



# Oregon

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**From: Oregon Board of Pharmacy**  
**Date: September 3, 2014**  
**Re: Hydrocodone Rescheduling Information**

**Federal Law has rescheduled all hydrocodone combination products (HCPs) as Schedule II, effective October 6, 2014.**

The new scheduling impacts all hydrocodone-containing products, including liquids such as Tussionex, Hycodan and all generic equivalent products. Single-entity hydrocodone has always been a C-II drug.

**INVENTORY:** All pharmacies and any persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with or possess) hydrocodone products, must take an inventory of their current stock on October 6, 2014. Please keep a record of this inventory on site.

**C-II RECONCILIATION:** Beginning October 6, 2014, pharmacies are required to include HCPs in C-II reconciliation audits, pursuant to OAR 855-019-0300(5)(e) and OAR 855-041-6610(1)(b).

**STORAGE:** Regulations require pharmacies to store C-II drugs in a locked area or secure storage system in accordance with 21 CFR 1301.75

- Retail pharmacies may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
- Hospital pharmacies are required to store Schedule II drugs in a locked area or secured storage system according to OAR 855-041-6610(1)(d), however, hospital pharmacies will be given until April 8, 2015 to comply with this rule.

**RECORDKEEPING:** All hydrocodone prescriptions and invoices must be filed with C-II prescriptions and invoices beginning October 6, 2014.

## **PRESCRIPTIONS:**

Prescriptions for HCPs **written before October 6, 2014** are:

- valid for up to six months, from original date of issuance – through April 8, 2015.
- valid if written by prescribers with C-III prescriptive authority

Prescriptions for HCPs **written on or after October 6, 2014** are:

- rescheduled as C-II. (Note, Oregon law does not speak to the expiration of a C-II; pharmacists and prescribers must use professional judgment)
- valid only if written by prescribers with C-II prescriptive authority

This 'phase in' period completely ends April 8, 2015.

Note: Not all pharmacy prescription processing systems may be capable of accommodating this distinction. Corporate/outlet policy may be more restrictive. It is recommended that communication between pharmacists, prescribers and patients is thoughtful and ongoing during this transitional phase.

Prescription Considerations:

- Electronic prescribing of scheduled drugs (including C-II) is permitted in Oregon, if the pharmacy and prescriber have authenticated software systems in accordance with 21 CFR 1311. See ORS 475.185(1)(a) clarified during the 2014 Legislative session: [https://www.oregonlegislature.gov/bills\\_laws/lawsstatutes/2014R1orLaw0055ss.pdf](https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2014R1orLaw0055ss.pdf)
- Federal and state rules permit a prescriber to issue multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of HCPs. Prescriptions must be written in accordance with 21 CFR 1306.12.
- A practitioner may verbally issue an emergency prescription for a C-II for an amount deemed to cover the emergency period of time. A written prescription must be mailed (postmarked) or delivered to the pharmacy within 7 days in accordance with 21 CFR 1306.11.
- For HCP prescriptions written before October 6, 2014, a pharmacy may assign a new prescription number for an authorized refill with proper documentation of reference to original prescription.
- There is no legal quantity limit on a single C-II prescription; however as with any prescription the pharmacist must perform a DUR for appropriateness. Additionally, large quantities can potentially create a challenge for third party drug coverage.

For the complete Final Rule published in the Federal Register on August 22, 2014, please visit <http://go.usa.gov/mc8d>