STATEMENTS OF POLICY

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Return to Stock of Undelivered Medications

The State Board of Pharmacy (Board) adopts this statement of policy regarding the return to stock of undelivered medication to read as set forth in Annex A.

Section 5(a)(9)(xi) of the Pharmacy Act (63 P. S. § 390-5(a)(9)(xi)) prohibits the return to stock of unused medication once it has left the premises of the pharmacy. However, many prescriptions sit in the pharmacy but are never picked up. These prescriptions never leave the control of the pharmacy and may be returned to the stock of the pharmacy. In addition, many prescriptions are sent out for delivery with a pharmacy staff member but never get delivered to the patient. The Board views the premises of the pharmacy as not only the licensed physical structure, but as extending to delivery services that are provided by pharmacy staff. The drugs are still under the control of the pharmacy while they are being delivered to patients by pharmacy staff. Therefore, the pharmacy is able to ensure that the integrity of the drugs is maintained. The Board has determined that it is appropriate for these medications to be returned to the stock of the pharmacy under certain circumstances.

This statement of policy sets forth the guidelines that should be considered when returning undelivered medication to the pharmacy's stock. These guidelines will insure that the integrity of the drugs is maintained and patient safety is not compromised.

The statement of policy set forth in Annex A is effective upon publication in the *Pennsylvania Bulletin* and applies to the return to stock of medication that has not been delivered and has not left the control of the pharmacy.

RICHARD R. SMIGA, R.Ph.,
Chairperson

(*Editor's Note*: The regulations of the Board, 49 Pa. Code Chapter 27, are amended by adding a statement of policy in § 27.102 to read as set forth in Annex A.)

Fiscal Note: 16A-5411. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STATEMENTS OF POLICY

§ 27.102. Return to stock of undelivered medication—statement of policy.

(a) *Background and purpose.* Section 5(a)(9)(xi) of the act (63 P. S. § 390-5(a)(9)(xi)) prohibits the return to stock of medication once it has left the premises of the pharmacy. However, many prescriptions do not get delivered to patients and, therefore never leave the control of the pharmacy. These prescriptions may be returned to the active stock of the pharmacy. This section sets forth the guidelines that should be considered when returning undelivered medication to the pharmacy's active stock. This section will insure that the integrity of the drugs is maintained and patient safety is not compromised.

(b) *Guidelines.* The following guidelines should be considered when returning undelivered medications to stock to assure that the quality of medications is maintained:

(1) Prescriptions that have not been picked up by or delivered to patients should be checked periodically.

(2) Prescriptions not delivered to patients should be assessed by a pharmacist to determine whether they might safely be returned to stock.

(3) Products deemed eligible for redispensing should never be mixed within stock bottles of different lot numbers or with different expiration dates. Manufacturers' stock bottles should never be over-filled. The only safe manner in which drugs can be returned to stock bottles is in those pharmacies in which all medications are tracked by lot numbers and expiration dates.

(4) In those instances in which medication cannot be properly and safely returned to the original stock bottle, the medication may be held in the pharmacy in the container in which it has been repackaged. It is recommended that pharmacies develop an internal manner for so identifying and dating these products.

(5) Medications held for redispensing should be used as soon as possible. Medications held for redispensing, lacking original lot numbers and expiration dates, should only be dispensed to patients up to 6 months from the date the drugs were first prepared for dispensing.

(6) If the manufacturer or the United States Food and Drug Administration orders a recall for a drug product, pharmacists should assume products held in containers without lot numbers are included in the recall and proceed accordingly.

[Pa.B. Doc. No. 03-2025. Filed for public inspection October 17, 2003, 9:00 a.m.]

DEPARTMENT OF ENVIRONMENTAL PROTECTION

[25 PA. CODE CH. 16]

Water Quality Toxics Management Strategy

The Department of Environmental Protection (Department) is proposing to amend Chapter 16 (relating to water quality toxics management strategy—statement of policy). These proposed amendments complement the review and revision of Chapter 93 (relating to water quality standards).

This Commonwealth's water quality standards, which are set forth in part in Chapter 93, implement the provisions of sections 5 and 402 of The Clean Streams

Law (35 P. S. §§ 691.5 and 691.402) and section 303 of the Federal Clean Water Act (33 U.S.C.A. § 1313). Water quality standards consist of the uses of the surface waters of this Commonwealth, the specific numeric and narrative criteria necessary to achieve and maintain those uses and an antidegradation policy. Chapter 16 is a water quality policy for regulating toxic pollutants. It sets forth the guidelines for development of criteria for toxic substances and lists the water quality criteria and analytical methods and detection limits for toxic substances. Chapter 16 is directly referenced as a support policy document in § 93.8a (relating to toxic substances).

Two public meetings and two public hearings have been scheduled as indicated in this proposed statement of policy.

Contact Persons

For further information contact Edward R. Brezina, Chief, Division of Water Quality Assessment and Standards, Bureau of Water Supply and Wastewater Management, 11th Floor, Rachel Carson State Office Building, P. O. Box 8467, Harrisburg, PA 17105-5984, (717) 787-9637; or Michelle Moses, Assistant Counsel, Bureau of Regulatory Counsel, 9th Floor, Rachel Carson State Office Building, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Additional of Proposed Statement of Policy

Copies of the proposed statement of policy may be obtained from Mary Houghton, Division of Water Assessment and Standards, Bureau of Water Supply and Wastewater, 11th Floor, RCSOB, P. O. Box 8647, Harrisburg, PA 17105-8467, (717) 787-9637, email: mhoughton@state.pa.us. This proposal is available electronically through the Department's website http://www.state.pa.us, choose Participant!, Regulations open for Comment.

Summary of Amendments

§ 16.24. Metals criteria.

The Department proposes to update the chronic conversion factor for mercury to 0.85. The United States Environmental Protection Agency (EPA) recently stated that this factor, which was previously applied only to the Great Lakes, also applies to National waters. (See National Recommended Water Quality Criteria for Priority Pollutants, April 1999.) The Department also proposes to delete the footnote that applied to the previous mercury conversion factor because it is no longer applicable.

§ 16.61. Special provisions for the Great Lakes System.

The Department proposes language changes to match recent changes to Chapter 93, pertaining to the Great Lakes Initiative. There are also corrections to the Great Lakes Aquatic Life and Human Health Criteria table as follows: The chemical name cadmium is misspelled. To clarify that the criteria for gamma-BHC (Lindane) is a threshold human health number, not a cancer risk level, the symbol in the list will be changed. To clarify that the criterion applies to total PCBs, the PP NO 18P will be deleted and the CAS number will be removed. In paragraph (6), the spelling of chlorinated will be corrected.

§ 16.101. Introduction.

To be more accurate, it is proposed that throughout §§ 16.101 and 16.102 (relating to introduction and approved EPA analytical methods and detection limits), "Table 2" be renamed Table 2A (Inorganics) and Table 2B (Organics).

§ 16.102. Approved EPA Analytical Methods and Detection Limits.

In subsection (a), corrections were made to the list of abbreviated method descriptions. The Department proposes to update and clarify Chapter 16, Appendix A, Tables 1 and 2. This proposal is a result of recent updates to approved methods in 40 CFR Part 136. In Table 1 there are several updates because of new toxicity data. Most of the methods in Tables 2A and 2B have been updated because the EPA recently published updates. In footnote 2, the spelling of benzidine will be corrected. Following is a brief summary of the proposals for each Table:

Appendix A, Table 1—Water Quality Criteria for Toxic Substances

In accordance with Federal guidelines, the Department purposes to update the aquatic life criterion equations for cadmium. The Department will also correct the chronic aquatic life criterion for 4,4-DDT, which was subject to a typographical error during the previous Triennial Review.

Appendix A, Table 2—Approved Analytical Methods and Detection Limits

In Table 2A Inorganics, there are several updates. The Table includes EPA new, approved method numbers from the *Standard Methods for the Examination of Water and Wastewater, 20th Edition* and the *ASTM Annual Book of Standards, 1999*. In accordance with 40 CFR Part 136, Appendix C, the following parameters have updated detection limits: antimony, copper, iron, magnesium and zinc. EPA method 1631, *Mercury in Water by Oxidation, Purge and Cold Vapor Atomic Fluorescence Spectrometry*, has been added as an approved method for the detection of mercury. Corrections were also made to the list of footnotes in this section to update changes made to the list.

In Table 2B Organics, the approved test procedures for nonpesticides organic compounds have updated the EPA method numbers for GC/MS isotope detection. Also, in accordance with 40 CFR Part 136, Appendix C, the following parameters have updated detection limits: chloroethane, methyl bromide, methyl chloride, benzo(a)anthracene, benzo(ghi)perylene and isophorone. In footnote 2 of this section the spelling of benzidine will be corrected.

Public Comments

Written comments, suggestions or objections regarding the proposed amendments may be sent to Mary Houghton, Division of Water Quality Assessment and Standards, Bureau of Water Supply and Wastewater Management, 11th Floor, Rachel Carson State Office Building, P. O. Box 8467, Harrisburg, PA 17105-8467. Comments submitted by facsimile will not be accepted; however, the Department will accept comments submitted by e-mail. Electronic comments may be submitted to mhoughton@state.pa.us. A subject heading of the proposal and return name and address must be included in each e-mail transmission. Comments must be received by December 17, 2003.

Public Meetings and Public Hearings

The Department will hold two public meetings and public hearings on the proposed amendments to the Chapter 16. These public meetings and hearings will take place on the same date and at the same location where the Environmental Quality Board will conduct public hearings on the proposed amendments to Chapter 93. At the public meetings for the Chapter 16 amendments, the

public meetings will provide the Department with the opportunity to explain the proposed amendments and respond to questions from participants. The Chapter 16 public hearings will be for the purpose of accepting comments from the public. The public meetings will begin at 2 p.m. and the public hearings at 3 p.m. on the following dates:

December 2, 2003	Four Points By Sheraton Pittsburgh North 910 Sheraton Drive Mars, PA 16046
December 4, 2003	Courtyard by Marriott 16 Glenmaura National Blvd. Moosic, PA 18507

Persons wishing to present testimony at a Chapter 16 hearing are requested to contact Mary Houghton, (717) 787-9637, mhoughton@state.pa.us at least 1 week in advance of the hearing to reserve a time to present testimony. Oral testimony is limited to 10 minutes for each witness and one designated witness for each organization. Witnesses are requested to submit three written copies of their testimony to the hearing chairperson.

Persons with a disability who wish to attend a hearing and require an auxiliary aid, service of other accommodation to participate should contact Mary Houghton at the previous telephone number or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users) to discuss how their needs may be accommodated.

KATHLEEN A. MCGINTY,
Secretary

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