Louisiana Board of Pharmacy

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BULLETIN No. 14-05

To: All pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and candidates
All practitioners with prescriptive and/or dispensing authority for controlled substances
All distributors with legal authority for prescription drugs and/or controlled substances

From: Malcolm J Broussard, Executive Director

Date: September 15, 2014

Re: New Federal Rule Re-Schedules All Hydrocodone Combination Drug Products

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The U.S. Drug Enforcement Administration (DEA) has published a Final Rule re-scheduling all hydrocodone combination drug products *from* Schedule III *to* Schedule II. The rule was published in the August 22, 2014 edition of the *Federal Register* and becomes effective 45 days later, on October 6, 2014.

This federal rule places all hydrocodone combination drug products in Schedule II of the federal list of controlled substances. The re-scheduling of these products on the state list of controlled substances will be accomplished by the state legislature in the spring of 2015. In the interim, this federal rule will supersede the state classification; all of our licensees holding state and federally-issued credentials are obligated to adhere to the more stringent requirements applicable to controlled substances listed in Schedule II. The federal rules can be found in *21 CFR 1300 to end*, and the state rules can be found in *LAC 46:LIII.Chapter 27* of the Board's rules

Manufacturers, Distributors, and Reverse Distributors

- Effective October 6, your continued possession and distribution of hydrocodone combination products shall require a current Louisiana Controlled Dangerous Substance (CDS) License as well as a current DEA registration, both with an affirmative indicator for Schedule II. Any entity not in possession of both of these credentials and which is holding hydrocodone combination products shall dispose of such products, by any lawful method appropriate for prescription drug products listed in Schedule III, prior to October 6.
- In the event the entity conducted its previous inventory using estimated counts as allowed for Schedule III controlled substances, a new inventory using exact counts should be conducted on October 6; and further, the inventory records for these products shall be stored with similar records for Schedule II products and separately from similar records for products listed in Schedules III, IV, and V.
- Effective October 6, the sale of any hydrocodone combination product shall require the purchaser to demonstrate the possession of a current Louisiana CDS license and a current DEA registration, both with an affirmative indicator for Schedule II, and further, such sales shall require the use of the DEA Form 222 or the electronic equivalent thereof.
- For those entities interested in the exchange program for the relabeling of Schedule III products with new Schedule II labels, we encourage your review of the federal register notice, in particular the section on Quotas found on Page 49680.

Practitioners

- Effective October 6, your continued possession, acquisition, prescribing and/or dispensing of hydrocodone combination products shall require a current Louisiana CDS license and a current DEA registration, both with an affirmative indicator for Schedule II. In the event you are in

possession of any hydrocodone combination products and you do not have a Schedule II indicator on both your state and federal credentials, you shall dispose of such products, by any lawful method appropriate for prescription drug products listed in Schedule III, prior to October 6.

- For those practitioners holding such products and dispensing them to patients, you shall conduct a complete inventory of these products on October 6. Contrary to the allowances of estimated counts for Schedule III controlled substances, products listed in Schedule II shall be inventoried using a precise count. Further, the inventory records for Schedule II products shall be segregated from the inventory records for products listed in Schedules III, IV, and V.
- Prescriptions for hydrocodone combination products **issued prior to October 6** shall expire six months after the date of issue. Any refills authorized on the original prescription remain valid for the life of the prescription; however, any refills remaining on April 8, 2015 shall be automatically voided.
- Prescriptions for hydrocodone combination products **issued on or after October 6** shall comply with the usual limitations applicable to products listed in Schedule II – may be issued in written or electronic form, expires 90 days after the date of issue, and no refills.
- Prescriptions for hydrocodone combination products, as well as any other products listed in Schedule II, may be issued in series, provided the total quantity prescribed for the entire series does not exceed a 90-day supply.
- As a gentle reminder, a prescription for any controlled substance shall be dated on the date of issue. In the absence of any date of issue on a prescription for a controlled substance listed in Schedule II, the pharmacist is obligated to recognize the document as an invalid prescription. The pharmacist is not permitted to add the date of issue to a prescription for a controlled substance listed in Schedule II, even after consultation with the prescriber.
- We encourage prescribers using electronic drug databases to check with their vendors to ensure the correct controlled substance coding of hydrocodone combination drug products in the master drug file of their databases and information systems.

Pharmacies

- Effective October 6, your continued possession, acquisition, distribution, and/or dispensing of hydrocodone combination products shall require your possession of a current Louisiana CDS license and a current DEA registration, both with an affirmative indicator for Schedule II. In the event you are holding such products and do not have the required credentials, you shall dispose of the products, by any lawful means appropriate for prescription drug products listed in Schedule III, prior to October 6.
- Contrary to the allowances using estimated counts for products listed in Schedule III, your inventory of hydrocodone combination products on October 6 shall require precise counts. Moreover, your inventory records for these products must be maintained with other records for Schedule II products and segregated from the records for products listed in Schedules III, IV, and V.
- Hospital pharmacies are reminded of their requirement to maintain perpetual inventories for all products listed in Schedules I and II.
- Prescriptions for hydrocodone combination products **issued prior to October 6** shall expire six months after the date of issue. Any refills authorized on the original prescription remain valid for the life of the prescription; however, any refills remaining on April 8, 2015 shall be automatically voided.
- Prescriptions for hydrocodone combination products **issued on or after October 6** shall comply with the usual limitations applicable to products listed in Schedule II – may be issued in written or electronic form, expires 90 days after the date of issue, and no refills.
- Prescriptions for hydrocodone combination products, as well as any other products listed in Schedule II, may be issued in series, provided the total quantity prescribed for the entire series does not exceed a 90-day supply.
- We encourage you to check with your pharmacy information system vendor to ensure the correct controlled substance coding of hydrocodone combination drug products in the master drug file of your information system.