The following checklist is designed to provide pharmacists with an overview of federal law requirements associated with dispensing controlled substances. Pharmacists must also consult state law for existence of more restrictive and/or additional requirements.

**GENERAL PHARMACY REQUIREMENTS**

- Pharmacies dispensing controlled substances must be registered with the US DEA (Drug Enforcement Administration) and registrations must be renewed every 3 years. The certificate of registration must be maintained at the registered location for official inspection. If a person owns more than 1 pharmacy, each place of business must be separately registered.
- All records of controlled substances must be maintained for 2 years, separately from all other records. Records of Schedule II controlled substances must be further separated from Schedule III–V records.
- A pharmacy may not employ a person who will have access to controlled substances if he/she has been convicted of a felony offense relating to controlled substances, or has had an application for registration denied, had a registration revoked, or has surrendered a registration for cause.
- DEA permits pharmacies to disperse stocks of Schedule II–V controlled substances throughout the non-controlled stock to prevent theft.

**PRESCRIPTION PROCESSING REQUIREMENTS**

- A controlled substance prescription may be issued only by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is authorized to prescribe controlled substances by the jurisdiction in which he/she is licensed to practice, and is registered with DEA or exempted from registration.
- All controlled substance prescriptions must be dated and signed on the date when issued, and must include the following information:
  - Patient’s full name and address
  - Practitioner’s name, address, and DEA registration number
    - A practitioner who prescribes controlled substances in multiple states (jurisdictions) must have a separate DEA registration based on the practitioner’s license in each state.
    - A practitioner employed by a hospital or other institution (eg, hospitalist) may prescribe controlled substances under the hospital or institution registration, but must add to the hospital or institution registration number the internal code assigned by the hospital or institution.
  - Drug name, strength, and dosage form
  - Quantity prescribed
  - Directions for use
  - Number of refills, if applicable
- Prescriptions for detoxification or maintenance treatment of opioid dependency (buprenorphine or buprenorphine-naloxone) must include the practitioner’s DATA 2000 (Drug Addiction Treatment Act) waiver identification number (issued by the DEA) and the practitioner’s DEA registration number.
- A pharmacist may only dispense a faxed Schedule II prescription if the original written, signed prescription is presented to the pharmacist for review prior to dispensing and the original written, signed prescription is filed for recordkeeping purposes.
Dispensing from a faxed prescription and filing the faxed prescription for recordkeeping purposes is allowed when the prescription is written for a:
- Schedule II narcotic to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion;
- Schedule II controlled substance for a resident of a long-term care facility; or
- Schedule II narcotic for a patient residing in a hospice certified by Medicare or licensed by the state (practitioner must note on the prescription that the patient is a hospice patient).

**Prescription Dispensing Requirements**

- The pharmacist dispensing a controlled substance prescription to a non-institutionalized patient must affix to the container a label including the following information:
  - Pharmacy name and address
  - Serial (prescription) number
  - Date of initial dispensing
  - Name of the patient
  - Name of the prescribing practitioner
  - Directions for use
  - Cautionary statements, if any
  - The warning statement: “CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”
- Under federal law, there is no time limit for when a Schedule II prescription must be dispensed after being issued by the practitioner. However, the pharmacist must determine legitimate medical purpose and whether the prescription is still needed by the patient.
- The pharmacist may dispense a Schedule II prescription upon receiving oral authorization from a practitioner only in emergency situations, provided that the quantity is limited, full documentation takes place, and a written and signed prescription (with the words “Authorization for Emergency Dispensing” and the date of the oral authorization on the face of the prescription) is received by the pharmacy within 7 days.
- The pharmacist may partially dispense a Schedule II prescription if unable to supply the full quantity, provided that the quantity supplied is recorded and the remaining portion is dispensed within 72 hours of the first partial dispensing. A prescription for a terminally ill patient or long-term care facility patient may be partially filled for up to 60 days from the date of prescription issuance.
- The pharmacist may partially dispense a Schedule III–V prescription, provided that each partial dispensing is recorded in the same manner as a refilling. The total quantity dispensed in all partial dispensings cannot exceed the total quantity prescribed and no dispensing can occur after 6 months from the date of prescription issuance.
- A practitioner may issue multiple Schedule II prescriptions in accordance with the following requirements:
  - Quantity prescribed as a total of the multiple prescriptions issued cannot exceed a 90-day supply
  - The practitioner provides in writing on each prescription (except the first prescription) the earliest date (do not dispense before date) on which the prescription can be dispensed
  - Pharmacists may not dispense a prescription prior to the earliest date indicated on each prescription
- Refilling a Schedule II prescription is prohibited. Schedule III and IV prescriptions may be refilled up to 5 times with in 6 months after the date of issue (whichever occurs first). After that, a new prescription is required. Schedule V controlled substances may only be refilled as authorized on the prescription by the prescribing practitioner.
- On Schedule III–V refills, the dispensing pharmacist’s initials, the date on which the prescription was refilled, and the amount of drug dispensed on that refill must be recorded on the back of the prescription. As an alternative to recording refill information on the back of a prescription, an automated data processing system may be used for the storage and retrieval of refill information for prescriptions for controlled substances in Schedule III and IV, provided the following
conditions are met:
  o The system must provide online retrieval of original prescription information for those prescriptions that are currently authorized for refilling;
  o The system must provide online retrieval of the current refill history for Schedule III or IV controlled substance prescriptions;
  o Documentation that the refill information entered into the system each time a pharmacist refills an original prescription is correct must be provided by a hard-copy printout of each day’s controlled substance prescription refill data, with the printout being verified, dated, and signed by the individual pharmacist who refilled such a prescription; or in lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown;
  o The system has the capability of producing a printout of any refill data, which the user pharmacy is responsible for maintaining; and
  o The system must have an auxiliary procedure to be used for documentation of refills of Schedule III and IV controlled substance prescriptions in the event the system experiences downtime.

• Oral refill authorizations are permitted upon the following conditions:
  o Total quantity authorized, including amount on the original prescription, does not exceed 5 refills nor extends beyond 6 months from the date on the original prescription
  o The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription (showing who received the authorization from the prescribing practitioner who issued the original prescription)
  o Quantity of each additional refill authorized is equal to or less than the quantity authorized on the original prescription
  o Practitioner must execute a new and separate prescription for any additional quantities beyond the 5 refill, 6-month limitation

• A prescription for a controlled substance may be transferred between pharmacies only 1 time (except pharmacies sharing a real-time, on-line database, who may transfer up to the maximum permitted refills) and must comply with the following requirements:
  o Transfer is communicated between 2 licensed pharmacists (which includes other state-authorized persons that may dispense controlled substances under pharmacist’s supervision)
  o Transferring pharmacist:
    – Writes the word “VOID” on the face of the invalidated prescription;
    – Records on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred, and the name of the pharmacist receiving the transfer; and
    – Records on the invalidated prescription the date of the transfer and the name of the pharmacist transferring the prescription.
  o Receiving pharmacist:
    – Writes the word “TRANSFER” on the face of the transferred prescription;
    – Records on the prescription all required information;
    – Records date of issuance and number of refills on the original prescription;
    – Records date of original dispensing;
    – Records number of valid refills remaining and date(s) of last refill(s);
    – Records pharmacy’s name, address, DEA registration number, and prescription number from which the prescription information was transferred;
    – Records name of the pharmacist who transferred the prescription; and
    – Records pharmacy’s name, address, DEA registration number, and prescription number from which the prescription was originally dispensed.