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EPA Finalizes Management Standards for Hazardous Waste Pharmaceuticals

On December 12, 2018, the Environmental Protection Agency (EPA) released its long-awaited Management Standards for Hazardous Waste Pharmaceuticals Rule. This Rule creates streamlined management standards for hazardous waste pharmaceuticals (HWPs), adding new operational complexities for "health care facilities" and "reverse distributors." The Rule's application is limited to entities that fall under those two terms: it does not apply directly to pharmaceutical manufacturers or households generating pharmaceutical waste. It will, however, indirectly impact pharmaceutical manufacturers that rely on reverse distributors for credit processing and recall management.

In conjunction with the final management standards, the EPA eased regulatory burdens by amending the P075 hazardous waste listing to remove FDA-approved, over-the-counter (OTC) nicotine replacement therapies (NRTs) (nicotine patches, gums, and lozenges). This means that these NRT products will not be considered hazardous waste (HW) when discarded. As a "p-listed waste," NRTs were classified as acutely hazardous, and just 1 kg of acutely hazardous waste generated per month pushes a facility into the most stringently regulated large quantity generator (LQG) status. Now, NRTs will not impact generator status and can be discarded with a retail store's municipal waste.

Who Will the New Management Standards Apply To?

Health care facilities

The final Rule applies to very broad group of entities termed "health care facilities." As expected, health care facilities are entities that provide treatment or care to humans or animals or dispense pharmaceuticals: from hospitals to retail pharmacies. The EPA also includes drug compounders and long-term care facilities (LTCFs) in the definition of health care facility. Unlike the proposed Rule, coroners and medical examiners are not included.

Health care facilities that are above the very small quantity generator (VSQG) threshold will be significantly impacted by the Rule. The VSQG threshold is exceeded when a facility generates more than 100kg of HW per month, more than 1kg of acute HW per month, or more than 100 kg of acute HW spill material. For health care facilities, the facility must combine both HWPs and other HWs and determine whether it qualifies as a VSQG. Health care facilities that exceed the VSQG threshold must prepare to notify the EPA (within 60 days of the effective date of the Rule or in its biennial report) and implement the new standards.

The inclusion of LTCFs is significant because it will change management practices for LTCFs with more than 20 beds. (LTCFs with 20 or fewer beds are presumed to be VSQGs.) Under this new Rule, LTCFs cannot use the household hazardous waste exemption for HWPs from its central pharmacy or in the custody of the LTCF on behalf of a resident.

Health care facilities that are VSQGs may opt into the new standards but are otherwise largely free from Resource Conservation and Recovery Act (RCRA) regulation, and under this Rule, only subject to the sewering prohibition and new "RCRA empty" provisions. Unfortunately, nothing in the new Rule prevents a state—as some already do—from taking a more stringent approach and applying the new management standards to VSQGs.

Reverse distributors

Reverse distributors are entities that process prescription (Rx) pharmaceuticals for the facilitation or verification of manufacturer credit. Notably, the definition of reverse distributors is limited to Rx pharmaceuticals, as—in a change from the proposed to final Rule—the EPA has essentially carved out OTC pharmaceuticals, which the EPA understands to be managed by reverse logistics providers, not reverse distributors. Under the Rule, reverse distributors include wholesale distributors and third-party logistics providers when those entities perform the function of a reverse distributor.

It's important for such entities providing Rx pharmaceutical credit facilitation or verification to become familiar with the new standards, adjust operations, and notify the EPA within 60 days of the Rule's effective date. Unlike health care facilities, it does not matter whether a reverse distributor could qualify for VSQG status because the Rule applies to all reverse distributors.

What Are the New Management Standards?

Health care facilities

Under the new standards, health care facilities are subject to new, differing standards for potentially creditable HWPs and non-creditable HWPs; they are not subject to full RCRA Subtitle C requirements. For potentially creditable HWPs, no accumulation limits, container standards, or labeling requirements apply, although states may impose these requirements. Considered solid waste, these potentially creditable HWPs can be shipped to a reverse distributor without a manifest or hazardous waste transporter. Yet issues may arise if the carrier's terms of carriage prevents the transport of (solid) waste. There are minimum recordkeeping requirements for shipping papers and delivery confirmation of potentially creditable HWP shipments.

For non-creditable HWPs, which cannot be sent to reverse distributors, there are minimum container standards and "Hazardous Waste Pharmaceutical" labeling requirements, and non-creditable HWPs can only be accumulated for one year. These non-creditable HWPs cannot be sent to a reverse distributor. When transported for disposal, a uniform hazardous waste manifest is required, but the waste code can just state "PHARMS." Health care facilities do not have to characterize non-creditable HWPs by waste code and can elect to manage both hazardous and non-hazardous non-creditable pharmaceuticals together. The quantity of waste pharmaceuticals managed under the new standards doesn't count toward LQG status; in other words, once a health care facility is above VSQG status, the quantity of pharmaceutical waste generated does not trigger more stringent regulation.

Reverse distributors

Reverse distributors will have the most significant regulatory burdens under the Rule. They will be required to inventory and evaluate potentially creditable HWPs within 30 calendar days of receipt and maintain an inventory. Once evaluated, the HWPs may only be accumulated for 180 days on site. Also, HWPs that are aged on site may be kept 180 days past expiration. Reverse distributors must implement performance-based security requirements and have other requirements akin to an LQG: submit biennial reports, maintain contingency plans and emergency procedures, train employees, and inspect evaluated HWP storage areas weekly. However, the EPA is also reducing some reverse distributors' burdens by allowing waste codes to be added to containers any time during accumulation, a process that can be performed by a waste vendor.

What Are the Key Features?

Changes point of waste generation for Rx pharmaceuticals

The EPA has historically taken the position—in guidance—that reverse distribution systems do not trigger RCRA regulation until a credit determination, and a related discard determination, is made. Only at this point does a pharmaceutical become waste. This position has enabled drugs to flow freely to reverse distributors for appropriate processing, without triggering waste regulation.

The final Rule changes this position for Rx drugs, which the EPA now deems solid waste at a health care facility. On the other hand, OTC drugs are considered a product (i.e., not waste) until a reverse logistics center makes a discard decision. However, those OTC drugs must have a reasonable expectation of use/reuse. Placing drugs in such multiple regulatory categories at a health care facility may quickly lead to challenges for on-the-ground implementation and management.

Eliminates LQG status for hazardous waste pharmaceuticals

The Rule eliminates the distinction between small quantity generator (SQG) and large quantity generator (LQG) statuses. The management standards are much less stringent than LQG restrictions and apply to all reverse distributors and all health care facilities that are not VSQGs, regardless of the quantity of hazardous waste pharmaceuticals they generate. To obviate the need to track the quantity of waste generated, health care facility VSQGs can opt into the new standards.

Exempts drugs subject to FDA or CPSC recalls

In drafting the Rule, the EPA looked to the Food and Drug Administration's (FDA) and Consumer Product Safety Commission's (CPSC) oversight of recalls and determined that the RCRA will not apply to HWPs subject to a voluntary or federally mandated recall until a decision is made to send those HWPs for destruction. The EPA is allowing a similar grace period for HWPs subject to judicial holds, preservation orders, and investigations. This codification provides certainty and regulatory relief—at least at the federal level—for drug manufacturers managing recalls and the storage of HWPs for other specified legal purposes.

Creates conditional exemption for controlled substances

As indicated in the proposed Rule, the EPA has finalized a conditional exemption from hazardous waste regulation for those drugs that are both a controlled substance and HW upon discard, so long as they are managed and disposed of in compliance with the Secure and Responsible Drug Disposal Act regulations at a combustor or incinerator. This exclusion also applies to controlled substances from ultimate users that are mixed with non-controls and collected by a collector registered with the Drug Enforcement Administration (DEA). This exclusion eliminates a challenging EPA/DEA dual regulatory scheme, reducing waste management burdens and disposal costs.

Reduces "RCRA empty" requirements for containers that held hazardous waste pharmaceuticals

Recognizing how challenging it is for health care facilities to have "RCRA empty," triple-rinsed medical devices, syringes, and paper cups, and how easily p-listed residues in non-empty containers push health care facilities into LQG status, the EPA reduced its RCRA empty requirements. Under the Rule, a bottle, vial, ampule, or unit-dose container is considered empty, and the residues are not regulated as hazardous waste, if the pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container. The EPA specifies different empty rules for syringes and IV bags. In short, containers no longer need to be triple-rinsed, easing regulatory burdens on health care facilities.

Prohibits sewering

The Rule notably prohibits sewering of all hazardous waste pharmaceuticals. This restriction applies broadly to all health care facilities and reverse distributors, including VSQG health care facilities.

When Will the Rule Become Effective?

The Rule will become effective at the federal level, and the sewering prohibition will apply in all states, six months after publication in the *Federal Register*. Authorized states must subsequently adopt the Rule's management standards and modify their state regulations. Until this occurs, the new standards will not apply in the state. Because the amendment to P075 to exclude FDA-approved OTC NRTs is less stringent than current regulations, states are not required to adopt the amendment. States can—and very well may—retain NRTs' status as acute hazardous waste. States can also, in updating their regulations, include more stringent requirements than the federal standards. Because the RCRA allows states to impose more stringent standards, health care facilities and reverse distributors should closely monitor implementation in each state of operation and implement state-by-state management changes accordingly. This development and the considerations it engenders may support defendants' efforts to convince the government to dismiss FCA cases.

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If you have any questions or would like additional information, please contact your Alston & Bird attorney or any of the following:

Environment, Land Use & Natural Resources Group

Doug Arnold
404.881.7637
doug.arnold@alston.com

Paul Beard
916.498.3354
paul.beard@alston.com

Meaghan Goodwin Boyd
404.881.7245
meaghan.boyd@alston.com

Nicki Carlsen
213.576.1128
nicki.carlsen@alston.com

Edward Casey
213.576.1005
ed.casey@alston.com

Nicole DeMoss
404.881.4945
nicole.demoss@alston.com

Jeffrey Dintzer
213.576.1063
jeffrey.dintzer@alston.com

Skip Fulton
404.881.7152
skip.fulton@alston.com

Maureen Gorsen
916.498.3305
maureen.gorsen@alston.com

Ronnie Gosselin
404.881.7965
ronnie.gosselin@alston.com

Maya Lopez Grasse
213.576.2526
maya.grasse@alston.com

Nate Johnson
213.576.1151
nate.johnson@alston.com

Clay Massey
404.881.4969
clay.massey@alston.com

Kevin S. Minoli
202.239.3760
kevin.minoli@alston.com

Clynton Namuo
213.576.2671
clynton.namuo@alston.com

Elise Paeffgen
202.239.3939
elise.paeffgen@alston.com

Geoffrey Rathgeber
404.881.4974
geoff.rathgeber@alston.com

Max Rollens
213.576.1082
max.rollens@alston.com

Phil Sandick
404.881.7632
phil.sandick@alston.com

Jocelyn Thompson
415.243.1017
jocelyn.thompson@alston.com

Andrea Warren
213.576.2518
andrea.warren@alston.com

Jonathan Wells
404.881.7472
jonathan.wells@alston.com

Matt Wickersham
213.576.1185
matt.wickersham@alston.com

Food, Drug & Device/FDA Group

Cathy L. Burgess
202.239.3648
cathy.burgess@alston.com

Brendan Carroll
202.239.3216
brendan.carroll@alston.com

Daniel G. Jarcho
202.239.3254
daniel.jarcho@alston.com

Justin Mann
202.239.3115
justin.mann@alston.com

Seth Olson
202.239.3734
seth.olson@alston.com

Marc J. Scheineson
202.239.3465
marc.scheineson@alston.com

ALSTON & BIRD

WWW.ALSTON.COM

ATLANTA: One Atlantic Center ■ 1201 West Peachtree Street ■ Atlanta, Georgia, USA, 30309-3424 ■ 404.881.7000 ■ Fax: 404.881.7777
BEIJING: Hanwei Plaza West Wing ■ Suite 21B2 ■ No. 7 Guanghua Road ■ Chaoyang District ■ Beijing, 100004 CN ■ +86 10 8592 7500
BRUSSELS: Level 20 Bastion Tower ■ Place du Champ de Mars ■ B-1050 Brussels, BE ■ +32 2 550 3700 ■ Fax: +32 2 550 3719
CHARLOTTE: Bank of America Plaza ■ 101 South Tryon Street ■ Suite 4000 ■ Charlotte, North Carolina, USA, 28280-4000 ■ 704.444.1000 ■ Fax: 704.444.1111
DALLAS: Chase Tower ■ 2200 Ross Ave. ■ Suite 2300 ■ Dallas, Texas, USA, 75201 ■ 214.922.3400 ■ Fax: 214.922.3899
LOS ANGELES: 333 South Hope Street ■ 16th Floor ■ Los Angeles, California, USA, 90071-3004 ■ 213.576.1000 ■ Fax: 213.576.1100
NEW YORK: 90 Park Avenue ■ 15th Floor ■ New York, New York, USA, 10016-1387 ■ 212.210.9400 ■ Fax: 212.210.9444
RALEIGH: 555 Fayetteville Street ■ Suite 600 ■ Raleigh, North Carolina, USA, 27601-3034 ■ 919.862.2200 ■ Fax: 919.862.2260
SAN FRANCISCO: 560 Mission Street ■ Suite 2100 ■ San Francisco, California, USA, 94105-0912 ■ 415.243.1000 ■ Fax: 415.243.1001
SILICON VALLEY: 1950 University Avenue ■ 5th Floor ■ East Palo Alto, California, USA, 94303-2282 ■ 650-838-2000 ■ Fax: 650.838.2001
WASHINGTON, DC: The Atlantic Building ■ 950 F Street, NW ■ Washington, DC, USA, 20004-1404 ■ 202.239.3300 ■ Fax: 202.239.3333