State of Washington Adopts Statewide Drug Take-Back Legislation

On March 22, 2018, the Governor of the State of Washington signed the Secure Drug Take-Back Act, Chapter 196, 2018 Wash. Laws, which establishes the first statewide drug take-back program in the nation. The Act requires manufacturers of "covered drugs" to establish, implement, and fund take-back programs for safe and secure collection and disposal of unwanted medications. The Act will go into effect on June 7, 2018, and "covered manufacturers" will need to submit their proposed programs by July 1, 2019.

Covered Drugs

Under the Act, "covered drugs" means prescription (including controlled substances) and nonprescription drugs, brand name and generic drugs, drugs for veterinary use for household pets, and drugs in medical devices and combination products. §§ 2(4)(a), 2(13), 2(17). These include drugs administered via ingestion, injection, and inhalation. The Act excludes "exposed" needles and sharps, and "used drug products that are medical wastes" from the definition of covered drugs. §§ 2(1), 2(4)(b)(ix).

Covered drugs are only those drugs that "covered entities" no longer want, and that the covered entities have abandoned or discarded or intend to abandon or discard. § 2(4)(a).

Covered Entities

"Covered entities" are state residents or other nonbusiness entities, not hospitals, clinics, health care provider's offices, veterinary clinics, pharmacies, law enforcement agencies, or other businesses. § 2(5).

Covered Manufacturers

"Covered manufacturers" are entities engaged in the manufacture of covered drugs sold in or into Washington. § 2(6). The "manufacture" of a drug generally means the production, preparation, propagation, compounding, or processing of the drug, substance, or device. § 2(16); RCW 18.64.011(21). It also includes the packaging and labeling of the substance or device. Id. If the manufacturer of a drug is otherwise identified to the state (as discussed below), "covered manufacturers" do not include a private label distributor or retail

March 26, 2018

AUTHORS

Don Patterson
Principal
+1.202.789.6032
dpatterson@bdlaw.com

Dacie Meng
Associate
+1.202.789.6017
dmeng@bdlaw.com

Rachel Roberts
Associate
+1.206.315.4814
rroberts@bdlaw.com

ABOUT B&D

Beveridge & Diamond's over 100 lawyers in eight U.S. offices focus on environmental and natural resources law, litigation and alternative dispute resolution. We help clients around the world resolve critical environmental and sustainability issues relating to their products, facilities, and operations.

Learn more at bdlaw.com

Beveridge & Diamond

bdlaw.com

pharmacy that sells the drug under the retail pharmacy's store label, a repackager, or a nonprofit 501(c)(3) health care corporation that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by that corporation or an affiliate. § 2(6)(a)–(c).

Identification of Covered Manufacturers

Within 90 days of the Act's effective date, retail pharmacies, private label distributors, and repackagers must identify the manufacturers for any drugs they sell under their own labels. § 4(2). By the same date, drug wholesalers that sell a drug in or into Washington must provide a list of drug manufacturers to the Department of Health (the "Department") and must update that list on January 15th each year. § 4(1).

If a person or entity receives a letter of inquiry from the Department about whether it is a covered manufacturer, the person or entity must respond within sixty days. § 4(3). If the person or entity does not believe it is a covered manufacturer, it must state the basis for such belief, provide a list of any drugs it sells, distributes, repackages, or otherwise offers for sale in Washington, and identify the name and contact information of the manufacturer for each drug identified. § 4(3).

Program Proposals

Covered manufacturers must establish and implement a drug take-back program independently, as part of a group, or through membership in a drug take-back organization. § 3. Proposals are due by July 1, 2019. § 5(1). The Department must approve or reject a proposal within 120 days of receiving it. § 5(3)(a). If a proposal is rejected, the Department must provide the reasons in writing, and the applicant will then have 90 days to submit a revised proposal, which the Department must approve or reject within 90 days. § 5(3)(b). If the Department rejects a revised proposal, the Department may require submission of a further revised proposal, develop and impose changes to the proposal, require the applicant to participate in a previously approved program, or find the covered manufacturer(s) out of compliance and take enforcement action. § 5(3)(c).

Once a proposal is approved, operation must begin within 180 days. § 5(5)(a). Failure to conform to the approved proposal may subject the participating covered manufacturers to enforcement. § 11(3)(a).

The law lists the information required for the proposals, including information about each participating manufacturer, the collectors, the collection system, the system of promotion, the handling and disposal system, and all transporters and disposal facilities to be used. § 5(2).

Authorized Collectors

Program operators must notify potential "authorized collectors" of the opportunity to participate in the drug take-back program. § 6(1)(a). "Authorized collectors" are defined to include a person or entity registered with the United States Drug Enforcement Administration to collect controlled substances for the purpose of destruction, a law enforcement agency, or an entity authorized by the Department to provide an alternative collection mechanism for non-controlled substances. § 2(2), 2(3).

No authorized collectors are required to participate in a program, § 6(b), but a program must include any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offers to participate without compensation and meets the statutory requirements. § 6(c). A collection site may also be located at (1) a substance use disorder treatment program, (2) a long-term care facility where a pharmacy or a hospital or clinic with an on-site pharmacy operates a secure collection receptacle, or (3) any other authorized collector willing to participate and able to meet the statutory requirements. § 6(d).

Convenience Standard

Each program must provide for a collection system meeting the "convenience standard," which is defined differently for population centers (i.e., a city or town and the unincorporated area within a 10-mile radius from the center of the city or town) and other parts of the state. §§ 5(2)(c), 6(3)(c)(iii). Each population center must have at least one collection site, plus one additional collection site for every 50,000 residents of the city or town located within the population center. § 6(3)(c)(i). On islands and in areas outside of population centers, there must be a collection site at each potential authorized collector that is regularly open to the public, qualified, and willing to participate in the program. § 6(3)(c)(ii). Collection sites must be operated by "authorized collectors." § 2(3).

In addition to collection sites, programs must establish locations to distribute mail-back packages or must hold periodic collection events in areas that are underserved by collection sites, as determined by the Department. § 6(3)(d). Note that mail-back distribution locations need not be authorized collectors.

Programs must also offer mail-back services for covered drugs via a toll-free call center and website. § 6(3)(e). Programs must provide a mail-back program for all retail pharmacies that offer to distribute prepaid, preaddressed mailers. § 6(3)(e).

Finally, to the extent permissible under applicable state and federal laws, programs must provide alternative collection methods for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles, through a mail-back program, or at periodic collection events. § 6(3)(f). The Department must review and approve of any such alternative collection methods before their implementation. § 6(3)(f).

Disposal

Programs must dispose of covered drugs at a permitted hazardous waste disposal facility that meets federal requirements as of the effective date of the law. § 8(1). If disposal at a hazardous waste disposal facility is infeasible based on cost, logistics, or other considerations, the Department may also grant approval for disposing of some or all collected covered drugs at a permitted large municipal waste combustor facility meeting federal requirements as of the effective date of the law. § 8(2). Program operators may also petition for approval for final disposal technologies or processes that provide superior environmental and human health protection than that provided by hazardous waste disposal facilities or permitted municipal waste combustors, or equivalent protection at less cost. § 8(3). The law lays out the relevant considerations and criteria for approving such a petition. § 8(3).

Education and Promotion

Each program must provide a system of promotion, education, and public outreach about the safe storage and secure collection of covered drugs. § 7(1). The law requires each program to, at a minimum: promote the safe storage of drugs; discourage residents from disposing of covered drugs in solid waste collection, sewer, or septic systems; promote the use of the program; establish a toll-free telephone number and website; prepare educational and outreach materials on these topics; disseminate such materials to pharmacies, health care facilities, and other interested parties; and, work with authorized collectors to develop the collection receptacle design and instructions. § 7(2).

Pharmacies, other entities that sell medication in Washington, and local health jurisdictions and governmental bodies are encouraged to promote secure disposal of covered drugs through one or more approved programs. §§ 7(3), 7(4). State agencies responsible for health, solid waste management, and wastewater treatment must, through their standard educational methods, promote safe storage, secure disposal through a drug take-back program, and the phone number and website for approved programs. § 7(4). The Department must also conduct a survey of covered entities and a survey of pharmacists, health care providers, and veterinarians, after the first year and every two years thereafter to evaluate public awareness and the programs.

Fees and Reporting

Manufacturers will be required to submit an annual report by July 1st after the first full year of implementation and each July 1st thereafter. § 10.

Manufacturers will also be required to pay a fee to reimburse the Department's administration, oversight, and enforcement costs associated with the program by October 1, 2019, and annually thereafter. § 12(1). By July 1, 2019, the Department will set the annual fee to recover the costs associated with administration, oversight, and enforcement. § 12(1). The costs recovered by the Department will include the costs of administering the public awareness surveys. § 12(1). The Department will not, however, impose fees in excess of its actual administrative, oversight, and enforcement costs, and the fees collected from each program operator in 2020 and later years may not exceed ten percent of the program's annual expenditures, as provided in the annual report. § 12(b). The fees may be adjusted annually and will be deposited in a secure drug take-back program account. §§ 12(1)(c), 12(c), 13.

Preemption

Drug take-back ordinances already exist in several counties in Washington, including King, Kitsap, Pierce, Whatcom, Clallam, and Skagit. For 12 months after a drug take-back program approved by the state begins operating, a county may enforce a grandfathered ordinance (i.e., an ordinance that is in effect on the effective date of the state law, and meets or exceeds the requirements of the state law with respect to safe and secure collection and disposal). §§ 16(1)(a), 16(4). During that time, compliance with the grandfathered ordinance will satisfy the state requirements. § 16(1)(a). In such a county enforcing a grandfathered ordinance, the program operator of a state-approved take-back program must work with the county and the Department to incorporate the local program into the state-approved program on or before the end of the 12-month period. § 16(1)(b).

At the end of the 12-month period, the state law will preempt all existing or future laws enacted by a county, city, town, or other political subdivision of the state regarding a drug take-back program or other program for the collection, transportation, and disposal of covered drugs, or promotion, education, and public outreach relating to such a program. § 16(3).

Additionally, after the state law goes into effect, no political subdivision may enact or enforce a local law requiring a retail pharmacy, clinic, hospital, or local law enforcement agency to provide for collection and disposal of covered drugs from entities covered under the state law. § 16(2). As noted above, the state law itself does not require any person or entity to serve as a collector. § 6(1)(b).

Enforcement

If a covered manufacturer fails to participate in a program, the Department will provide written notice. § 11(2)(a). If the covered manufacturer continues to sell a covered drug in or into Washington without participating in a program, the Department may assess a penalty. § 11(2)(b).

If the Department determines that a program is in violation of the law or that it does not conform to the approved proposal, the Department may send a written notice of warning. § 11(3)(a). If the program does not come into compliance, the Department may assess a penalty on the program operator and on participating covered manufacturers. § 11(3)(a). If the Department determines that a program is in violation of the law and the violation creates a condition that constitutes an immediate hazard to the public or the environment, the Department may immediately suspend operation of the program and assess a penalty. § 11(3)(b).

Drug wholesalers and retail pharmacies may also be subject to penalties for failure to provide a list of drug manufacturers to the Department. § 11(4).

In particular, in enforcing the Act, the Department may require a person or entity to engage in or refrain from engaging in certain activities and may assess a civil fine of up to $2,000 per day. § 11(5)(b)–

(d). The Department also has authority to require an informal administrative conference. § 11(5)(a). The Department may not, however, prohibit a covered manufacturer from selling a drug in or into Washington. § 11(5)(d).

Beveridge & Diamond's Pharmaceuticals and Health Care industry group assists pharmaceutical companies on a wide range of environmental and product-related matters in the US and overseas. For more information, please contact the authors.