



RESCHEDULING OF HYDROCODONE COMBINATION PRODUCTS **EFFECTIVE OCTOBER 6, 2014**

UPDATED 10/08/2014

Effective October 6, 2014, all hydrocodone combination products (HCPs) will be classified as schedule II controlled substances pursuant to a rule adopted by the United States Drug Enforcement Administration (DEA) on August 22, 2014. **Please note: Cough syrups that contain hydrocodone will also be classified as schedule II controlled substances when this rule takes effect.**

In order to ensure compliance with state and federal controlled substance requirements, the State of Ohio Board of Pharmacy advises that all pharmacists and prescribing practitioners adhere to the following requirements for schedule II drugs:

- **Security:** HCPs are subject to schedule II security requirements and must be handled and stored pursuant to [21 U.S.C. 821](#) and [823](#), and in accordance with [21 CFR 1301.71-1301.93](#) as of October 6, 2014.
- **Prescriptions:** No prescription for HCPs issued (**i.e. when provided by a prescriber to the patient**) on or after October 6, 2014 shall authorize any refills. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with [21 CFR 1306.22-1306.23](#), [1306.25](#), and [1306.27](#), if such dispensing occurs before April 8, 2015. After April 8, 2015, no refills on HCPs issued prior to October 6, 2014 are permitted. A store may transfer a prescription to another pharmacy if it has refills and is written before October 6th, 2014. **Please note: According to the DEA, the refill must be treated like a refill on a C-III prescription. Meaning a pharmacy CANNOT issue new C-II prescriptions and then tie those back to the original prescription to cover refills. Additionally, transfer of refills must be treated as a C-III prescription.**
- **Nurse Practitioner and Physician Assistant Refills:** According to the DEA, if a prescription was legally issued it is valid for 6 months from the date written. Therefore, any prescriptions from an authorized nurse practitioner or physician assistant for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with [21 CFR 1306.22-1306.23](#), [1306.25](#), and [1306.27](#), if such dispensing occurs before April 8, 2015.
- **Inventory:** For any substance listed in schedule II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents. An exact count inventory of all HCPs should be conducted on or before



October 6, 2014 (Ohio Administrative Code 4729-9-14). **Please note: Effective January 1, 2015, OAC 4729-9-14 will require a terminal distributor of dangerous drugs or prescriber to conduct annual controlled substance drug inventories. For more information, please see: www.pharmacy.ohio.gov/inventory.**

- **Wholesalers and Manufacturers:** An official written order for any schedule II controlled substances shall be signed in triplicate by the person giving the order or by their authorized agent. The original shall be presented to the person who sells or dispenses the schedule II controlled substances named in the order and, if that person accepts the order, each party to the transaction shall preserve their copy of the order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of Chapter 3719. of the Revised Code. Compliance with the federal drug abuse control laws, respecting the requirements governing the use of a special official written order constitutes compliance with this division (Ohio Revised Code 3719.04).
- **Personally Furnishing Drugs:** No schedule II controlled substances (HCPs) shall be personally furnished to any patient by a clinical nurse specialist, certified nurse-midwife, certified nurse practitioner or physician assistant (Ohio Revised Code 3719.06). "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting (Ohio Administrative Code 4729-5-01).
- **Prescription Filing:** Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions (Ohio Administrative Code 4729-5-09). Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, should be filed in the prescription file for schedules III, IV, and V prescriptions. Any new prescriptions for HCPs issued on or after October 6, 2014 must be filed in the prescription file for schedule II prescriptions.
- **Hospice Patients:** Preprinted prescription forms for hospice patients may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber. Verbal drug orders for schedule II controlled substances cannot be transmitted to the pharmacy by the hospice nurse at the direction of the prescriber. (Ohio Administrative Code 4729-5-14).
- **Partial Dispensing:** HCPs prescriptions must adhere to partial dispensing procedures for schedule II drugs listed in Ohio Administrative Code 4729-5-26. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be partially dispensed in accordance with [21 CFR 1306.23](#) if such dispensing occurs before April 8, 2015.
- **Faxed Prescriptions:** Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

- A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.
- A narcotic substance issued for a patient enrolled in hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.
- A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code. (Ohio Administrative Code 4729-5-30).

In order to ensure compliance with state and federal controlled substance requirements, the State of Ohio Board of Pharmacy encourages all pharmacists and prescribing practitioners to read and follow the D.E.A. requirements for controlled substances before processing prescriptions or prescribing HCPs.

The State of Ohio Board of Pharmacy is committed to ensuring your compliance with this rule change. If you have any questions or need additional assistance, please call 614-466-4143 or email by visiting: <http://www.pharmacy.ohio.gov/Contact.aspx>.

For more information, including additional federal restrictions, on the DEA's HCP rule please visit: http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm. Specific questions can also be directed to the following DEA Resident Offices:

CINCINNATI RESIDENT OFFICE

36 East 7th Street, Suite 1900
 Cincinnati, OH 45202
 Diversion Number: (513) 684-3671
 Diversion Fax: (513) 684-3080
Jurisdiction: Southern Ohio

CLEVELAND RESIDENT OFFICE

Courthouse Square
 1375 East 9th Street Suite 700
 Cleveland, OH 44114
 Diversion Number: (216) 274-3600
 Diversion Fax: (216) 664-1307
Jurisdiction: Northern Ohio

COLUMBUS RESIDENT OFFICE

500 South Front Street, Suite 612
 Columbus, OH 43215
 Diversion Number: (614) 255-4200
 Diversion Fax: (614) 469-5788
Jurisdiction: Central and Southern Ohio