



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



May 21, 2018

Attention: Richard LaShier and Barnes Johnson
U.S. Environmental Protection Agency
Office of Resource Conservation and Recovery
Docket ID No. EPA-HQ-OLEM-2016-0177; FRL-9965-27-OLEM
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: The Retail Associations' Request for Enforcement Discretion on the User Fee Effective Date for the Electronic Hazardous Waste Manifest System, Docket Number EPA-HQ-OLEM-2016-0177; FRL-9965- 27-OLEM

Dear Messrs. LaShier and Johnson:

On behalf of our members, the National Association of Chain Drug Stores ("NACDS") and the Retail Industry Leaders Association (collectively the "Retail Associations") are writing to the U.S. Environmental Protection Agency's ("EPA") Office of Resource Conservation and Recovery ("ORCR") to ask for enforcement discretion for EPA's scheduled effective date for applying a fee schedule for user fees for the electronic hazardous waste manifest system ("e-Manifest System"). Generally, until retailers and pharmacies are able to use existing e-Manifest systems to submit e-Manifests to ORCR, we believe the Agency should grant enforcement discretion and only charge a user fee of \$4.00 per manifest per location, regardless of whether that manifest is in the non-electronic form of a data file upload, image upload, or mailed paper. Once ORCR provides appropriate guidance and authorization for retailers and pharmacies to file e-Manifests using existing systems, ORCR should then charge the higher user fee rates for non-electronic manifests and the \$4.00 rate for e-Manifests, as outlined in the January 3, 2018 Final Rule on User Fees, for the e-Manifest System.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries.

RILA is an organization of the world's most successful and innovative retailer and supplier companies – the leaders of the retailer industry. RILA members represent more than \$1.5 trillion in annual sales and operate more than 100,000 stores, manufacturing facilities, and distribution centers nationwide. Our member retailers and suppliers have facilities in all 50 states and the District of Columbia, as well as internationally, and employ millions of workers domestically and worldwide.

On January 3, 2018, ORCR published a Final Rule establishing a timeline and methodology for assessing user fees for use of the e-Manifest system. Those fees range from an estimated \$4.00 fee per manifest per location for electronic manifests to an estimated \$20.00 fee per manifest per location for mailed paper manifests. The effective date of the user fees is June 30, 2018.

Despite a rapidly approaching effective date, the ORCR e-Manifest System is not yet fully functional. Accordingly, unless the system becomes fully functional in less than two months, retailers and pharmacies will be unable to file electronic manifests and pay the \$4.00 fee. Rather, they will be forced to submit their manifests non-electronically, incurring additional costs per manifest per location, paying as much as \$16.00 more per manifest per location than if the pharmacy or retailer had filed an e-Manifest.

Even if the e-Manifest System is fully functional by June 30, it is impractical and unreasonable to expect pharmacies and retailers to be ready to directly use ORCR's e-Manifest System to file e-Manifests. To do so would require treatment, storage, and disposal facilities ("TSDF") to submit massive amounts of retailer and pharmacy location-specific data to ORCR's e-Manifest system, a time consuming and unnecessary process that would take industry much longer than two months to complete. Instead, the more efficient and better course of action is to allow TSDFs to use their existing e-Manifest systems, with existing complete retailer and pharmacy location data, to submit e-Manifests to ORCR. This allows TSDFs to leverage existing systems with the same end result as directly using ORCR's e-Manifest System, the electronic submission of manifests to ORCR. Based on informal meetings between various stakeholders and ORCR staff, we understand that ORCR recognizes the great burden on stakeholders to force them to directly use ORCR's e-Manifest System, and that ORCR has no objection to industry using existing e-Manifest systems to submit electronic manifests.

Unfortunately, industry is unable to use their existing e-Manifest systems to file e-Manifests with ORCR and there is no reason to believe that this situation will change in the next two months. First, ORCR has yet to provide industry with programming instructions to allow industry to use existing e-Manifest systems to interface with ORCR's e-Manifest System. Second, ORCR has yet to communicate to industry an acceptable technical option for pharmacies and retailers to electrically sign e-Manifests in order to meet the electronic signature standards as set forth in the Cross-Media Electronic Reporting Rule ("CROMERR"). Presently, there is no lawful method for pharmacies and retailers to e-sign manifests for electronic submission. Without ORCR action on these two issues, pharmacies and retailers cannot submit e-Manifests using existing e-Manifest systems and are forced to use a non-electronic method for filing e-Manifests with a corresponding higher user fee.

Members of the Retail Associations are ready to embrace the e-Manifest System. However, they need additional guidance and standards from ORCR to use existing e-Manifest systems to interface with ORCR's e-Manifest System. Given the need for ORCR action, the Retail Associations ask ORCR to delay fully implementing the e-Manifest fee schedule until ORCR is able to provide industry with complete programming instructions and a technical option for e-signatures that meets the CROMERR standard. Until that time and until industry has sufficient time to prepare for existing systems to interface with

ORCR's e-Manifest System, we ask that ORCR impose a single \$4.00 fee per manifest per location regardless of the form of that manifest. Even if a pharmacy or retailer is able to use data file uploads instead of e-Manifests, under the existing fee schedule, that pharmacy or retailer would be required to incur an additional \$3.00 fee per manifest per location. For a retailer or pharmacy with 10,000 stores and multiple manifests per store filed multiple times per year, the additional cost from being unable to file e-Manifests could be hundreds of thousands of dollars per year for that single pharmacy or retailer. Obviously, these costs are even higher if the pharmacy or retailer is forced to use mailed paper manifests, as those manifests carry an even higher fee than data file uploads.

EPA recognized the need for regulatory relief for retailers and pharmacies in the September 2016 publication of the "Strategy for Addressing the Retail Sector under RCRA's Regulatory Framework", which outlined measures that EPA was taking, or intended to take, to address retail sector issues. EPA also recognized the particular challenges for pharmacy retailers in the preamble of the Proposed Pharmaceutical Waste Rule. Without the regulatory relief from the Pharmaceutical Waste Rule, pharmacy chains often trigger Large Quantity Generator ("LQG") requirements due to very small amounts of nicotine replacement therapy wastes that are currently classified as acutely hazardous. Although they generate less than 1% of the hazardous waste manifested across all generators, retail chains have the largest amount of individual location sites, and consequently, the largest number of manifests. As discussed in comments on the e-Manifest Proposed Rule provided by the Environmental Technology Council, retailers generate very small amounts of waste that are often required to be manifested separately in order to meet disposal requirements. For example, separate manifests are needed for controlled substances to ensure compliance with Drug Enforcement Agency regulations. As a result, a typical pickup will have two to three manifests for less than 200 pounds of waste. These unique disposal and regulatory requirements, combined with pick-ups every 90 days across thousands of facilities, result in tens of thousands of manifests annually for retailers to ship very small quantities of waste. On this scale, the difference between a \$20 fee per manifest and a \$4 fee per manifest is material and should be a factor in EPA's decision to use enforcement discretion to delay fully implementing the manifest fee schedule.

In conclusion, we thank you for your consideration of our enforcement discretion request. We look forward to working with ORCR to implement a fully functional e-Manifest system in the future, once additional programming instructions are available, and a technical e-signature option is available that is CROMERR-compliant.

Sincerely,

A handwritten signature in cursive script that reads "Chris Smith".

Christopher R. Smith, J.D., LL.M.
Director of Federal Public Policy
National Association of Chain Drug Stores

A handwritten signature in blue ink, appearing to read "Austen Jensen". The signature is fluid and cursive, with the first name "Austen" being more prominent than the last name "Jensen".

Austen Jensen
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