

STATE OF MAINE
Professional and Financial Regulation Office
of Professional and Occupational Regulation
Board of Pharmacy
35 State House Station, Augusta, Maine 04333

ADVISORY RULING

No. 2017-01

Advisory Ruling Requested by: Mark Polli, Director of Pharmacy Compliance
Delhaize America Shared Services, LLC
145 Pleasant Hill Road
Scarborough, Maine 04074

Topic: Time Limitations for Controlled Substance
Prescriptions

REQUEST FOR ADVISORY RULING

By email dated February 8, 2017, Mr. Mark Polli requested an opinion as to whether Maine Board of Pharmacy Rule Chapter 3, Section 2(2)(B) (the “Board Rule”) prohibits a pharmacist from filling or refilling a prescription drug order for a controlled substance more than 90 days after the date of the prescription. Pursuant to the authority granted in 5 M.R.S. § 9001 and Board of Pharmacy Rule Chapter 3, the Board considered the request at its March 2, 2017 meeting and now issues the following advisory ruling.

FACTS

Mr. Polli’s pharmacy receives prescription drug orders for controlled substances. Mr. Polli notes that these orders often contain authorizations for refills of the prescription drug order. Mr. Polli indicates that an insurer has been denying coverage for requests for refills of schedule III-IV controlled substances when the refill occurs more than 90 days after the date of the prescription.

According to Mr. Polli, the insurer has indicated that these denials are based on its belief that the Board Rule prohibits filling or refilling a prescription more than 90 days after the prescription is written, irrespective of whether the prescription is presented to the pharmacy prior to the expiration of the 90-day period. In essence, the insurer’s position is that under the Board Rule, all prescriptions drug order for controlled substances expire 90 days after they are written.

APPLICABLE LAW

The Board Rule states that “[n]o pharmacist may fill a prescription drug order for a controlled substance that is presented to the pharmacist more than 90 days after the date of the prescription.” 02-392 C.M.R. ch. 19, § 2(2)(B).

This provision must be read in relation to a relevant federal Drug Enforcement Agency regulation, 21 C.F.R. § 1306.22 which states:

No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times

The federal regulation does not contain any provisions regarding when the prescription must be presented to the pharmacist. *Id.*

DISCUSSION AND RULING

By the plain language of the Board Rule, it is clear that the only time-based limitation placed on prescription drug orders for a controlled substance is that the prescription must be *presented* to the pharmacist no more than 90 days after the date it was written. *See* 02-392 C.M.R. ch. 19, § 2(2)(B). Rules of statutory construction dictate that the words of statutes and regulation must be given their plain meaning. *See Levine v. State Farm Mut. Auto. Ins. Co.*, 2004 ME 33, ¶ 19, 843 A.2d 24. As a verb, *present* is defined as follows: “to offer for observation, examination, or consideration; show or display.” American Heritage Dictionary, “*present*” (5th ed., 2017).

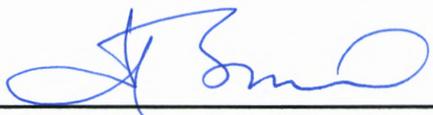
Thus, as long as the prescription is shown or offered for examination to the pharmacist within 90 days after the date it was written, the Board Rule does not prohibit a pharmacist from filling or refilling the prescription beyond the 90-day period. However, pharmacists must still comply with 21 C.F.R. § 1306.22, which prohibits filling or refilling a prescription for a Schedule III or IV controlled substance more than six months after the date it was issued.

The plain language of the Board Rule contains no limitations on filling or refilling a prescription beyond 90 days of the date of the prescription, as long as the prescription was presented to the pharmacist before the expiration of the 90-day period.

SCOPE OF ADVISORY RULING

The Board cautions that other factors may exist in other overriding state and/or federal laws or regulations for patient-eligible recipients that participate in specialized programs such Medicaid, MaineCare, or Medicare programs in which case, the pharmacist is responsible for insuring that prescription drug orders are filled in accordance with these mandates.

This advisory ruling is not binding upon the Maine Board of Pharmacy, but justifiable reliance upon this ruling shall be considered in mitigation of any penalties sought to be assessed in any subsequent enforcement action initiated by the Board.

SIGNED  Dated 4/10/2017
Joseph Bruno, Board President