

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKINGCIVIL INFRACTIONS – AMENDMENTS TO THE SCHEDULE OF FINES
FOR
HAZARDOUS WASTE INFRACTIONS

The Director of the Department of Health, pursuant to the authority set forth in section 104 of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985, as amended (D.C. Law 6-42; D.C. Official Code § 2-1801.04 (2001)), and paragraph 2(b) of Mayor's Order 2004-46, 51 DCR 4128 (2004), hereby gives notice of his intent to adopt amendments to the Hazard Waste Infractions in section 3652, chapter 36 in Title 16 of the District of Columbia Municipal Regulations (DCMR), in not less than sixty (60) days from the date of publication of this notice in the *D.C. Register*. The proposed rules would replace the existing schedule of fines in 16 DCMR § 3652, published at 52 DCR 4903 (2005), for violations of District of Columbia laws and regulations pertaining to hazardous waste. Further, the proposed amendments to the schedule of fines shall not become effective until approved by the Council of the District of Columbia, or sixty days (60 days) after submission of these proposed rules to the Council, if the Council has not disapproved these rules, and until publication of the final rules in the *D.C. Register*.

The Director has adopted new hazardous waste management regulations in 20 DCMR chapters 42 and 43, which are published at 52 DCR 9653 (2005). The proposed amendments to the schedule of fines correspond to the new hazardous waste management regulations.

Based on the above, the Director proposes the following amendments to the schedule of fines for civil infractions:

Section 3652 of Title 16 DCMR is amended to read as follows:

3652 HAZARDOUS WASTE MANAGEMENT INFRACTIONS

3652.1 Violation of any of the following provisions shall be a Class 1 infraction:

- (a) 20 DCMR § 4202.2 (unlawful disposal of hazardous waste or used oil);
- (b) 20 DCMR §§ 4202.3(a) or 4279.6(a) (use of a surface impoundment for treatment, storage, or disposal of hazardous waste or used oil);
- (c) 20 DCMR §§ 4202.2(b) or 4279.6(a) (use of waste piles to treat or store hazardous waste or used oil);
- (d) 20 DCMR § 4202.3(c) (use of land treatment to manage or dispose of hazardous waste);

- (e) 20 DCMR § 4202.3(d) (use of landfills for hazardous waste disposal);
- (f) 20 DCMR § 4202.3(e) (land disposal of hazardous waste or any mixture of hazardous waste and any other constituent, whether hazardous or not);
- (g) 20 DCMR § 4202.3(f) or 4279.6(b) (use of used oil for dust suppression);
- (h) 20 DCMR § 4202.3(g) (use of waste or other material, contaminated or mixed with dioxin or any other hazardous waste, for dust suppression or road treatment);
- (i) 20 DCMR § 4202.3(h) (burning, processing, or incineration of hazardous waste, hazardous waste fuels, or mixtures of hazardous wastes and other materials in any type of incinerator, boiler, or industrial furnace);
- (j) 20 DCMR §§ 4202.3(i) or 4279.6(c) (burning used oil, whether on-specification or off-specification);
- (k) 20 DCMR § 4202.3(j) (burning of wastes that meet the comparable fuel or synthesis gas (syngas) fuel specifications);
- (l) 20 DCMR § 4202.3(k) (underground injection of hazardous waste);
- (m) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.11 by reference), (failure of person who generates a solid waste to determine if the waste is a hazardous waste);
- (n) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.12 by reference), (failure of generator to obtain EPA identification number before treating, storing, disposing, transporting, or offering for transportation hazardous waste);
- (o) 20 DCMR § 4263.1, (which incorporates 40 CFR § 263.11 by reference), (failure of transporter to obtain EPA identification number before transporting hazardous waste);
- (p) 20 DCMR § 4263.2 (transporter storing manifested shipments of hazardous waste at a transfer facility without a RCRA permit);
- (q) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.21 by reference), (failure of transporter to deliver entire quantity of hazardous waste to designated facility, alternate designated facility, next designated transporter, or a place outside the United States; or to contact generator for further directions);

- (r) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.30(a) by reference), (failure of transporter to take immediate action to protect human health or the environment in the event of discharge during transport);
- (s) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.30(c) and (d) by reference), (failure of transporter to comply with discharge notification and reporting requirements);
- (t) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.31 by reference), (failure of transporter to cleanup any hazardous waste discharge, or to take required or approved response action);
- (u) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(1) by reference), (failure of owner or operator of remediation waste management site to obtain EPA identification number);
- (v) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(3) by reference), (failure of owner or operator of remediation waste management site to control access to the site);
- (w) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(4) by reference), (failure of owner or operator of remediation waste management site to inspect site);
- (x) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(6) by reference), (failure of owner or operator of remediation waste management site to take precautions with respect to ignitable, reactive, and incompatible wastes);
- (y) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(7) by reference), (failure of owner or operator of remediation waste management site to meet design, construction, operation, or maintenance requirements for units located within a one hundred-year (100-year) floodplain);
- (z) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(10) by reference), (failure of owner or operator of remediation waste management site to develop and maintain procedures to prevent accidents or develop and maintain a contingency and emergency plan);
- (aa) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(11) by reference), (failure of owner or operator of remediation waste management site to designate employee to coordinate emergency response measures);
- (bb) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.11 or 265.11 by reference), (failure of owner or operator to obtain EPA identification number);

- (cc) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.14(a) or (b) or 265.14(a) or (b) by reference), (failure of owner or operator to control access to active portion of facility);
- (dd) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.15(a) or 265.15(a) by reference), (failure of owner or operator to inspect facility);
- (ee) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.17 or 265.17 by reference), (failure of owner or operator to take precautions to prevent accidental ignition or reaction of ignitable or reactive waste);
- (ff) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.56 or 265.56 by reference), (failure of owner or operator to follow required emergency procedures);
- (gg) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.73 or 265.73 by reference), (failure of owner or operator to comply with operating record requirements);
- (hh) 20 DCMR §§ 4264.1 and 4265.1 (which incorporate 40 CFR §§ 264.74 or 265.74 by reference), (failure of owner or operator to furnish records upon request and make records available for inspection);
- (ii) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.111 or 265.111 by reference), (failure of owner or operator to comply with closure performance standard);
- (jj) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.114 or 265.114 by reference), (failure of owner or operator to properly dispose of or decontaminate equipment, structures, or soils);
- (kk) 20 DCMR § 4270.1 (which incorporates 40 CFR § 270.1(c) by reference), (failure to have required RCRA permit);
- (ll) 20 DCMR § 4270.1 (which incorporates 40 CFR § 270.10(f) by reference), (physical construction of hazardous waste management facility without finally effective RCRA permit);
- (mm) 20 DCMR §§ 4273.1 or 4273.2 (failure of universal waste handler to submit written notification of universal waste management before generating universal waste or receiving universal waste from other universal waste handlers);
- (nn) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.11(a) or 273.31(a) by reference), (universal waste handler prohibited from disposing of universal waste);

- (oo) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.11(b) or 273.31(b) by reference), (universal waste handler prohibited from diluting or treating universal waste);
- (pp) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.13(a) or 273.33(a) by reference), (failure of universal waste handler to manage universal waste batteries in a way that prevents releases to the environment);
- (qq) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.13(b) or 273.33(b) by reference), (failure of universal waste handler to manage universal waste pesticides in a way that prevents releases to the environment);
- (rr) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.13(c) or 273.33(c) by reference), (failure of universal waste handler to manage universal waste thermostats in a way that prevents releases to the environment);
- (ss) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.13(d) or 273.33(d) by reference), (failure of universal waste handler to manage universal waste lamps in a way that prevents releases to the environment);
- (tt) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.18(a) or 273.38(a) by reference), (failure of universal waste handler to send or take universal waste to a place other than another universal waste handler, a destination facility, or foreign destination);
- (uu) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.51(a) by reference), (universal waste transporter prohibited from disposing of universal waste);
- (vv) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.51(b) by reference), (universal waste transporter prohibited from diluting or treating universal waste);
- (ww) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.54(a) by reference), (failure of universal waste transporter to immediately contain release of universal waste or other residues from universal waste);
- (xx) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.55(a) by reference), (universal waste transporter transporting universal waste to a place other than a universal waste handler, destination facility, or foreign destination);
- (yy) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.60(a) by reference), (failure of owner or operator of destination facility to comply with notification requirements and permitting requirements of 40 CFR Part 270);

- (zz) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.61(a) by reference), (owner or operator of destination facility sending or taking universal waste to a place other than a universal waste handler, another destination facility, or foreign destination);
- (aaa) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.61(b) by reference), (failure of owner or operator of destination facility to comply with requirements for rejected shipments);
- (bbb) 20 DCMR § 4279.1 (which incorporates 40 CFR §§ 279.22(d), 279.43(c), 279.45(h), or 279.54(g) by reference), (failure to respond to release or discharge of used oil);
- (ccc) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.42 by reference), (failure of transporter to obtain EPA identification number before engaging in used oil activity);
- (ddd) Section 6(c)(15) of the Solid Waste Facility Permit Act of 1995, effective February 27, 1996, as amended (D.C. Law 11-94; **D.C. Official Code § 8-1055(c)(15)**) (failure of owner or operator of solid waste facility to develop and submit to the Department an inspection, monitoring, and control plan to detect and prevent handling of hazardous, infectious, or radioactive wastes);
- (eee) Section 6(c)(16) of the Solid Waste Facility Permit Act of 1995 (**D.C. Official Code § 8-1055(c)(16)**) (failure of owner or operator of solid waste facility to secure shipment containing hazardous, infectious, or radioactive waste);
- (fff) Section 6(c)(17) of the Solid Waste Facility Permit Act of 1995 (**D.C. Official Code § 8-1055(c)(17)**) (failure of owner or operator of solid waste facility to properly dispose of hazardous, infectious, or radioactive waste); or
- (ggg) 20 DCMR §§ 4305.2 and 4305.3 (failure or refusal to conduct monitoring or testing or to take response or corrective measures as directed in a Notice of Violation, Threat, or Release);

3652.2 Violation of any of the following provisions shall be a Class 2 infraction:

- (a) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.12(c) by reference), (generator offering hazardous waste to transporter or treatment, storage, or disposal facility that has not received an EPA identification number);
- (b) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.20(b) by reference), (failure of generator to designate a facility that is permitted to handle the waste described on the manifest);

- (c) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.20(d) by reference), (failure of generator to designate alternate facility or instruct transporter to return waste, if transporter is unable to deliver the hazardous waste to designated facility);
- (d) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.23 by reference), (failure of generator to comply with requirements for use of manifest);
- (e) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.30 by reference), (failure of generator to package hazardous waste in accordance with DOT regulations);
- (f) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.31 by reference) (failure of generator to label hazardous waste in accordance with DOT regulations);
- (g) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.32 by reference), (failure of generator to mark hazardous waste in accordance with DOT regulations);
- (h) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.33 by reference), (failure of generator to placard hazardous waste or to offer the initial transporter the appropriate placards in accordance with DOT regulations);
- (i) 20 DCMR §§ 4262.1 and 4262.4 (which incorporate 40 CFR § 262.34 by reference, subject to modification), (accumulation of hazardous waste by generator for more than ninety (90) days, or for more than the time periods specified in 40 CFR § 262.34(d), (e), or (f));
- (j) 20 DCMR §§ 4262.1 and 4262.4 (which incorporate 40 CFR § 262.34(a)(2) by reference, subject to modification), (failure by generator to clearly mark accumulation start date on each container);
- (k) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.34(a)(3) by reference), (accumulation of hazardous waste without labeling or marking container or tank with the words "hazardous waste");
- (l) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.34(a)(4) by reference), (accumulation of hazardous waste without meeting requirements of 40 CFR Part 265, subparts C and D; § 265.16; or § 268.7(a)(5));
- (m) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.41 by reference), (failure to submit biennial report by March 1st of each even-numbered year);
- (n) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(a) by reference), (acceptance of hazardous waste by transporter without a properly signed

- manifest; or, for exports, an EPA Acknowledgement of Consent or tracking document, as applicable);
- (o) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(b) by reference), (failure of transporter to sign and date manifest and return signed copy of the manifest to generator before leaving the generator's property);
 - (p) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(c) by reference), (failure of transporter to ensure that manifest, or for exports, EPA Acknowledgement of Consent or tracking document, as applicable, accompanies the hazardous waste);
 - (q) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(f) by reference), (failure of initial rail transporter to meet manifest requirements);
 - (r) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(g) by reference), (failure of transporter who transports hazardous waste outside of United States to meet manifest requirements);
 - (s) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.22 by reference), (failure of transporter to maintain copies of manifest and shipping papers, as required);
 - (t) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(5) by reference), (failure of owner or operator of remediation waste management site to provide personnel with required training);
 - (u) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(12) by reference), (failure of owner or operator of remediation waste management site to develop, maintain, and implement a plan to meet the requirements in 40 CFR § 264.1(j)(2) through (j)(6) and (j)(9) through (j)(10));
 - (v) 20 DCMR § 4264.1 (which incorporates 40 CFR § 264.1(j)(13) by reference), (failure of owner or operator of remediation waste management site to maintain records documenting compliance with 40 CFR § 264.1(j)(1) through (j)(12));
 - (w) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.14(c) or 265.14(c) by reference), (failure of owner or operator to post required warning sign(s));
 - (x) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.15(d) or 265.15(d) by reference), (failure of owner or operator to record inspections in an inspection log or summary, as required, or to retain records for three (3) years from the date of the inspection);

- (y) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.16 or 265.16 by reference), (failure of owner or operator to ensure that facility personnel successfully complete required training or instruction program);
- (z) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.32 or 265.32 by reference), (failure of owner or operator to equip facility as required);
- (aa) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.33 or 265.33 by reference), (failure of owner or operator to test and maintain required equipment);
- (bb) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.34 or 265.34 by reference), (failure of owner or operator to provide required access to communications or alarm systems);
- (cc) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.35 or 265.35 by reference), (failure of owner or operator to maintain required aisle space);
- (dd) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.51 or 265.51 by reference), (failure of owner or operator to have a facility contingency plan);
- (ee) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.56 or 265.56 by reference), (failure of owner or operator to follow required emergency procedures);
- (ff) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.71 or 265.71 by reference), (failure of owner or operator to comply with manifest system requirements);
- (gg) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.75 or 265.75 by reference), (failure of owner or operator to submit a completed biennial report to the Director by March 1 of each even-numbered year);
- (hh) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.76 or 265.76 by reference), (failure of owner or operator to submit unmanifested waste report to Director within fifteen (15) days of receiving the waste);
- (ii) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.77 or 265.77 by reference), (failure of owner or operator to submit to the Director required additional reports);

- (jj) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.117 or 265.117 by reference), (failure of owner or operator to comply with requirements for post-closure care and use of property);
- (kk) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.171 or 265.171 by reference), (failure of owner or operator to transfer hazardous waste from a container that is not in good condition);
- (ll) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.196 or 265.196 by reference), (failure of owner or operator of tank system to comply with requirements for response to leaks or spills or disposition of tank systems or secondary containment systems that are unfit for use);
- (mm) 20 DCMR § 4266.1 (which incorporates 40 CFR § 266.70(b)(1) by reference), (failure of person who generates, transports, or stores recyclable materials utilized for precious metal recovery to comply with notification requirements under § 3010 of RCRA);
- (nn) 20 DCMR § 4266.1 (which incorporates 40 CFR § 266.70(c) by reference), (failure of persons who store recycled materials utilized for precious metal recovery to comply with recordkeeping requirements);
- (oo) 20 DCMR § 4266.1 (which incorporates 40 CFR § 266.80(b)(1)(i) and (2)(i) by reference), (failure of owner or operator of facility that stores spent lead-acid batteries before reclaiming them, but that does not reclaim them through regeneration, to comply with notification requirements under § 3010 of RCRA);
- (pp) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.14 and 273.34 by reference), (failure of universal waste handler to label or mark a universal waste to identify the type of universal waste);
- (qq) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.15 or 273.35 by reference), (accumulation by universal waste handler of a universal waste for longer than one (1) year without meeting requirements for extension of time);
- (rr) 20 DCMR § 4273.1 (which incorporates 40 CFR §§ 273.17(a) or 273.37(a) reference), (failure of universal waste handler to immediately contain all releases);
- (ss) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.39(a) by reference), (failure of large quantity universal waste handler to keep a record of universal waste shipments received at a facility);

- (tt) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.39(b) by reference), (failure of large quantity universal waste handler to keep a record of universal waste shipments sent from the handler to other facilities);
- (uu) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.39(c) by reference), (failure of large quantity universal waste handler to comply with record retention requirements);
- (vv) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.61(c) by reference), (failure of owner or operator of destination facility to immediately notify the Department of illegal shipments);
- (ww) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.62(a) by reference), (failure of owner or operator of destination facility to keep a record of universal waste shipments received at the facility);
- (xx) 20 DCMR § 4273.1 (which incorporates 40 CFR § 273.62(b) by reference), (failure of owner or operator of destination facility to comply with record retention requirements);
- (yy) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.22(a) by reference), (storage of used oil in units other than tanks, containers, or units subject to regulation under 40 CFR Parts 264 or 265);
- (zz) 20 DCMR § 4279.19 (which incorporates 40 CFR § 279.22(b) by reference), subject to modification in 20 DCMR § 4279, (failure to comply with requirements for containers and aboveground tanks used to store used oil);
- (aaa) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.22(c) by reference), (failure to clearly label or mark container, tank, or fill pipe with the words "used oil");
- (bbb) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.24 by reference), (failure of used oil generator to ensure that used oil is transported by transporter that has obtained an EPA identification number);
- (ccc) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.43(a) by reference), (failure of used oil transporter to deliver all used oil received to specified facilities);
- (ddd) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.43(b) by reference), (failure of used oil transporter to comply with applicable DOT requirements);
- (eee) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.45(b) by reference), (owner or operator of used oil transfer facility storing used oil in units other

than containers, tanks, or other units subject to regulation under 40 CFR Parts 264 or 265);

- (fff) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.45(c) by reference), (failure of owner or operator of used oil transfer facility to comply with requirements for containers and aboveground tanks used to store used oil);
- (ggg) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.45(d), (e), or (f) by reference), (failure of owner or operator of used oil transfer facility to meet requirements for secondary containment for containers or tanks);
- (hhh) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.45(g) by reference), (failure of owner or operator of used oil transfer facility to clearly label or mark containers, tanks, or fill pipes with the words "used oil");
- (iii) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.46 by reference), (failure of used oil transporter to comply with tracking or record retention requirements);
- (jjj) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.51(a) by reference), (failure of used oil processor or re-refiner to obtain EPA identification number before engaging in used oil activity);
- (kkk) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.52 by reference), (failure of used oil processor or re-refiner to comply with general facility standards);
- (lll) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.54 by reference), (failure of used oil processor or re-refiner to comply with used oil management standards);
- (mmm) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.56 by reference), (failure of used oil processor or re-refiner to comply with tracking or record retention requirements);
- (nnn) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.57 by reference), (failure of used oil processor or re-refiner to comply with operating record and reporting requirements);
- (ooo) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.58 by reference), (failure of used oil processor or re-refiner to use a used oil transporter who has obtained an EPA identification number to ship used oil off-site);
- (ppp) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.71 by reference), (used oil fuel marketer initiating shipment of off-specification used oil in violation of the prohibitions in 40 CFR § 279.71);

- (qqq) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.72(b) by reference), (failure of used oil generator, transporter, or processor/re-refiner to comply with record retention requirements);
- (rrr) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.73(a) by reference), (failure of used oil fuel marketer to obtain EPA identification number);
- (sss) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.74 by reference), (failure of used oil fuel marketer to comply with tracking requirements);
- (ttt) 20 DCMR § 4279.1 (which incorporates 40 CFR § 279.75 by reference), (failure of used oil generator, transporter, or processor/re-refiner to obtain burner certification); or
- (uuu) Section 6(c)(16) of the Solid Waste Facility Permit Act of 1995 (**D.C. Official Code § 8-1055(c)(16)**) (failure of owner or operator of solid waste facility to immediately notify the Department and detain shipment to allow for inspection by the Department, if incoming shipments are found to contain hazardous, infectious, or radioactive wastes).

3652.3 Violation of any of the following provisions shall be a Class 3 infraction:

- (a) 20 DCMR § 4206.1 (failure to retain records on-site);
- (b) 20 DCMR § 4261.7(a) (failure of conditionally exempt small quantity generator to comply with the notice requirements of § 3010 of RCRA);
- (c) 20 DCMR § 4261.1 (which incorporates 40 CFR § 261.4(e) by reference), (failure of generator or sample collector to comply with requirements for the proper labeling and packaging of treatability study samples);
- (d) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.40(b) by reference), (failure of generator to keep a copy of each biennial report and exception report for the required period of time);
- (e) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.40(c) by reference), (failure of generator to keep records of test results or waste analyses for the required period of time);
- (f) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.42(a)(1) by reference), (failure of large quantity generator to contact transporter or owner or operator of treatment, storage, or disposal facility if generator does not receive properly signed copy of manifest within thirty-five (35) days);

- (g) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.42(a)(2) by reference), (failure of large quantity generator to submit required exception report);
- (h) 20 DCMR § 4262.1 (which incorporates 40 CFR § 262.42(b) by reference), (failure of generator of greater than one hundred (100) kilograms but less than one thousand (1000) kilograms of hazardous waste in a calendar month to comply with requirements for exception reporting);
- (i) 20 DCMR §§ 4262.1 and 4262.5 (which incorporate 40 CFR § 262.43 by reference), (failure of generator to submit reports required by the Director regarding quantities and disposition of waste);
- (j) 20 DCMR § 4263.1 (which incorporates 40 CFR § 263.20(d) by reference), (failure of transporter to obtain date of delivery and required signature on manifest, and to keep and deliver appropriate copies);
- (k) 20 DCMR § 4263.3 (transporter parking a vacuum or pump truck or tanker containing hazardous waste at a transfer facility or at any other location in the District of Columbia for more than twenty-four (24) hours);
- (l) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.172 or 265.172 by reference), (failure of owner or operator to use a container that will not react with, or otherwise be incompatible with, the waste to be stored);
- (m) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.173 or 265.173 by reference), (failure of owner or operator to properly manage containers);
- (n) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.174 or 265.174 by reference), (failure of owner or operator to inspect areas where containers are stored);
- (o) 20 DCMR §§ 4264.1 and 4265.7 (which incorporate 40 CFR § 264.175 by reference), (failure of owner or operator to design or operate containment system in accordance with the requirements of 40 CFR § 264.175);
- (p) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.176 and 265.176 by reference), (failure of owner or operator to place containers holding ignitable or reactive waste required distance from property line);
- (q) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.177 or 265.177 by reference), (failure of owner or operator to comply with special requirements for incompatible wastes and materials);

- (r) 20 DCMR §§ 4264.1 and 4265.7 (which incorporate 40 CFR § 264.178, by reference), (failure of owner or operator storing containers of hazardous waste to comply with closure standards in 40 CFR § 264.178);
- (s) 20 DCMR §§ 4264.1 and 4264.8(c) or §§ 4265.1 and 4265.8(c), respectively (which incorporate 40 CFR §§ 264.193 or 265.193 by reference), (failure of owner or operator of tank system to provide secondary containment);
- (t) 20 DCMR §§ 4264.1 and 4265.1 (which incorporate 40 CFR §§ 264.194 or 265.194 by reference), (failure of owner or operator of tank system to comply with general operating requirements);
- (u) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.195 or 265.195 by reference), (failure of owner or operator of tank system to perform required inspections);
- (v) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.197 or 265.197 by reference), (failure of owner or operator of tank system to perform required closure or post-closure care);
- (w) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.198 or 265.198 by reference), (failure of owner or operator of tank system to comply with special requirements for ignitable or reactive wastes);
- (x) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.199 or 265.199 by reference), (failure of owner or operator of tank system to comply with special requirements for incompatible wastes or incompatible wastes and materials);
- (y) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.201 by reference), (failure of generator of between one hundred (100) and one thousand (1,000) kilograms per month that accumulates hazardous waste in tanks to comply with the special requirements in 40 CFR § 265.201);
- (z) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.373 by reference), (failure of owner or operator to comply with general operating requirements for thermal treatment);
- (aa) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.377 by reference), (failure of owner or operator to comply with monitoring and inspection requirements when thermally treating hazardous waste);
- (bb) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.381 by reference), (failure of owner or operator at closure to remove all hazardous waste and hazardous waste residues from thermal treatment process or equipment);

- (cc) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.401 by reference), (failure of owner or operator of facility that treats hazardous waste by chemical, physical, or biological methods to comply with general operating requirements);
- (dd) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.403 by reference), (failure of owner or operator of facility that treats hazardous waste by chemical, physical, or biological methods to comply with inspection requirements);
- (ee) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.404 by reference), (failure of owner or operator of facility that treats hazardous waste by chemical, physical, or biological methods, at closure, to remove all hazardous waste and hazardous waste residues);
- (ff) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.405 by reference), (failure of owner or operator of facility that treats hazardous waste by chemical, physical, or biological methods, to comply with special requirements for ignitable or reactive waste);
- (gg) 20 DCMR § 4265.1 (which incorporates 40 CFR § 265.406 by reference), (failure of owner or operator of facility that treats hazardous waste by chemical, physical, or biological methods to comply with special requirements for incompatible wastes or incompatible wastes and materials);
- (hh) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.573 or 265.443 by reference), (failure of owner or operator of drip pad to comply with design or operating requirements);
- (ii) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.575 or 265.445 by reference), (failure of owner or operator of drip pad to comply with closure standards);
- (jj) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.1101 or 265.1101 by reference), (failure of owner or operator of containment building to comply with design or operating standards);
- (kk) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.1102 or 265.1102 by reference) (failure of owner or operator of containment building to comply with the standards for closure or post-closure care);
- (ll) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.1201 or 265.1201 by reference), (failure of owner or operator who stores munitions or explosive hazardous wastes to comply with the design and operating standards);

- (mm) 20 DCMR §§ 4264.1 or 4265.1 (which incorporate 40 CFR §§ 264.1202 or 265.1202 by reference), (failure of owner or operator who stores munitions or explosive hazardous waste to comply with the standards for closure or post-closure care);
- (nn) Section 6(c)(17) of the Solid Waste Facility Permit Act of 1995 (**D.C. Official Code § 8-1055(c)(17)**) (owner or operator of solid waste facility allowing hazardous, infectious, or radioactive waste to remain on-site for more than twenty-four (24) hours);
- (oo) Section 6(c)(18) of the Solid Waste Facility Permit Act of 1995 (**D.C. Official Code § 8-1055(c)(18)**) (failure of owner or operator of solid waste facility to provide monthly report to the Department); or
- (pp) Violation of any provision of the District of Columbia Hazardous Waste Management Act of 1977, effective March 16, 1978, as amended (D.C. Law 2-64; D.C. Official Code §§ 8-1301 to 8-1314 (2001)), or the Hazardous Waste Management Regulations, 20 DCMR chapters 42 and 43, that is not cited elsewhere in 16 DCMR § 3652.

Persons wishing to comment on the proposed rules may submit written comments no later than sixty (60) days after the date of publication of this notice in the *D.C. Register*, to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained from 8:15 a.m. to 4:45 p.m., Monday through Friday, excluding holidays, from the Department of Health, Environmental Health Administration, Bureau of Hazardous Material and Toxic Substances, 51 N Street, N.E., 3rd Floor, Washington, D.C. 20002. Copies are available for a fee of \$2.00 to cover the cost of copying.

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth in section 19(a)(3) of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980, (D.C. Law 3-98; D.C. Official Code § 47-2885.18.01(a)(3)); the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01); Mayor's Order 98-48, dated April 15, 1998, Section 4902 of the Fiscal Year 2002 Budget Support Act of 2001, effective October 3, 2001, (D.C. Law 14-28; D.C. Official Code § 7-731); Section 15 of the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990, (D.C. Law 8-137; D.C. Official Code § 48-714(a)); and Mayor's Order 98-88, dated May 29, 1998; hereby gives notice of his intent to take final rulemaking action to adopt the following amendments to Chapter 13 of Title 22 of the District of Columbia Municipal Regulations (DCMR) in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

The purpose of the amendments is to authorize the issuance of, and implement procedures for the issuance of, prescriptions for legend drugs and medical devices by telephone facsimile and electronic transmission in the District of Columbia.

The following rulemaking action is proposed:

22 DCMR Chapter 13, PRESCRIPTIONS AND DISTRIBUTION, is amended as follows:

Section 1300 is amended to read as follows:

1300 GENERAL PROVISIONS

- 1300.1 This chapter shall apply to all categories of prescriptions drugs.
- 1300.2 Unless otherwise prohibited in this chapter or by District or federal law, a pharmacist may accept as valid for dispensing, a written prescription, an oral prescription, a telephone facsimile prescription, or an electronic prescription, issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices.
- 1300.3 A prescription shall only be issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices. If the prescription is for a controlled substance, the practitioner must also have a valid federal Drug Enforcement Agency (DEA) registration number and if applicable, a valid District of Columbia controlled substance registration or be exempt from registration pursuant to § 302 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5,

1981, (D.C. Law 4-29, D.C. Official Code § 48-901.01).

- 1300.4 A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner only pursuant to the directions and order of the practitioner, and in conformance with the applicable federal and District of Columbia laws and regulations, and this chapter.
- 1300.5 A prescription shall only be filled by a licensed pharmacist or individual practitioner legally authorized to dispense a prescription.
- 1300.6 Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription they dispense. If the pharmacist questions the accuracy or authenticity of prescription, he or she shall verify the order with the practitioner prior to dispensing.
- 1300.7 Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist knows or should have known that the prescription was issued on the basis of an internet-based or telephone consultation without a valid patient-practitioner relationship.
- 1300.8 A pharmacist may dispense a prescription in the absence of a valid patient-practitioner relationship only under the following exceptions:
- (a) In the event of a medical emergency; or
 - (b) When the prescriber is taking calls for the patient's regular practitioner.
- 1300.9 Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he or she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

Section 1301 is amended to read as follows:

1301 WRITTEN PRESCRIPTION ORDERS

- 1301.1 In addition to conforming to all applicable federal and District requirements, a written prescription drug order shall contain the following:
- (a) The printed or typed full name, address, and telephone number of the practitioner;

- (b) The original, legal signature of the practitioner, in ink;
- (c) The date of issuance;
- (d) The full name of the patient;
- (e) The name, strength and quantity of the drug prescribed, directions for use, and number of refills, when applicable; and
- (f) Be written in ink, indelible pencil or typewriter.

1301.2 In addition to the requirements of § 1301.1, a prescription drug order for a controlled substance shall also include the following:

- (a) The patient's address;
- (b) The practitioner's Federal Drug Enforcement Administration (DEA) registration number;
- (c) The practitioner's District of Columbia controlled substances registration number, if applicable;
- (d) Be signed by the practitioner in the same manner as the practitioner would sign a check or legal document (for example: "J.H. Smith" or "John H. Smith").

1301.3 Any person who is exempted from registration under federal or District of Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.

1301.4 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.

1301.5 The service identification number for a Public Health Service employee is his or her social security identification number. Each prescription shall have the name of the individual stamped or printed on it, as well as the signature of the individual.

1301.6 The dispensing pharmacist shall document the following information on each prescription order that has been dispensed:

- (a) The name or initials of the pharmacist who performed the final verification; and
- (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include but not be limited to, a change in quantity, directions, or number of refills.

1301.7 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of a pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

Section 1302 is amended to read as follows:

1302 ORAL PRESCRIPTION ORDERS

1302.1 A pharmacist shall not dispense an oral prescription drug order for a controlled substance listed in Schedule II except as provided in § 1306.5 of this chapter.

1302.2 An oral prescription drug order from a practitioner or a practitioner's designated agent shall:

- (a) Only be received by a pharmacist; and
- (b) Be immediately reduced to writing.

1302.3 In addition to conforming to all applicable federal and District requirements, an oral prescription drug order shall contain the following:

- (a) The full name, address, and telephone number of the practitioner;
- (b) The date of issuance;
- (c) The full name and address of the patient;
- (d) The name, strength, and quantity of the drug, directions for use, and number of refills, when applicable; and
- (e) The name of the practitioner's designated agent authorized to orally communicate the prescription to the pharmacist.

1302.4 In addition to the requirements of § 1302.3, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:

- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number; and
- (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable.

1302.5 The dispensing pharmacist shall document the following information on the written record of each prescription order that has been dispensed:

- (a) The name or initials of the pharmacist who performed the final verification; and
- (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.

1302.6 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of a pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1302.7 For any person who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions for controlled substances issued by the exempted practitioner the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act, in lieu of the registration number of the practitioner required by this chapter.

1302.8 For an official who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.

1302.9 For any Public Health Service employee that is exempted from registration under federal or District of Columbia statute, the pharmacist shall include the individual's social security identification number, office, title, and business address on the prescription.

Section 1303 is amended to read as follows:

1303 TELEPHONE FACSIMILE PRESCRIPTION ORDERS

1303.1 A practitioner shall not transmit a prescription via telephone facsimile if in doing so it would interfere with a patient's freedom to choose a pharmacy, or without a patient's consent.

- 1303.2 A pharmacist shall not dispense a telephone facsimile prescription drug order for a controlled substance listed in Schedule II, except as permitted under § 1306 of this chapter.
- 1303.3 A telephone facsimile prescription shall be transmitted only by a practitioner or a practitioner's designated agent directly from the practitioner's office or a health care facility to the pharmacy with no intervening person having access to the prescription drug order.
- 1303.4 To maintain the confidentiality of patient records:
- (a) The pharmacy and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and telephone facsimile transmissions; and
 - (b) The pharmacy shall implement and maintain procedures, system controls and other efforts to ensure compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), federal and District laws regarding the confidentiality and protection of patient information.
- 1303.5 The pharmacy shall implement and maintain procedures to verify the authenticity of the telephone facsimile transmission and its source of origin which may include:
- (a) Maintenance of a practitioner's telephone facsimile number reference;
 - (b) Verification of the telephone number of the originating telephone facsimile equipment; and
 - (c) Telephone verification with the practitioner's office that the prescription as transmitted via telephone facsimile contains the same exact information it contained when originated by the practitioner and contains no alterations by any intervening parties.
- 1303.6 In addition to conforming to all applicable federal and District requirements, a telephone facsimile prescription drug order shall contain the following at the time it is transmitted:
- (a) A prescription bearing the following information:
 - (1) The printed or typed full name, address, telephone number and facsimile number of the practitioner;
 - (2) The signature of the practitioner;

- (3) The date of issuance;
 - (4) The full name and address of the patient;
 - (5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable; and
 - (6) A statement which indicates that the prescription was transmitted via telephone facsimile;
- (b) Along with the prescription, the following information shall be transmitted:
- (1) The name, address, and facsimile number of the pharmacy to which the prescription was transmitted;
 - (2) The date the prescription was transmitted via facsimile to the pharmacy, if the date is different from the date of issuance of the prescription;
 - (3) If transmitted by a designated agent, the full name of the designated agent; and
 - (4) A clearly legible statement that:
 - (A) The telephone facsimile transmission is intended only for the recipient to which it was addressed and contains information that is confidential;
 - (B) The recipient is prohibited from distribution or dissemination of the information contained in the transmission unless permitted by federal or District law; and
 - (C) If the recipient is not the intended recipient or the authorized agent of the intended recipient, the recipient should immediately notify the sender by telephone and return the original message to the sender.

1303.7

In addition to the requirements of § 1303.6, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:

- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number;
- (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable;
- (c) Be signed by the practitioner in the same manner as the practitioner would

sign a check or legal document (for example: "J.H. Smith" or "John H. Smith"); and

(d) Any other requirements under District or federal law.

- 1303.8 Any person who is exempted from registration under federal or District of Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.
- 1303.9 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1303.10 The service identification number for a Public Health Service employee is his or her social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.
- 1303.11 The dispensing pharmacist shall document the following information on each facsimile prescription order that has been dispensed:
- (a) The name or initials of the pharmacist who performed the final verification; and
 - (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.
- 1303.12 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of a pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

Section 1304 is amended to read as follows:

1304 ELECTRONIC PRESCRIPTION ORDERS

- 1304.1 A practitioner shall not electronically transmit a prescription if in doing so it would interfere with a patient's freedom to choose a pharmacy, or without a patient's consent.

- 1304.2 A pharmacist shall not dispense an electronic prescription for a controlled substance listed in any schedule, unless otherwise authorized by federal law.
- 1304.3 An electronic prescription may be transmitted only by a practitioner or a practitioner's designated agent:
- (a) Directly to a pharmacy through a computer to computer transmission; or
 - (b) Processed by a commercial intermediary that is duly licensed or authorized to operate in the District of Columbia, if applicable, and which guarantees the confidentiality and security of the transmission process.
- 1304.4 The original electronic transmission shall be readily retrievable through the pharmacy computer system and shall be immediately reduced to hardcopy and filed in accordance with District of Columbia regulations.
- 1304.5 To maintain the confidentiality of patient records:
- (a) The pharmacy computer system and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and electronic transmissions; and
 - (b) The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, system controls, and other efforts to ensure compliance with HIPAA, federal and District laws concerning the confidentiality and protection of patient information.
- 1304.6 The Director of Pharmacy or Pharmacist in Charge shall create and maintain an ongoing security program and procedures which are capable of identifying misuse or unauthorized use of electronic signatures;
- 1304.7 The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, computer system controls, and other efforts to:
- (a) Verify the authenticity of the electronic transmission and its source of origin;
 - (b) Ensure that the electronic transmission contains the same exact information it contained when originated by the practitioner;
 - (c) Ensure that the electronic transmission contains no alterations by any intervening parties;
 - (d) Prevent unauthorized access and changes to electronically transmitted prescriptions; and

- (e) Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the validity of the transmission.

1304.8 In addition to conforming to all applicable federal and District requirements, an electronic prescription order shall contain the following information at the time it is transmitted:

- (a) A prescription bearing the following information:

- (1) The full name, address, and telephone number of the practitioner;
- (2) The electronic signature of the practitioner;
- (3) The date of issuance;
- (4) The full name and address of the patient;
- (5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable; and
- (6) A statement which indicates that the prescription was electronically transmitted;

- (b) Along with the prescription, the following information shall be transmitted:

- (1) The name, address, and facsimile number of the pharmacy to which the prescription was transmitted;
- (2) The date the prescription was transmitted via facsimile to the pharmacy, if the date is different from the date of issuance of the prescription;
- (3) If transmitted by a designated agent, the full name of the designated agent; and
- (4) A clearly legible statement that:
 - (A) The electronic transmission is intended only for the recipient to which it was addressed and contains information that is confidential;
 - (B) The recipient is prohibited from distribution or dissemination of the information contained in the transmission unless permitted by federal or District law; and
 - (C) If the recipient is not the intended recipient or the authorized agent of the intended recipient, the recipient should immediately notify the

sender by telephone and permanently delete and destroy all copies of the transmitted material.

- 1304.9 The dispensing pharmacist shall document the following information on each electronic prescription order that has been dispensed:
- (a) The name or initials of the pharmacist who performed the final verification; and
 - (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.
- 1304.10 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of a pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.
- 1304.11 Electronic transmission technology shall not be used to circumvent or violate any provision of District or federal laws or regulations.

Section 1305 is amended to read as follows:

1305 ISSUANCE OF CONTROLLED SUBSTANCE PRESCRIPTIONS

- 1305.1 The prescribing practitioner and the pharmacist shall be jointly responsible for compliance with this chapter in prescribing and dispensing a controlled substance.
- 1305.2 A prescription for a controlled substance shall be issued or dispensed only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.
- 1305.3 A prescription for a controlled substance shall be issued for treatment of individual patients. A prescription for a controlled substance shall not be issued to an individual practitioner for general dispensing purposes.
- 1305.4 A prescription for a controlled substance listed in any schedule shall be used for the purpose of continuing the patient's dependency only when its issuance is pursuant to authorized clinical treatment in a narcotic treatment rehabilitation program.
- 1305.5 Any person issuing a prescription and any person knowingly filling a prescription which is not in conformity with this chapter shall be subject to the penalties provided for violations of the Act and this chapter.
- 1305.6 An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a

prescription within the meaning and intent of the Act, and a person knowingly filling such a prescription, and the person issuing it, shall both be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Section 1306 is amended to read as follows:

1306 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- 1306.1 Except as otherwise authorized in this section, a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, shall only be dispensed pursuant to a valid written prescription signed by the prescribing practitioner, unless otherwise authorized by federal law.
- 1306.2 A prescription for a controlled substance listed in Schedule II shall not be filled if submitted more than thirty (30) days after the date on which the prescription was issued.
- 1306.3 A prescription for a controlled substance listed in Schedule II shall not be refilled and shall be cancelled out by a line drawn through the entire prescription order, with the date dispensed and initials of the person that dispensed the drug.
- 1306.4 A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via telephone facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to issuance of the controlled substance to the patient or the patient's representative. The original prescription shall be maintained in accordance with the requirements of this chapter and as required under federal and District law.
- 1306.5 In emergency situations, as defined under § 1306.6 of this chapter, a pharmacist may dispense Schedule II drugs upon the oral prescription of a practitioner. The pharmacist shall comply with the following requirements as set forth in 21 CFR § 1306.11(d) and failure to do so may result in suspension or revocation of a pharmacy registration:
- (a) The quantity prescribed and dispensed is limited to no more than a seven (7) day supply to treat the patient during the emergency period (dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescribing individual practitioner);
 - (b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required by District and federal law;

- (c) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call back to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure the practitioner's identity; and
- (d) Within seven (7) days after authorizing an emergency oral prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1301 of this chapter, the prescription shall:
 - (1) Have written on its face "Authorization for Emergency Dispensing," and the date of the oral order; and
 - (2) The written prescription shall be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach the written prescription to the oral emergency prescription which was previously reduced to writing. The pharmacist shall notify, in writing, the Director if the prescribing individual practitioner fails to deliver a written prescription to him or her. Failure of the pharmacist to notify the Director shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

1306.6

As used in this section "emergency situation" means those situations in which the prescribing practitioner determines the following:

- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;
- (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and
- (c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

1306.7

A prescription for a Schedule II controlled substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the institutional or home health care pharmacy by

telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.

1306.8 A prescription for a Schedule II controlled substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.

1306.9 A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care program certified or paid for by Medicare under Title XVIII or a hospice program which is licensed by the District may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by telephone facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirement of this Title and federal and District law.

1306.10 An individual practitioner may administer or dispense directly to a patient a Schedule II controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.

1306.11 An institutional practitioner may administer or dispense directly, (but not prescribe) a controlled substance listed in Schedule II only pursuant to:

- (a) A valid written prescription signed by the prescribing individual practitioner;
or
- (b) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.

Section 1307.3 is amended to read as follows:

1307.3 A Prescription for Schedule II controlled substance for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units and in accordance with federal law. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist shall also observe the following:

- (a) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient;

- (b) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient";
- (c) A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the federal and District law;
- (d) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist;
- (e) The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed; and
- (f) Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

Section 1309 is amended to read as follows:

1309 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV AND V

- 1309.1 Unless otherwise permitted under federal law, a pharmacist shall dispense directly a controlled substance listed in Schedule III, IV or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act only pursuant to:
- (a) A valid written prescription signed by the prescribing practitioner;
 - (b) A telephone facsimile of a written prescription, signed by the prescribing practitioner, transmitted by the practitioner or the practitioner's designated agent to the pharmacy; or
 - (c) An oral prescription of a practitioner immediately reduced to writing by the pharmacist containing all information required under § 1302 of this chapter.
- 1309.2 An individual practitioner may administer or dispense directly to a patient a Schedule III, IV or V controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.
- 1309.3 An institutional practitioner may administer or dispense directly, but not

prescribe, a controlled substance listed in Schedule III, IV, or V only pursuant to:

- (a) A valid written prescription signed by an individual practitioner;
- (b) A telephone facsimile of a written prescription or order for medication transmitted by the individual practitioner or the practitioner's designated agent to the institutional practitioner or pharmacist;
- (c) An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required under § 1302 of this chapter; or
- (d) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.

Section 1310.3 is amended to read as follows:

1310.3 Each refilling of a prescription shall be entered on the back of the prescription, or on another appropriate, uniformly maintained, readily retrievable record such as a patient profile. The following information must be retrievable by the prescription number:

- (a) The name of the controlled substance, or the name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially;
- (b) The strength and dosage form of the controlled substance;
- (c) The date of each refilling and the quantity dispensed;
- (d) The identity or initials of the dispensing pharmacist for each refill; and
- (e) The total number of refills for that prescription.

Section 1310.6 is amended to read as follows:

1310.6 The prescribing practitioner may authorize additional refills of a Schedule III, IV or V prescription controlled substance on the original prescription through an oral refill authorization transmitted to the pharmacist provided that the following conditions are met:

- (a) The total quantity authorized, including the amount of the original prescription, does not exceed five (5) refills or extend beyond six (6) months from the date of issue of the original prescription;

- (b) The pharmacist obtaining the oral authorization shall record the date, quantity of refill, and number of additional refills authorized, on the reverse of the original prescription and initial the prescription documenting that he or she received the authorization from the prescribing practitioner who issued the original prescription; and
- (c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

Section 1310.7 is amended to read as follows:

- 1310.7 Additional quantities of prescription controlled substances listed in Schedule III, IV or V, beyond the five (5) refill, six (6) month limitation, shall only be authorized by a prescribing practitioner through the issuance of a new and separate prescription.

A new section 1310.8 is added to read as follows:

- 1310.8 As an alternative to the procedures provided under § 1310.3 of this chapter, an automated data processing system may be used for the storage and retrieval of refill information for prescription drug orders for controlled substances in Schedule III, IV, or V, subject to the conditions outlined under 21 CFR § 1306.22(b).

Section 1315.2 is amended to read as follows:

- 1315.2 The prescription shall contain all requirements specified for prescriptions of Schedules II, III, IV, or V respectively, as listed within this chapter and shall be packaged and mailed in conformance with the applicable federal laws and regulations of the U.S. Department of Justice, Drug Enforcement Administration 21 CFR §§ 1300 *et seq.*, and the U.S. Postal Service 18 U.S.C. § 1716.

Section 1316 is amended to read as follows:

1316 TRANSFER BETWEEN PHARMACIES OF PRESCRIPTION INFORMATION FOR REFILL PURPOSES

- 1316.1 The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible, subject to the requirements of § 1316.3 of this chapter, between pharmacies on a one-time basis only. However, pharmacies utilizing a linked pharmacy system may transfer up to the maximum number of refills permitted by law.
- 1316.2 The transfer of original prescription information for a non-controlled substance for the purpose of refill dispensing is permissible subject to the requirements of § 1316.3 of this chapter.

1316.3

Any authorized transfer of original prescription information between non-linked pharmacy systems for the purpose of refill dispensing shall be subject to the following requirements:

- (a) The transfer shall be communicated directly between two licensed Pharmacists;
- (b) The transferring pharmacist shall record on the invalidated prescription, in hardcopy or electronically, the following information:
 - (1) The words "VOID" and "TRANSFER";
 - (2) The name, address, and telephone number of the pharmacy to which it was transferred;
 - (3) The name of the pharmacist receiving the prescription information;
 - (4) For controlled substances, the DEA registration number of the prescriber and of the pharmacy to which the prescription is being transferred and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy to which the prescription is being transferred; and
 - (5) The date of the transfer and the name of the pharmacist transferring the information;
- (c) The pharmacist receiving the transferred prescription information shall reduce to writing the following information:
 - (1) Write the word "TRANSFER" on the face of the transferred prescription;
 - (2) All information required to be on a prescription pursuant to 21 CFR § 1306.05 and this chapter;
 - (3) Date of issuance of original prescription;
 - (4) Original number of refills authorized on original prescription;
 - (5) Date of original dispensing;
 - (6) Number of valid refills remaining ;
 - (7) The transferring pharmacy's name, address, and telephone number;

- (8) Name of pharmacist who transferred the prescription; and
- (9) For controlled substances, the DEA registration number of the prescriber and the pharmacy from which the prescription was transferred, and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy from which the prescription information was transferred;

- 1316.4 Direct pharmacist to pharmacist communication is not required between pharmacies utilizing a linked pharmacy system to transfer prescription drug orders or information for dispensing purposes. However, the common electronic file shall contain a complete record of each prescription drug order and refill dispensed, and a hard copy record of each prescription drug order accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order.
- 1316.5 The original and transferred prescription(s) shall be maintained for a period of two (2) years from the date of initial filling in accordance with District of Columbia regulations.
- 1316.6 Pharmacies electronically accessing the same prescription record shall satisfy all information requirements as required of a manual prescription transferral.
- 1316.7 A pharmacist at the transferring pharmacy may not refill a prescription that has been transferred to another pharmacy.
- 1316.8 The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order.

A new section 1317 is added to read as follows:

1317 ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES

- 1317.1 The administering or dispensing directly (but not prescribing) of controlled substances listed in any schedule to a controlled substance dependent person for the purpose of detoxification or for continuing his or her dependence upon these drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be permissible; provided, that the following conditions are met:
- (a) Approval is obtained before the initiation of this program by submission of a "Notice of Claimed Investigation Exemption for a New Drug" to the Food and Drug Administration [which will be reviewed concurrently by FDA for scientific merit and by the Pharmaceutical Control Division, for drug control

requirements]; and

- (b) That the clinical investigation thereafter accords with this approval, as required by the Federal Act and Federal regulations.

1317.2 Any practitioner who violates any of the provisions of the federal law or regulations shall be in violation of this chapter.

1317.3 Nothing in this chapter shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) controlled substances to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or issued for the person's use at one time. The emergency treatment may be carried out for not more than three (3) days and may not be renewed or extended.

1317.4 The rules of this chapter are not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense controlled substances to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

Section 1323.2 is amended to read as follows:

1323.2 A registrant desiring to discontinue business activities with respect to controlled substances (by transferring those business activities to another person), shall submit in person or by registered or certified mail, return receipt requested, to the Department of Health, Health Care Regulation and Licensing Administration, Pharmaceutical Control Division, at least fourteen (14) days before the date of the proposed transfer (unless the Director waives this time limitation in individual instances), the following information:

- (a) The name, address, registration number, and authorized business activity, of the registrant discontinuing the business (registrant-transferor);
- (b) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
- (c) Whether the business activities will be continued at the location registered by the person discontinuing the business, or moved to another location (if the latter, the address of the new location should be listed); and
- (d) The date on which the transfer of controlled substances will occur.

The section heading for 1330 is amended to read as follows:

1330 **GENERICALLY EQUIVALENT PRESCRIPTION DRUGS**

The section heading for 1332 is amended to read as follows:

1332 **DRUG MANUFACTURERS AND DISTRIBUTORS FEES**

Section 1399.1 is amended to read as follows:

1399.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

Act—District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01).

Administer—the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Adulterated drug or medical device— as defined in § 501 of the Federal Food, Drug and Cosmetic Act, (Pub. L. 96-354, 21 USC § 351) as amended.

Automated data processing system—a system utilizing computer software and hardware for the purpose of recordkeeping.

Community/Retail pharmacy—a pharmacy that provides services to the public or general community on an outpatient bases, whether at retail, through third party payment, or other measure of no or minimum cost to the consumer.

Compounding—the preparation or mixing, of a drug or device as the result of a practitioner's prescription drug order or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

Computer generated facsimile— a computer to facsimile transmission sent by a computer that has a facsimile modem through which documents can be sent.

Controlled premises— (1) places where original or other records or documents required under the Act are kept or requested to be kept, and (2) places or establishments, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, distribute, dispense, conduct research with, or otherwise dispose of controlled substances.

Controlled substances—those drug items or chemicals regulated under the Federal Controlled Substances Act of 1970, (Pub.L. 91-513, 21 USC § 801 et

seq.) as amended; and the District of Columbia Uniform Controlled Substances Act of 1981, (D.C. Law 4-29, D.C. Official Code § 48-901 et seq.) as amended.

Department—The District of Columbia Department of Health.

Director— The Director of the District of Columbia Department of Health.

Dispense—the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or medical device to a patient or patient's agent.

Distribute—the actual, constructive, or attempted transfer from one person to another, other than by administering or dispensing, of a drug or medical device whether or not there is an agency relationship.

Drug—

- (a) Any substance recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium or other official drug compendium or any supplement to any of them;
- (b) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;
- (c) Any chemical substance (other than food) intended to affect the structure or any function of the body of man or other animal; and
- (d) Any substance intended for use as a component of any items specified in subparagraph (a), (b), or (c) of this paragraph, but not including medical devices or their components, parts, or accessories.

Electronic—relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities.

Electronic prescription—a prescription drug order which is transmitted by an electronic device to the receiver (pharmacy), or which is transmitted computer to computer between a practitioner's office and a pharmacy. An electronic prescription includes computer generated facsimile prescription drug orders but does not include telephone facsimile prescription drug orders.

Electronic record—a record created, generated, sent, communicated, received, or stored by electronic means.

Electronic signature—a confidential, unique, personalized electronic

security code, key, number or other identifier attached to or logically associated with a record that is used for secure electronic data transmissions which identifies and authenticates the signatory and is executed or adopted by the signatory with the intent to sign the record.

Generically equivalent drugs— drugs that are:

- (a) Pharmaceutical equivalents in that they contain identical amounts of the same active drug ingredients in the same dosage form and meet compendial or other applicable standards of identity strength, quality, and purity;
- (b) Bioequivalents in that they do not present a known or potential bioequivalence problem or if they do present such a known or potential problem they are shown to meet an appropriate bioequivalence standard; and
- (c) Adequately labeled and are manufacture under conditions which, at a minimum, comply with FDA Current Good Manufacturing Practice Regulations.

HIPAA—The Federal Health Insurance Portability and Accountability Act of 1996.

Individual Practitioner—an individual who is licensed or registered in the District of Columbia to prescribe a prescription drug or medical device in the course of his or her professional practice, including a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse. It does not include a pharmacist, pharmacy, or an institutional practitioner.

Institutional practitioner— an intern, resident physician, fellow, or person in an equivalent professional position who:

- (a) Is not yet licensed under District of Columbia law to administer, dispense, or prescribe controlled substances;
- (b) Is enrolled in a bona fide professional training program in a base hospital or institutional training facility registered by the Federal Drug Enforcement Administration and District of Columbia; and
- (c) Is authorized by the base hospital or institutional training facility to administer, dispense, or prescribe controlled substances.

Linked pharmacy system— pharmacies within the same retail name chain utilizing a common electronic file or database to transfer prescription drug orders or information for dispensing purposes between or among pharmacies within the same retail chain which also participates in the same common prescription file.

Mayor—the Mayor of the District of Columbia or the Mayor's designated agent.

Medical device—an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (a) Recognized in the official National Formulary, the official United States Pharmacopoeia, or any supplement thereto;
- (b) Intended for use in the diagnosis of disease or any other condition, or in the cure, mitigation, treatment, or prevention disease in man or other animal; or
- (c) Intended to affect the structure of any function of the body of man or other animal, and which does achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which does not depend upon being metabolized for the achievement of any of its principal intended purposes.

Misbranded drug or medical device—as defined in section 501 of the Federal Food, Drug and Cosmetic Act, (Pub. L. 96-354, 21 USC § 352) as amended.

Narcotic Drug— any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

- (a) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium;
- (b) Poppy straw and concentrate of poppy straw;
- (c) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed;
- (d) Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- (e) Ecgonine, its derivatives, their salts, isomers and salts of isomers; or
- (f) Any compound, mixture, or preparation which contains any quantity of these substances.

Narcotic treatment program— a program engaged in maintenance or detoxification treatment with narcotic drugs.

Original prescription—the original written prescription drug order; the original oral drug order that has been reduced to writing by the pharmacist; the original telephone facsimile prescription, or the original electronic prescription.

Over-the-counter drug—drugs which may be sold without a prescription and which are packaged for use by the consumer and labeled in accordance with the requirements of the laws and regulations of the District of Columbia and the federal government.

Patient-practitioner relationship—means that at a minimum the practitioner has met face to face with the patient, has obtained a patient history, and conducted a physical examination or evaluation adequate to establish a diagnosis, identify underlying conditions and contraindications to the treatment recommended.

Pharmacist—a person who is licensed in the District of Columbia to engage in the practice of pharmacy.

Pharmacy—any establishment or institution, or any part thereof, where the practice of pharmacy is conducted; drugs are compounded or dispensed, offered for sale, given away, or displayed for sale at retail; or prescriptions are compounded or dispensed.

Practice of pharmacy—the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices, and the maintenance of proper records therefore; the responsibility of advising, where regulated or otherwise necessary, of therapeutic values and content, hazards, and use of drugs and devices; and the offering of performance of those acts, services, operations, and transactions necessary in the conduct, operation, management, and control of a pharmacy.

Practitioner—an individual licensed, registered, certified, or otherwise permitted by law to prescribe, dispense, and to administer drugs or medical devices, or to conduct research with respect thereto, within the course of such persons' professional practice or research.

Prescriber— the practitioner who issues a prescription.

Prescription—any order for a drug, medicinal chemical, or combination or mixtures thereof, or for a medically prescribed medical device, in writing, dated and signed by an authorized health professional or given orally to a pharmacist by an authorized health professional or the person's authorized agent and immediately reduced to writing by the pharmacist or pharmacy intern, specifying the address of the person for whom the drug or device is ordered and directions for use to be placed on the label.

Prescription drug— any of the following:

- (a) a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
- (1) "Caution: Federal law prohibits dispensing without prescription";
or
 - (2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian.
- (b) a drug which is required by any applicable federal, or District of Columbia law or regulation to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only; or
- (c) a drug which is restricted to use by health professionals and allied practitioners for research.

Proprietor of a pharmacy—a person designated as proprietor in an application for a pharmacy license. The proprietor may be an individual, a corporation, a partnership, or an unincorporated association, and shall at all times own a controlling interest in the pharmacy.

Provider pharmacy—the community pharmacy or the institutional pharmacy providing remote pharmacy services.

Registrant—a person who is registered under the District of Columbia Uniformed Controlled Substances Act of 1981 effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01).

Remote automated medication system—an automated medication system that is located in a health care facility that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

Remote pharmacy services—the provision of pharmacy services, including the storage and dispensing of prescription drugs, in a facility that is not at the same location as the provider pharmacy.

Remote site—a facility not located at the same location as the pharmacy at which remote pharmacy services are provided using an automated medication dispensing system.

Reverse distributor—a duly authorized party who receives drugs, including controlled substances, acquired from another duly authorized party for the purpose of:

- (a) returning unwanted, unusable, or outdated controlled substances to the

manufacturer or the manufacturer's agent; or

(b) where necessary, processing such substances or arranging for processing such substances for disposal.

Starter dose— a dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered.

Security procedure—a procedure employed for the purpose of verifying that an electronic signature, record, or performance is that of a specific person or for detecting changes or errors in the information in an electronic record. The term includes a procedure that requires the use of algorithms or other codes, identifying words or numbers, encryption, or callback or other acknowledgment procedures.

Telepharmacy system—a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

- (a) audio and video;
- (b) still image capture; and
- (c) store and forward.

Telephone Facsimile prescription—a prescription drug order which is transmitted by a telephone electronic device which sends an exact image to the receiver (pharmacy).

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 the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 9:00 a.m. and 5:00 p.m. at the address listed above.

D.C. OFFICE OF PERSONNEL**NOTICE OF PROPOSED RULEMAKING**

The Director, D.C. Office of Personnel, with the concurrence of the City Administrator, pursuant to Mayor's Order 2000-83, dated May 30, 2000, and in accordance with Title XVIII of the District of Columbia Government Comprehensive Merit Personnel Act of 1978, effective March 3, 1979 (D.C. Law 2-139; D.C. Official Code § 1-618.01 *et seq.*) (2001), hereby gives notice of the intent to adopt the following rules in not less than thirty (30) days from publication of this notice in the *D.C. Register*. These rules would amend section 1803 of Chapter 18, Employee Conduct, of Title 6 of the District of Columbia Municipal Regulations (DCMR), to amend sections 1803.2 and 1803.3 of the chapter to clarify what a District government employee should do if he or she receives a gift, and what an employee may do if he or she is invited to a holiday party or similar event. Additionally, a few minor changes are being made to sections 1803.1, 1803.5, 1803.9, 1803.11, and 1803.12 of the section. Upon adoption, these rules will amend Chapter 18, Employee Conduct, of the DCMR, published at 31 DCR 6794 (October 31, 1986), and amended at 35 DCR 764 (February 5, 1988), 36 DCR 3860 (June 2, 1989), 40 DCR 8358 (December 3, 1993), 48 DCR 3074 (April 6, 2001), 48 DCR 9639 (October 19, 2001), 50 DCR 10517 (December 5, 2003), and 52 DCR 10406 (November 25, 2005).

CHAPTER 18**EMPLOYEE CONDUCT**

Section 1803 is amended as follows:

1803 RESPONSIBILITIES OF EMPLOYEES

Sections 1803.1 through 1803.3 are amended to read as follows:

- 1803.1 (a) An employee shall avoid action, whether or not specifically prohibited by this chapter, which might result in or create the appearance of the following:
- (1) Using public office for private gain;
 - (2) Giving preferential treatment to any person;
 - (3) Impeding government efficiency or economy;
 - (4) Losing complete independence or impartiality;

- (5) Making a government decision outside official channels; or
- (6) Affecting adversely the confidence of the public in the integrity of government.

(b) In all cases arising under section 1803 of this chapter, employees are encouraged to consult with their supervisors or the agency's ethics counselor.

1803.2 (a) Except as noted in section 1803.3 of this section, a District government employee shall not solicit or accept, either directly or through the intercession of others, any gift from a prohibited source.

(b) For the purposes of this section, the following terms shall have the meaning ascribed:

Gift – any gratuity, favor, loan, entertainment, or other like thing of value.

Prohibited source – any person or entity that:

- (1) Has or is seeking to obtain contractual or other business or financial relations with the District government;
- (2) Conducts operations or activities that are subject to regulation by the District government; or
- (3) Has an interest that may be favorably affected by the performance or non-performance of the employee's official responsibilities.

(c) An employee who receives a gift that cannot be accepted under the provisions of this section shall:

- (1) Return the gift to the donor or reimburse the donor the market value of the gift; or
- (2) If the gift is perishable and it would not be practical to return it to the donor, donate the gift to charity, share it with the office staff, or destroy it.

1803.3 The restrictions outlined in section 1803.2 of this section do not apply to the following:

- (a) Bona fide personal relationships such as those between an employee and his or her family or personal friends;
- (b) The acceptance of food and refreshments of nominal value on infrequent occasions:

- (1) In the ordinary course of a luncheon or dinner meeting, or while on an inspection tour where an employee may properly be in attendance; or
 - (2) In connection with an annual holiday party or event sponsored by an entity other than the District government, provided that the employee shall notify his or her supervisor in time sufficient for the supervisor to make a meaningful judgment to approve or disapprove the employee's attendance. When making the determination the supervisor may consider such factors as the agency's interests and any appearance of a conflict of interest. The supervisor shall disapprove the employee's attendance if there is an actual conflict of interest.
- (c) The acceptance of loans from banks or other financial institutions on customary terms to finance proper and usual activities of employees such as the acquisition of a car, home, or appliance;
 - (d) The acceptance of unsolicited advertising or promotional material such as pens, pencils, note pads, calendars, and like items of nominal value; or
 - (e) The acceptance of a voluntary gift of nominal value or of a cash donation in a nominal amount which is presented on a special non-recurring occasion such as marriage, illness, or retirement, but excluding birthdays, or other annually-recurring events.

1803.4 An employee shall not solicit a contribution from another employee for a gift to an official superior, make a donation as a gift to an official superior, or accept a gift from an employee receiving less pay. This subsection does not preclude the presentation or acceptance of a voluntary gift of nominal value or of a cash donation in a nominal amount when given on a special, infrequent occasion such as marriage, illness, or retirement.

Section 1803.5 is amended to read as follows:

- 1803.5 For the purposes of section 1803.4 of this section, the term nominal means an individual cash donation of no more than \$10 or an individual voluntary gift of no more than \$10 in market value.
- 1803.6 An employee shall not accept a gift, present, or decoration from a foreign government unless authorized by Congress as provided by the Constitution and in 5 U.S.C. § 7342.
- 1803.7 An employee shall not receive any salary or anything of monetary value from a private source as compensation for his or her services to the government (18 U.S.C. § 209).

- 1803.8 An employee shall report directly and without undue delay to his or her agency head and to the Office of the Inspector General of the District of Columbia any information concerning conduct which he or she knows, or should reasonably know, involves corrupt or other criminal activity, or conflict of interest:
- (a) On the part of another District employee, which concerns that person's employment or office; or
 - (b) On the part of a person dealing with the District government, which concerns that person's dealings with the District government.

Section 1803.9 is amended to read as follows:

- 1803.9 An agency head who has information concerning conduct as described in section 1803.8 of this section shall immediately report such information to the Office of the Inspector General of the District of Columbia.
- 1803.10 An employee shall not interfere with or obstruct an investigation by a District or federal agency of misconduct by another District employee or by a person dealing with the District.

Sections 1803.11 and 1803.12 are amended to read as follows:

- 1803.11 Coercion, harassment, or retaliatory action shall not be taken against an employee acting in good faith under section 1803.8 of this section.
- 1803.12 All employees of the District government shall comply with the requirements of the Freedom of Information Act of 1976, effective March 29, 1977, as amended (D.C. Law 1-96; D.C. Official Code § 2-531 *et seq.*) (2005 Supp.).
- 1803.13 Nothing contained in these regulations shall preclude the Mayor from serving as an honorary chair or honorary member of a nonprofit entity's fundraising event, so long as the entity for which funds are raised supports a nongovernmental bona fide charitable activity benefiting the District of Columbia. Use of the Mayor's name or title in fundraising solicitations or announcements of general circulation shall be in accordance with such terms and limitations as the Mayor may prescribe by Mayor's order or by direction in particular cases. The authority granted by this subsection shall not extend to the use of the Mayor's name or title in solicitations made by or on behalf of the Mayor directly to individual contributors.
- 1803.14 (a) It is the policy of the District government to avoid conflicts of interest concerning the award, implementation, monitoring, and performance of contracts for services. As a means of assisting District government agencies to evaluate real or potential conflicts of interest in this area, a new hire will be required to disclose to the personnel authority upon

initial appointment such previous employment relationships (whether in the private or public sectors) as the personnel authority may direct, including full disclosure of any ongoing economic benefits to the employee from previous employment relationships.

- (b) The new hire will make such disclosure to the personnel authority as part of the new hire processing conducted by the personnel authority, and to the employee's supervisor upon arrival at the employing agency.
- (c) The personnel authority will communicate the information required to be disclosed under this section to the head of the employing agency, and will advise the employee in writing of the restrictions imposed by sections 1803.14 (d) and (e) of this section.
- (d) For one (1) year after the date of initial employment with the District government, an employee required to make a disclosure under this section will be screened from, and shall not participate in any manner, in the District government's decision to enter into, extend, modify, or renew a contract or consultancy engagement with the employee's former employer (hereafter, "procurement action").
- (e) The one-year (1-year) restriction from participation in any procurement action prescribed in section 1803.14 (d) of this section will be extended for as long as the employee receives an ongoing economic benefit from a former employer. It will be the employee's responsibility to advise his or her immediate supervisor of the continued receipt of the ongoing economic benefit from a former employer.
- (f) Notwithstanding the prohibitions set forth in sections 1803.14 (d) and (e) of this section, the head of the employing agency may authorize an employee required to make a disclosure under this section, as part of the employee's official duties, to do any of the following: (1) participate in the oversight or review of the work-product or performance of a former employer that is currently a contractor or consultant with the District government; (2) serve as the District government's liaison with the former employer; or (3) otherwise communicate with the former employer on matters pending before the employee's employing agency.
- (g) The determination to require that the employee perform any of the duties listed in section 1803.14 (f) of this section will be based upon the written determination of the agency head, made in light of all relevant circumstances, that the interest of the District government in the employee's participation outweighs the concern that a reasonable person might question the integrity of the District government's programs or operations. Applying this standard, the agency head may determine that the employee's participation reasonably may be permitted in certain

activities involving the employee's former employer, but not in others. In all instances under this section in which the employee is prohibited from participation, the employee will be screened from the receipt of any information regarding the former employer's matter that is pending before the District government.

- (h) An agency head may delegate the responsibility for making any of the determinations prescribed in this section to other personnel in the agency. The person in the agency making any such determinations may consult with the D.C. Ethics Counselor or with the agency's ethics counselor.
- (i) For the purposes of this section, an "ongoing economic benefit from a former employer" will include any pension, annuity, stock option, bonus, cash or in-kind distribution in satisfaction of equitable interest, payment of all or a portion of the premiums on a life or health insurance policy, or any other comparable benefit; and a "former employer" is any person or organization: (1) for which the employee has, within the one (1) year preceding his or her employment by the District government, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee, or (2) from which the employee receives an ongoing economic benefit.

Comments on these proposed regulations should be submitted, in writing, to Ms. Lisa R. Marin, SPHR, Director of Personnel, 441 4th Street, N.W., Suite 310S, Washington, D.C. 20001, within thirty (30) days of the date of publication of this notice in the *D.C.*

Register. Additional copies of these proposed rules are available from the above address.