

As you are aware, the Drug Enforcement Administration (DEA) made carisoprodol (Soma®) a Schedule IV drug effective January 11, 2012. As of January 11, 2012, carisoprodol may only be dispensed in accordance with the Controlled Substances Act. The DEA has officially issued a Guidance Statement regarding carisoprodol prescriptions that is now available on its Web site at http://www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html. The text of the statement has been reprinted below.

The Kansas Board of Pharmacy has received multiple inquiries regarding legally valid prescriptions for carisoprodol that were written before January 11, 2012, that have valid refills remaining. According to the Bureau of Narcotics and Dangerous Drugs and the DEA's Guidance Statement, licensees may continue to dispense these prescriptions if the prescription was written by an authorized DEA registration with a DEA number. If the prescriber does not have a DEA number, those prescriptions should be canceled and not dispensed. Licensees are encouraged to communicate this information to pharmacy staff to ensure compliance.

STATEMENT FROM THE DEA:

Information Regarding Carisoprodol Prescriptions

On December 12, 2011, DEA published a [Final Rule \(76 FR 77330\)](#) in the Federal Register making carisoprodol a schedule IV controlled substance. The Final Rule states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with [21 C.F.R. §§ 1306.03–1306.06, 1306.21, and 1306.22–1306.27](#).

Accordingly, as of January 11, 2012, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met: the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 C.F.R. § 1306.04); the prescription contains all the information required by 21 C.F.R. § 1306.05; and the number of refills authorized by the prescribing practitioner is five or less ([21 U.S.C. § 829\(b\)](#)).

Practitioners and pharmacists are responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state. As [21 C.F.R. § 1306.04](#) states, “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

The Controlled Substances Act (CSA) also provides that a prescription for a schedule IV controlled substance may not be filled or refilled more than six months after the date the prescription was issued. 21 U.S.C. § 829(b). Therefore, if a prescription for a drug containing carisoprodol was issued before January 11, 2012, and refills were authorized, as of January 11, 2012 those refills (no more than five) must be dispensed no later than six months after the date the prescription was issued.

As stated in the December 12, 2011, Final Rule, effective January 11, 2012, any person who engages in any activity involving carisoprodol is subject to the criminal, civil, and administrative

provisions of the CSA and DEA regulations. This means, among other things, that as of January 11, 2012, persons who prescribe, administer, or dispense carisoprodol by means of the Internet are subject to all applicable provisions of the [Ryan Haight Online Pharmacy Consumer Protection Act of 2008 \(74 FR 15596\)](#), and the regulations issued thereunder.