Rescheduling of Hydrocodone Combination Products

The information presented below is meant to supplement the information that PPA provided to its membership on October 14, 2014 regarding the DEA final rule on the rescheduling of Hydrocodone Combination Products (HCP’s).

At the recent Pennsylvania State Board of Pharmacy meeting, held at Wilkes University Nesbitt School of Pharmacy on October 21, 2014, the issue of the Board’s position on HCP refills was raised. Pharmacist-Attorney Jerry Musheno attended the meeting and requested that the Board issue specific guidance on the topic, since it impacted patient care and there were many pharmacists with questions on the issue.

The Board reaffirmed that they are unable, under state law, to issue advisory opinions on such matters, separate from going through the entire regulatory review process. So PPA is offering the following information to help inform PA pharmacists in their decision making.

As noted below, the DEA has issued guidance that effectively treats HCP prescriptions that were written before October 6, 2014 as schedule III prescriptions, and HCP prescriptions that were written on or after October 6, 2014 as schedule II prescriptions. In doing so, the DEA achieved the dual objective of reducing the risk of abuse and diversion for HCP products, while at the same time allowing for a smooth transition in the medical management of those on existing HCP therapy.
According the DEA guidance in the final rule that rescheduled HCP products from schedule III to schedule II:

*No prescription for HCPs issued 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.*

By way of background, the vast majority of states are either totally silent on the implementation of the DEA regulations and guidance or have supported their implementation as written. In the absence of any PA state law or regulation that would conflict with the federal DEA regulation and guidance, we are issuing the following guidance and reminders.

Listed below are some of the more important topics that are impacted by the DEA guidance and, where applicable, the difference between treatment of HCP’s as schedule II and schedule III prescriptions respectively:

**Prescription Transfers:** A pharmacy may transfer a prescription to another pharmacy if it has refills and is written before October 6th, 2014. Transfer of refills must be treated as a C-III prescription.

**Mid Level Practitioner Refills:** Any prescriptions for HCPs from an authorized mid-level practitioner such as a nurse practitioner or physician assistant 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 pharmacy shall make an exact count or measure of the contents. Pharmacies should
have conducted an exact count inventory of all HCPs on the day they became rescheduled from schedule III to schedule II (i.e. October 6, 2014).

**Prescription Filing:** Prescriptions for schedule II controlled substances shall be maintained in a file separate from all other records of the pharmacy in accordance with Pennsylvania Code Title 28 Chapter 25.56. 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.

**Partial Dispensing:** HCPs prescriptions issued on or after October 6, 2014 must adhere to partial dispensing procedures for schedule II drugs in accordance with 21 CFR 1306.13. 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:** In accordance with Pennsylvania Code, Title 49, Chapter 27.20, a pharmacist may fill a prescription for a Schedule II controlled substance which was received on a facsimile machine if the original prescription signed by the medical practitioner is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained as the original pharmacy record. There are three exceptions to the requirement that the pharmacist review the original of the prescription received on a facsimile machine before dispensing a Schedule II controlled substance. A pharmacist may fill and dispense a prescription for a Schedule II controlled substance which was received on a facsimile machine and may use the facsimile as the original pharmacy record of the following:
(i) A prescription for a Schedule II controlled narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intra-spinal infusion in the patient’s home. (ii) A prescription for a Schedule II controlled substance for a resident of a long-term care facility. (iii) A prescription for a Schedule II controlled narcotic substance for a patient enrolled in a hospice care program. The above provisions on faxed HCP prescriptions would apply to prescriptions issued on or after October 6, 2014.

**Attorney General Prescription Log:** Pennsylvania's Attorney General's office has advised that pharmacies should follow the federal guidelines but is also asking that pharmacies report all HCP prescriptions, including refills allowed by the DEA rule to them on the monthly schedule II log. We would strongly suggest that pharmacies comply with this request.

There has been a lot of confusion over whether Pennsylvania’s law is stricter than federal law. **Pennsylvania law is not stricter than federal law.** Refills of schedule II prescriptions are not permitted under federal law or any state law. As it is written, the DEA regulatory guidance would have no practical application in any state if it hinged on whether the particular state allowed refills on schedule II prescriptions.

Ultimately, each pharmacy must carefully weigh its own situation and determine how to proceed. For example, some pharmacy chains have elected not to allow refills on HCP prescriptions that were written before October 6, 2014. In addition, some health plans have also elected not to allow refills on HCP prescriptions that were written before October 6, 2014. These entities have adopted this stance for various pharmacy quality and safety processes and payer reimbursement issues (e.g. computer system cannot accommodate refills for HCP’s). These reasons for not allowing refills on HCP’s are legally acceptable. However, pharmacies not bound by these
restrictions are legally permitted to follow the stated DEA guidance (i.e., and allow refills where applicable for HCP prescriptions written before October 6, 2014) since the State Board has not offered any explanation or issued any emergency rulemaking that would conflict with the DEA guidance.