA number. Pharmacists should verify all prescriptions with or without the unique identification number and they can refuse to fill buprenorphine or buprenorphine/naloxone prescriptions or partially fill them if they are in doubt. Physicians who are registered to prescribe buprenorphine or buprenorphine/naloxone for opioid dependence should be encouraged to inform their pharmacies of their intent to do so.]

Confidentiality and Privacy

Special Federal regulations apply to the confidentiality of substance abuse treatment information (38 USC 7332 for the Veterans Health Administration (VHA) and 42 CFR Part 2 for non-VHA facilities), and to the privacy and confidentiality of health records in general (HIPAA).

38 USC 7332: Implications for VHA pharmacists

Title 38 U.S. code section 7332 provides for confidentiality of certain medical records in the VHA (see http://www4.law.cornell.edu/uscode/38/7332.html). Records of the identity, diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia which is carried out by or for the Department, unless exempted, shall be confidential and may be disclosed only for the purposes and under the circumstances expressly authorized by the applicable subsections of the code. The prohibitions of this section shall not prevent any interchange of records within and among those components of the Department furnishing health care to veterans, or determining eligibility for benefits under this title or between such components furnishing health care to veterans and the Armed Forces.

Therefore, patient-identifying information may be disclosed or redisclosed without the patient's written consent between VHA providers and VHA pharmacists in the course of providing buprenorphine or buprenorphine/naloxone to veterans for the treatment of opioid dependence. Disclosure between fee-based providers and VHA pharmacists is also considered to fall within the treatment exemptions and can occur without the patient's written consent.

42 CFR Part 2: An Overview for Non-VHA Pharmacists

(NOTE: THIS SECTION STILL NEEDED TO BE REVIEWED AND CLEARED BY SAMHSA)

In order for a physician to verify a buprenorphine or buprenorphine/naloxone prescription, or indeed to disclose any patient-identifiable drug abuse treatment information to any third party, the physician should have a signed consent form from the patient that meets the requirements of 42 CFR Part 2. There are also prohibitions on a pharmacist's further disclosure of patient-identifying drug abuse treatment information when a physician directly transmits a prescription to or otherwise communicates with a pharmacist. 42 CFR Part 2 does not apply to the pharmacy when a patient personally delivers a prescription to the pharmacist and when there has been no direct communication from the physician to the pharmacist.

Scenario 1: Patient presents a prescription to the pharmacist

> This is NOT a disclosure under the regulations. Patients are free to disclose information about themselves; the regulations limit what the program or physician can say about the patient.
>
> The pharmacist is not bound by the prohibition on redisclosure.

Scenario 2: Physician telephones or faxes prescription to pharmacy

> This is disclosure by a program (physician) covered by the regulations. Need patient consent.
>
> The pharmacy is bound by the regulations not to use or disclose the information except pursuant to the regulations, including for billing purposes (note that this is different from HIPAA which permits disclosures for billing purposes without patient authorization).

Solution: Physician obtains compound consent (allows consent among > 2 parties) for disclosure to pharmacy for filling prescription and for the pharmacy's billing procedures. (Note that pharmacy should be notified if consent is revoked.) Pharmacy complies with security provisions of the regulations (section 2.16).Preventing Abuse and Diversion

Pharmacists will not be responsible for policing the validity of all physician ID numbers or for ensuring the 30-patient physician and group limits but they should use the same professional judgment in acting upon suspect prescriptions or other evidence of diversion or abuse, as they would with suspected misuse of other scheduled narcotic medications.

DEA Protocol

The DEA issues patient ID numbers and will track patient limits and monitor for buprenorphine abuse and diversion. Data finding will be very physician-dependent and voluntary.

Five qualified physicians per division (delineated by the DEA) will be inspected per FY.

> Administration and Dispensing: full audit of controlled substances records
>
> Prescribing: Requires records. The content of the records is up to the discretion of the physician. If there is no separate log, then the DEA must check the patient's medical record. The log should contain a record of what was dispensed, who dispensed the medication, and when it was dispensed.

Pharmacies identified by the physician will be audited to determine the number of prescriptions written by the qualified physician.

[Note: In the VA, both methadone clinics and pharmacies keep methadone records. At this time, it is expected that the record-keeping requirements for buprenorphine will be similar to those of methadone. Any updates related to this will be provided as they become available.]

Pharmacy Management of Buprenorphine Medications

Federal and state regulations for stocking and handling buprenorphine are the same as those for other Schedule III narcotics.

Physicians/Pharmacist Training Courses

For information on training, please check SAMHSA's buprenorphine Web site (**http://buprenorphine.samhsa.gov/index.html**) or call CSAT's toll-free buprenorphine information center (866-BUP-CSAT).

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