



# Louisiana Board of Pharmacy

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## BULLETIN No. 14-03

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: July 15, 2014

Re: New State & Federal Requirements for Certain Controlled Substances

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The 2014 Louisiana Legislature adopted several laws relative to the scheduling and use of certain controlled substances. In addition, the federal Drug Enforcement Administration (DEA) has announced the scheduling of a drug currently listed as a prescription drug. The details of these new requirements are listed below.

### **Act 397 (SB 618) of 2014 Legislature – effective August 1, 2014**

This law places carisoprodol (Soma<sup>®</sup> *et al*) products (with the exception of the combination product with codeine) in Schedule II of the Louisiana Uniform Controlled Substances Law. These products were previously listed in Schedule IV of the state list of controlled substances, and they are still listed in that schedule of the federal list of controlled substances. The combination product with codeine is already listed in Schedule III of the state and federal lists of controlled substances and remains in that schedule on both lists. Effective August 1, the distribution, prescribing and dispensing of carisoprodol products (except the codeine combination product) shall adhere to the usual requirements applicable to Schedule II controlled substances.

#### *Distributors*

- Effective August 1, your continued possession and distribution of carisoprodol products (with the exception of the combination product with codeine) shall require a current Louisiana Controlled Dangerous Substance (CDS) License with an affirmative indicator for Schedule II-N as well as a current DEA registration with an affirmative indicator for Schedule IV.
- Distributors holding a Louisiana CDS license and DEA registration are exempted from the storage, reporting, recordkeeping, and physical security requirements imposed by the state controlled substance laws and rules for carisoprodol products (with the exception of the combination product with codeine).
- Effective August 1, the sale of any carisoprodol product (with the exception of the combination product with codeine) shall require the purchaser to demonstrate the possession of a current Louisiana CDS license with an affirmative indicator for Schedule II-N as well as a current DEA registration with an affirmative indicator for Schedule IV.
- Since carisoprodol products (with the exception of the combination product with codeine) will be “Louisiana-only” Schedule II and not federal Schedule II products, there should be no requirement for the purchaser to use the DEA Form 222 (or electronic equivalent thereof) to order these products. Instead, the usual methods for the acquisition of controlled substances listed in other schedules should be sufficient.

- Since the purchaser of carisoprodol products (with the exception of the combination product with codeine) will be required to comply with the recordkeeping requirements applicable to all other Schedule II products, we encourage you to facilitate such efforts through the use of separate invoice documents for such products.

#### *Practitioners*

- Effective August 1, your continued possession, acquisition, prescribing and/or dispensing of carisoprodol products (with the exception of the combination product with codeine) shall require a current Louisiana CDS license with an affirmative indicator for Schedule II-N as well as a current DEA registration with an affirmative indicator for Schedule IV.
- Prescriptions for carisoprodol products (with the exception of the combination product with codeine) *issued prior to August 1* shall expire 90 days after the date of issue. Effective August 1, any refills originally authorized and still remaining on such prescriptions shall be automatically voided.
- Prescriptions for carisoprodol products (with the exception of the combination product with codeine) *issued on or after August 1* shall comply with the usual limitations applicable to Schedule II products – may be issued in written or electronic form, expires 90 days after the date of issue, and no refills.
- 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.
- Practitioners acquiring and holding carisoprodol products (with the exception of the combination product with codeine) shall comply with all of the storage, recordkeeping, and other requirements applicable to Schedule II, with the exception of the DEA 222 Order Form (or electronic equivalent thereof). Since the products at issue are “Louisiana-only” and not federal Schedule II products, the federal order form should not be required. The usual method for acquisition of other controlled substances should be sufficient.

#### *Pharmacies*

- Effective August 1, your continued possession, acquisition, dispensing and/or distribution of carisoprodol products (with the exception of the combination product with codeine) shall require a current Louisiana CDS license with an affirmative indicator for Schedule II-N [*with the exception of non-resident pharmacies*] as well as a current DEA registration with an affirmative indicator for Schedule IV.
- Prescriptions for carisoprodol products (with the exception of the combination product with codeine) *issued prior to August 1* shall expire 90 days after the date of issue. Effective August 1, any refills originally authorized and still remaining on such prescriptions shall be automatically voided.
- Prescriptions for carisoprodol products (with the exception of the combination product with codeine) *issued on or after August 1* shall comply with the usual limitations applicable to Schedule II products – may be issued in written or electronic form, expires 90 days after the date of issue, and no refills. Multiple partial fills are permitted provided the total quantity dispensed does not exceed the total quantity prescribed and none are dispensed more than 90 days after the prescription was issued
- Pharmacies acquiring and holding carisoprodol products (with the exception of the combination product with codeine) shall comply with all of the storage, recordkeeping, and other requirements applicable to Schedule II, with the exception of the DEA 222 Order Form (or electronic equivalent thereof). Since the products at issue are “Louisiana-only” and not federal Schedule II products, the federal order form should not be required. The usual method for acquisition of other controlled substances should be sufficient.

**DEA Federal Register Notice [FR 79:127] – effective August 18, 2014**

This federal rule places all tramadol (Ultram<sup>®</sup> et al) products in Schedule IV of the federal list of controlled substances. Prior to the effective date, tramadol was classified federally as a prescription drug product but not a controlled substance, and in Louisiana was classified as a prescription drug product as well as a 'drug of concern' but not a controlled substance. This federal rule will supersede the state classification; all of our licensees are obligated to adhere to the recordkeeping, physical security, and all other requirements applicable to controlled substances listed in Schedule IV.

- For those distributors, practitioners and pharmacies in possession of tramadol products on August 18, a complete inventory of such products shall be conducted to establish an opening inventory level. The inventory record shall be stored with other controlled substance inventory records. Effective August 18, your continued acquisition, possession, distribution, prescribing and/or dispensing of tramadol products shall require a current Louisiana CDS license and a current DEA registration, both with affirmative indicators for Schedule IV.
- Distributors, practitioners and/or pharmacies not in possession of both the state and federal controlled substance credentials noted above and which are holding tramadol products shall dispose of such products, by any lawful method appropriate for prescription drug products, prior to August 18.
- Effective August 18, the distribution of tramadol products shall require the purchaser to demonstrate possession of a current Louisiana CDS license and a current DEA registration, both with affirmative indicators for Schedule IV.
- Effective August 18, tramadol products distributed to purchasers shall bear a label containing all information required for controlled substances listed in Schedule IV. Practitioners and pharmacies holding tramadol products bearing a 'pre-scheduling' label may continue to use such stock containers for dispensing and medication administration purposes, but they may not further distribute such products with a 'pre-scheduling' label.
- Prescriptions for tramadol products *issued prior to August 18* shall expire six months after the date of issue. Originally authorized refills remaining on such prescriptions shall comply with the limitations applicable to Schedule IV products: the first five refills may be dispensed within the six months following the date of issue. In the event more than five refills were originally authorized, or in the event there are any refills remaining six months after the date of issue, all such refills shall be automatically voided.
- Prescriptions for tramadol products *issued on or after August 18* shall comply with the usual limitations applicable to Schedule IV products – may be issued in oral, written or electronic form, expires six months after the date of issue, and a maximum of five refills that were originally authorized provided that no refills are dispensed more than six months after the prescription was issued. Multiple partial fills are permitted provided the total quantity dispensed does not exceed the total quantity authorized [original + originally authorized refills] and none are dispensed more than six months after the prescription was issued.
- We encourage prescribers using electronic drug databases to check with their vendors to ensure the correct controlled substance coding of tramadol drug products in the master drug file of their databases and information systems.
- Pharmacies and other dispensers of tramadol prescriptions have been required to report their eligible prescription transactions to the Louisiana Prescription Monitoring Program (PMP) due to its status as a 'drug of concern.' With the new federal rule, it will no longer be a 'drug of concern' but a controlled substance listed in Schedule IV. All dispensers of tramadol prescriptions will still be required to report their eligible prescriptions to the Louisiana PMP. We encourage you to check with your pharmacy information system vendor to ensure the correct controlled substance coding of tramadol drug products in the master drug file of your information system.

**Act 865 (SB 496) of 2014 Legislature – effective August 1, 2014**

This law imposes a new requirement on prescribers of certain controlled substances, places an expiration date on prescriptions for drugs listed in Schedule II, and places quantity limits on the dispensing of prescriptions for certain controlled substances.

- A prescriber shall access the Louisiana Prescription Monitoring Program (PMP) database prior to initially prescribing any controlled substance listed in Schedule II to a patient for the treatment of non-cancer related chronic or intractable pain.
- A prescription for any controlled substance listed in Schedule II shall expire 90 days after the date of issue, and no pharmacy may dispense any medication for that expired prescription.
- With respect to prescriptions for any opioid derivatives listed in Schedules II or III issued by any prescriber not licensed by the State of Louisiana:
  1. The pharmacist shall not dispense more than a ten day supply of that prescription, the dosage of which shall not exceed the federal Food & Drug Administration (FDA) approved labeling for that product; and further, the pharmacist shall notify the prescriber of the supply dispensed and the cancellation of the remainder of the prescription; AND
  2. Within 60 days of the dispensing of the medication described above, such medication shall not be dispensed again for that patient when prescribed by a practitioner not licensed by the State of Louisiana.

For the benefit of pharmacies seeking to verify the presence and/or status of Louisiana licensure of various practitioners with legal authority to prescribe opioid derivatives listed in either Schedules II or III, we have listed the websites of their licensing agencies. For those agencies without website verification resources, we provide their office telephone number.

- Physicians (MD or DO), podiatrists (DPM), and physician assistants (PA)  
La. State Board of Medical Examiners – [www.lsbme.la.gov](http://www.lsbme.la.gov)
- Dentists (DDS)  
La. State Board of Dentistry – [www.lsbdo.org](http://www.lsbdo.org)
- Advanced practice registered nurses (APRN)  
La. State Board of Nursing – [www.lsbns.state.la.us](http://www.lsbns.state.la.us)
- Optometrists (OD)  
La. State Board of Optometry Examiners – (318) 335-2989
- Veterinarians (DVM)  
La. Board of Veterinary Medicine – (225) 342-2176

**Act 472 (SB 556) of 2014 Legislature – effective August 1, 2014**

This law changes the deadline by which pharmacies and other dispensers of controlled substances shall report their eligible dispensing transactions to the Louisiana PMP. Prior to the change, dispensers were required to report their data no more than seven days after the date of dispensing. Effective August 1, dispensers shall report their data no later than the next business day after the date of dispensing.