42646



## Commonwealth of Pennsylvania Department of Public Welfare Office of General Counsel

3<sup>rd</sup> Floor West, Health & Welfare Building Seventh & Forster Streets, Harrisburg, PA 17120 P O. Box 2675, Harrisburg, PA 17105-2675 Dec'd 1/10/09 12:15 pm

## Memo

Re:

To: Allen Warshaw, Chief Counsel; Ruth O'Brien, Senior Assistant Counsel

Copy: Mary Frances Grabowski, Senior Assistant Counsel

From: Kimberley L. Thomas, Assistant Counsel

**Date:** October 19, 2007

State Board of Pharmacy's Proposed Rulemaking

On September 29, 2007, the State Board of Pharmacy published a proposed rulemaking regarding revisions to current pharmacy practice at 37 Pa. Bull. 5260. Included among the revisions is the proposed addition of 49 Pa. Code § 27.18(i), which would permit prescriptions to be refilled for a period up to one year from the date of the prescription. Based on the Department's experience in the Medication Task Force Subcommittee of the Governor's Office of Health Care Reform, the Department's Bureau of Program Integrity and I have some comments to offer. Written comments, recommendations or objections regarding this proposed rulemaking are due to the State Board of Pharmacy within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

The language of the proposed regulation is as follows:

§ 27.18. Standards of practice.

(i) [[Reserved]] Prescriptions for nonproprietary drugs may be refilled for a period of 1 year from the date of the prescription if refills have been authorized by the prescriber. A nonproprietary drug which is refillable by statute on the basis of designation, such as ad lib, PRN or similar instruction, may be refilled for a period of 1 year from the date of the prescription.

The phrase "date of the prescription" is ambiguous. It should be clarified if the physician is required to date the prescription. Further, it should also be clarified whether the pharmacy may fill an undated prescription, whether a pharmacy is permitted to insert a date on an undated prescription that it is presented for filling, and, if so, whether the date of the initial filling of the prescription becomes the date of the prescription. There is a general concern that a patient could possess an undated prescription for some time before it is presented for filling, thereby delaying commencement of the one year period for refill of that prescription.

The phrase "authorized by the prescriber" is also ambiguous. It should be clarified to state when such authorization may or must occur. The Department's regulation at 55 Pa. Code § 1121.53(c) specifies that "[r]efills shall be authorized by the prescriber at the time the prescription is ordered." Without such specificity, a prescriber could authorize a prescription refill at any time during the proposed 1 year period.

If this proposed provision is finalized as currently written, the Department's regulation at 55 Pa. Code § 1121.53(c) should be re-evaluated. That provision reads:

(c) Payment for prescriptions is limited to quantities consistent with the medical needs of the patient not to exceed a 34-day supply or 100 units, whichever is greater.

Prescriptions may be refilled as long as the total authorization does not exceed a 6 months' or five refill supply, whichever comes first, from the time of original filling of the prescription. Refills shall be authorized by the prescriber at the time the prescription is ordered, and the quantity dispensed on the refills may exceed the quantity prescribed on the initial prescription only if noted at the time the licensed prescriber orders the initial prescription. (Emphasis added.)

Currently, the Medical Assistance ("MA") Program will only pay for prescription refills not exceeding a six month or five refill supply. For the Department's consideration is whether it wishes to maintain its stricter regulatory requirement or amend its regulation to follow what the Department of State has characterized as the codification of standard practice in its proposed rulemaking. Furthermore, the Department could also take that opportunity to consider whether to revise its regulation to commence the refill period from the date of the prescription rather than from the date of the original filling of the prescription. Finally, the MA Program also currently requires refills to be authorized at the time the prescription is ordered; for the Department's consideration is whether it wishes to maintain its stricter regulatory requirement or amend its regulation to follow the Department of State's provision which is capable of a more liberal interpretation.