

DEPARTMENT OF HEALTH

NOTICE OF SECOND PROPOSED RULEMAKING

The Director of the Department of Health (Department), pursuant to §§ 4 and 5 of the District of Columbia Unused Pharmaceutical Safe Disposal Act of 2009, effective March 5, 2010, D.C. Law 18-112, D.C. Official Code §§ 48-851.01, *et seq.* (2011 Supp.) (the Act) and Mayor's Order 2011-90, dated May 6, 2011, hereby gives notice of the intent to take final rulemaking action to adopt the following new chapter 5 of subtitle B (Public Health and Medicine) of title 22 (Health) of the District of Columbia Municipal Regulations (DCMR), entitled "Safe Disposal of Unused Pharmaceuticals in Health Care Facilities," in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

The adoption of chapter 5, which had until now been reserved, is necessary to ensure the safe, effective, and proper disposal of unused pharmaceuticals in the District of Columbia by requiring health care facilities to dispose of unused pharmaceuticals by means other than disposing of them in the sewer system.

These rules were previously published in the *D.C. Register* as a proposed rulemaking on August 19, 2011, at 58 DCR 7518. Written comments were received from the District of Columbia Hospital Association and the District of Columbia Health Care Association during the thirty (30)-day comment period. Based upon the review of the comments, additional changes have been made to the proposed rulemaking in §§ 500.2, 502.2, 503.2, 503.3, and 599.1. These changes include extending the effective date to October 1, 2012, addressing pharmaceutical products, which are defined as controlled substances, removing the specified required elements that must be maintained regarding the disposal records; requiring that the position title of the person responsible for implementing the program be included in the healthcare facility's policies and procedures; and clarifying the definition of pharmaceutical waste.

Therefore the rulemaking is being republished for an additional comment period.

Chapter 5 (Safe Disposal of Unused Pharmaceuticals in Health Care Facilities) of subtitle B (Public Health and Medicine) of title 22 (Health) is added as follows:

500 GENERAL PROVISIONS AND ENFORCEMENT

- 500.1 Effective January 1, 2011, a health care facility shall not dispose of any pharmaceutical product, used or unused, by flushing the product down a drain or by any other method that utilizes the public sewer system, except as authorized by this chapter.
- 500.2 Effective October 1, 2012, unless authorized by this chapter, a health care facility that is determined to have disposed of a pharmaceutical product by flushing the product down a drain or by any other method that utilizes the public sewer system, shall be:

- (a) Subject to a civil fine of up to one thousand dollars (\$1,000) per occurrence; and
- (b) Required to submit to the Board of Pharmacy, or its designee, a mitigation plan designed to prevent further such occurrences within thirty (30) days of receipt of a request for the mitigation plan.

500.3 The Director of the Department of Health (Director), or his or her agent, shall have the right to enter upon and into the premises of any health care facility:

- (a) At reasonable times;
- (b) After presenting proper identification; and
- (c) For the purpose of making inspections to determine compliance with this chapter and the District of Columbia Unused Pharmaceutical Safe Disposal Act of 2009, effective March 5, 2010, D.C. Law 18-112, D.C. Official Code §§ 48-851.01, *et seq.* (2011 Supp.) (Act).

500.4 An inspection or investigation conducted pursuant to this chapter and the Act may include, but shall not be limited to:

- (a) Review of policies and procedures manuals;
- (b) Inspection of all locations within the health care facility where pharmaceuticals and pharmaceutical waste are stored; and
- (c) Review of all records, receipts, and other documentation pertaining to the health care facility's pharmaceutical waste disposal.

500.5 Chapters 20 (Hospitals) and 32 (Nursing Facilities) of this subtitle shall supplement this chapter.

501 EXEMPTED PHARMACEUTICAL PRODUCTS

501.1 When absent of any additional additives, the following pharmaceutical products may be disposed of by flushing the product down the drain or by another method that uses the sewer system:

- (a) Sterile Water;
- (b) Dextrose solutions such as five percent (5%) dextrose in water (D5W);
- (c) Saline solutions such as nine tenths of a percent of sodium chloride (0.9% NaCl);

- (d) Lactated Ringers;
- (e) Potassium salts such as potassium chloride (KCl);
- (f) Calcium salts such as calcium chloride (CaCl) and Calcium Gluconate;
and
- (g) Magnesium salts such as magnesium sulfate (MgSo4).

502 DISPOSAL OF UNUSED PHARMACEUTICAL PRODUCTS

502.1 Pharmaceutical products may be disposed of through:

- (a) A waste to energy program; or
- (b) Another federally approved technology that is permitted to accept pharmaceutical waste.

502.2 Those pharmaceutical products which are defined as controlled substances under federal or District law shall be managed in accordance with federal and District laws and regulations.

502.3 Those pharmaceutical products which are defined as hazardous waste under federal or District law shall be managed in accordance with federal and District laws and regulations.

502.4 All antineoplastic and cytotoxic drugs shall be treated as hazardous waste and managed and disposed of in accordance with the applicable federal and District laws and regulations.

502.5 A health care facility may choose to manage its pharmaceutical waste at a more stringent or higher level of waste management than that required under applicable District or federal laws and regulations.

502.6 All pharmaceutical waste shall be separated from active pharmaceutical stock and clearly labeled as "pharmaceutical waste."

502.7 Pharmaceutical waste shall not be combined with other forms of waste.

503 RECORDKEEPING

503.1 The recordkeeping requirements of this section shall apply to all health care facilities, unless otherwise exempted by this chapter or the Director.

- 503.2 A healthcare facility shall maintain a complete and accurate record of its pharmaceutical waste disposal, for a period of three (3) years from the date of disposal.
- 503.3 A healthcare facility shall develop and maintain written policies and procedures for the management of its pharmaceutical waste.
- (a) These policies and procedures shall include, at a minimum, the following:
- (1) Documentation that the program has been reviewed and updated as needed not less than every two (2) years;
 - (2) The position title(s) of the person(s) within the facility responsible for program implementation; and
 - (3) Policies and procedures designed to educate facility staff and volunteers, as part of an orientation process and continuing on an annual basis thereafter, regarding proper pharmaceutical waste disposal; and
- (b) These policies and procedures may also include processes designed to minimize the creation of pharmaceutical waste, such as implementation of a pharmaceutical waste minimization program.

599 DEFINITIONS

599.1 As used in this chapter the following terms shall have the meanings ascribed:

Board - District of Columbia Board of Pharmacy

Department - Department of Health

Director - Director of the Department

Hazardous pharmaceutical waste - a pharmaceutical product that is defined as hazardous waste under federal or District law.

Health care facility – a hospital, assisted living facility, nursing home, or institutional pharmacy.

Institutional pharmacy – that physical portion of a health care facility where drugs, devices, and other materials used in the diagnosis or treatment of injury, illness, and disease are dispensed, compounded, or distributed and pharmaceutical care is provided.

Pharmaceutical product – a drug or biologic for human use regulated by the federal Food and Drug Administration.

Pharmaceutical waste - a pharmaceutical product that is no longer suitable for its intended purpose or is otherwise being discarded, but does not include pharmaceuticals excreted from the body during normal physiological functions and medical procedures.

Pharmaceutical waste minimization program - a program used to identify pharmaceuticals that need to be discarded, to decrease pharmaceutical waste, and to implement more environmentally sustainable practices regarding pharmaceutical waste disposal.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the *D.C. Register*, to Kenneth Campbell, General Counsel, Department of Health, Office of the General Counsel, 899 North Capitol Street, N.E., 5th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 8:00 a.m. and 4:00 p.m. at the address listed above, or by contacting Angli Black, Administrative Assistant, at Angli.Black@dc.gov, (202) 442-5977.