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EASTERN DISTRICT OF CALIFORNIA

SEALED

6 Attorneys for Plaintiff
United States of America
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9 IN THE UNITED STATES DISTRICT COURT
10 EASTERN DISTRICT OF CALIFORNIA
11

12 UNITED STATES OF AMERICA,
13 Plaintiff,
14 v.
15 STERICYCLE, INC.,
16 Defendant.

CASE NO. 2:26-cr-0043-DC
UNITED STATES' PRE-HEARING BRIEF
DATE: May 29, 2026
TIME: 9:30 a.m.
COURT: Hon. Dena Coggins

UNDER SEAL

17
18 **I. INTRODUCTION**

19 This matter is set for an entry of a deferred prosecution agreement (“DPA”) on May 29, 2026. In
20 advance of the hearing, the government offers this brief setting forth a summary of the relevant
21 procedural history and the government’s recommended order of events for the hearing.

22 **II. PROCEDURAL HISTORY**

23 The United States began a parallel criminal and civil investigation into Stericycle Inc., a corporate
24 defendant, in 2019. The investigations focused on Stericycle’s handling of controlled substances,
25 including its use of a nationwide transportation network that included temporary storage facilities that
26 were not registered with the DEA, and its failure to notify the DEA of certain diversion and losses of
27 controlled substances. During this criminal investigation, the United States executed a criminal search
28 warrant of one of Stericycle’s unregistered facilities in Rancho Cordova on February 11, 2020.

1 Following extensive negotiations between the United States and Stericycle, the parties have reached
2 corporate settlements resolving the government’s parallel investigations into the company’s misconduct.

3 Pursuant to the DPA,¹ Stericycle has agreed with the government to be charged by information.
4 The United States filed a sealed Information in the above-captioned case on April 9, 2026. The
5 Information charges Stericycle Inc, a corporate defendant, with one count of conspiracy to defraud the
6 United States, in violation of 18 U.S.C. § 371. The matter is currently scheduled for an arraignment on
7 the Information and a waiver of indictment on May 28, 2026 before the duty magistrate judge, and for a
8 hearing regarding the entry of the DPA on May 29, 2026 before this Court.

9 Under the civil settlement² with the United States, Stericycle agrees to pay \$37,810,000 to resolve
10 civil liability under the Controlled Substances Act relating to registration, record-keeping, and
11 security. These provisions are designed to minimize the risk of diversion and to facilitate the prompt
12 discovery and reporting of any diversion incidents regarding controlled substances.

13 **III. KEY TERMS OF THE DPA**

14 Stericycle, Inc. has agreed to be charged by information and to waive its right to indictment.
15 Pursuant to the fully executed DPA, Stericycle, Inc. also (a) knowingly waives its right to a speedy trial
16 pursuant to the Sixth Amendment, Title 18, United States Code, Section 3161, and Federal Rule of
17 Criminal Procedure 48(b); (b) knowingly waives any objection with respect to venue to any charges by
18 the United States arising out of the conduct described in the Statement of Facts (Attachment A to the
19 DPA); and (c) agrees that the charge in the Information and any charges arising from the conduct
20 described in the Statement of Facts are not time-barred by the applicable statute of limitations on the date
21 of the signing of the DPA.

22 The company has also agreed to maintain a Corporate Compliance Program that meets the criteria
23 set forth in Attachment C to the DPA. Additionally, the company has agreed to cooperate fully with the
24 United States in any and all matters relating to the conduct described in the DPA, the Statement of Facts,
25 and other conduct under investigation by the United States at any time during the DPA term until the
26

27 ¹ The partially executed agreement is already filed in this case. The United States will file a fully-
executed version prior to the May 29, 2026 hearing.

28 ² For the Court’s reference, a partially executed civil settlement is attached hereto as Exhibit 1.

1 later of the date upon which all investigations and prosecutions arising out of such conduct are
2 concluded, or the end of the term.

3 Under the DPA, the United States agrees to defer prosecution of the company pursuant to these
4 and other terms and agrees to dismiss the Information as to the defendant after a period of time not to
5 exceed 1.5 years, if all terms of the DPA are satisfied.

6 In anticipation of the DPA hearing, the government respectfully submits the following overview for
7 the Court:

- 8 • Waiver of Indictment by Stericycle, Inc. (to be completed on May 28, 2026, before the duty
9 magistrate).
- 10 • Form: Deferred Prosecution Agreement
 - 11 ○ One-year term
 - 12 ○ Parties request **waiver of speedy trial** for Term of DPA, a total of 18 months; the one-
13 year term of the DPA plus an additional six months for the government to dismiss the
14 information if the defendant complies with the terms of the DPA (DPA Paragraphs 2 and
15 16)
- 16 • Attachments to the DPA:
 - 17 ○ Attachment A: Statement of Facts
 - 18 ○ Attachment B: Certificate of Corporate Resolutions for Stericycle, Inc.
 - 19 ○ Attachment C: Corporate Compliance Program
 - 20 ○ Attachment D: Compliance Reporting Requirements
 - 21 ○ Attachment E: Disclosure Certification Form
 - 22 ○ Attachment F: Compliance Certification Form
 - 23 ○ Attachment G: Acknowledgement and Guaranty
- 24 • Charge in the Information:
 - 25 ○ **Sole Count:** 18 U.S.C. § 371 (conspiracy to defraud the United States)
- 26 • **Penalty Agreed to in DPA:**
 - 27 ○ Criminal Penalty: \$19,080,000

28 //

Criminal Penalty Calculation:

a. Offense Level. Based upon USSG § 2C1.1, the total offense level is 30, calculated as follows:

(a)(2) Base Offense Level	12
(b)(2) Value of benefit received more than \$3,500,000	+18
(Specifically, the parties stipulate and agree that the gain to the Company was \$9,540,000.)	
	—
TOTAL	30

Base Fine. Based upon USSG § 8C2.4(a)(1), the base fine is \$20,000,000.

b. Culpability Score. Based upon USSG § 8C2.5, the culpability score is 8, calculated as follows:

(a) Base Culpability Score	5
(b)(3) the organization had 5,000 or more employees and an individual within high-level personnel of the organization participated in, condoned, or was willfully ignorant of the offense	+5
(g)(3) The organization clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct	-1
	—
TOTAL	9

Calculation of Fine Range:

Base Fine	\$20,000,000
Multipliers	1.80 (min)/ 3.6 (max)
Fine Range	\$36,000,000 / \$72,000,000

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1 **IV. THE ENTRY OF THE DPA HEARING ON MAY 29, 2026**

2 The Government respectfully proposes that the Court consider conducting the proceedings as
3 follows:

- 4 1. Ask for appearances of the parties, including the government, the defendant, Stericycle Inc., and
5 the parent company, Waste Management, Inc.
- 6 2. Allocute the parties, such as by asking the following questions:
 - 7 a. [To the parties] I understand that there is a deferred prosecution agreement between the
8 Government and Stericycle. Is that correct?
 - 9 b. [To the government’s representative] Mr. Anderson, please summarize the Information,
10 the material terms of the DPA, and the mechanics of the cooperation and disclosure
11 requirements set forth in the DPA.
 - 12 c. [To the government’s representative] Mr. Anderson, I see you have signed on behalf of
13 the United States, is that correct?
 - 14 d. [To the defendant’s counsel] Mr. Terwilliger, I understand that you are a representative of
15 the Parent Company, Waste Management Inc., is that correct?
 - 16 e. [To the defendant’s counsel] Ms. Reynolds, I see that you have signed on behalf of
17 Stericycle, Inc., is that correct?
 - 18 f. [To the defendant’s counsel] Ms. Reynolds, who is the company representative?
 - 19 g. [To the defendant’s representative] And I understand you also authorized and prepared to
20 act on behalf of the company?
 - 21 h. [To the defendant’s representative] You are also authorized to waive speedy trial rights to
22 exclude time to allow the deferred prosecution to go forward under the agreement that has
23 been reached?
 - 24 i. [To the defendant’s representative] Do you have before you the deferred prosecution
25 agreement?
 - 26 j. [To the defendant’s representative] Who signed the deferred prosecution agreement on
27 behalf of Stericycle?
 - 28 k. [To the defendant’s representative] Attachment B to the deferred prosecution agreement is

1 a certificate of corporate resolutions for Stericycle approving the execution of the
2 deferred prosecution agreement and authorizing any and all other actions as may be
3 necessary or appropriate. Is this a true and correct copy of a resolution duly adopted by
4 the Board of Directors of Stericycle?

5 1. [To the parties] Does the deferred prosecution agreement contain all the terms and
6 understandings between the parties in this case?

7 m. [To the parties] Is there any reason known to any party as to why the DPA should not be
8 entered today?

9 3. Ask the parties if there is a motion to exclude time under the Speedy Trial Act, 18 U.S. Code §
10 3161(h)(2)³ to November 29, 2027 (a year and a half after the entry of the DPA).

11 4. Conclude the hearing.

12
13 Dated: May 26, 2026

ERIC GRANT
United States Attorney

14
15 By: /s/ ADRIAN T. KINSELLA
16 ADRIAN T. KINSELLA
17 MICHAEL D. ANDERSON
18 ADRIAN T. KINSELLA
19 DAVID E. THIESS
20 Assistant United States Attorneys

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27 ³ The subsection provides for the exclusion of time for “[a]ny period of delay during which
28 prosecution is deferred by the attorney for the Government pursuant to written agreement with the
defendant, with the approval of the court, for the purpose of allowing the defendant to demonstrate his
good conduct.”

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Attorneys for Plaintiff
United States of America

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

STERICYCLE, INC.,

Defendant.

CASE NO. 2:26-CS-0043-DC

UNITED STATES' PRE-HEARING BRIEF

DATE: May 29, 2026
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UNDER SEAL

Exhibit 1: Partially Executed Civil Settlement

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”), by and between (i) the United States of America, acting through the United States Attorney’s Office for the Eastern District of California, on behalf of the Drug Enforcement Administration (“DEA”), on the one hand (the “United States”), and (ii) Stericycle, Inc. (“Stericycle”), on the other hand. The United States and Stericycle are collectively referred to herein as “the Parties,” and each is individually referred to as a “Party.”

RECITALS

A. Stericycle is a business-to-business waste disposal company incorporated in Delaware and headquartered in Bannockburn, Illinois. Stericycle is a wholly owned subsidiary of Waste Management, Inc., which acquired all issued and outstanding shares of Stericycle on or about November 4, 2024.

B. Stericycle offers regulated waste disposal services and, between at least January 1, 2015 and April 6, 2020, acted as a reverse distributor registered with DEA to handle unwanted, unusable, or outdated controlled substances acquired from other DEA registrants. Stericycle’s reverse distribution business that is the subject of the Covered Conduct described below was located within its Environmental Solutions (“ESOL”) business unit, which was sold to another company on April 6, 2020. Within ESOL, Stericycle operated a reverse distribution business referred to as Strong-PAK (“SPAK”), wherein Stericycle collected controlled substances from pharmacies and transported them across the country to its DEA-registered facility in Indianapolis, Indiana for eventual destruction, through a nationwide network of facilities Stericycle owned or controlled.

C. Stericycle is and was at all times relevant to this Agreement required to conduct its operations in accordance with the provisions of the Controlled Substances Act, 21 U.S.C. §

801 *et seq.* (the “CSA”), and the regulations promulgated thereunder. The CSA requires DEA registrants such as Stericycle to comply with strict rules for registration, record-keeping, and security, which are designed to minimize the risk of diversion and to facilitate the prompt discovery and reporting of any diversion incidents that occur.

D. The United States contends that it has certain civil claims against Stericycle related to the handling of controlled substances in Stericycle’s SPAK DEA business for violations of the CSA during the period from January 1, 2015, through April 6, 2020 (the “Relevant Time Period”). Specifically, the United States contends the following:

1. During the Relevant Time Period, Stericycle repeatedly transported controlled substances to and from more than sixty unregistered facilities around the country in a manner inconsistent with Stericycle’s DEA registration and in violation of 21 U.S.C. § 842(a)(2). After picking up controlled substances from its pharmacy customers, Stericycle, contrary to applicable regulations, did not immediately store the controlled substances in accordance with security controls required by regulation or immediately transfer them to Stericycle’s registered location but instead transferred them to other unregistered facilities. (*See* 21 C.F.R. §§ 1317.95.) In many instances, packages of controlled substances were unlawfully transferred multiple times between unregistered Stericycle facilities before being transferred to a registered location.

2. Stericycle failed to obtain DEA registrations for most of the facilities used by Stericycle’s SPAK DEA business during the Relevant Time Period as required by the CSA and accompanying regulations, despite storing controlled substances there for extended periods. Stericycle drivers in the SPAK business also stored controlled substances on trucks parked at personal residences and in public storage lots. In utilizing its nationwide SPAK DEA transportation network to transport and store

controlled substances, Stericycle also repeatedly failed to utilize two employees during the transport of controlled substances for the purposes of destruction as required by regulation (21 C.F.R. §§ 1317.95(b)(2), (3)), repeatedly failed to transport controlled substances without unnecessary stops (21 C.F.R. § 1317.95(b)(1)), and repeatedly failed to destroy controlled substances within 30 days of receipt, as required by regulation (21 C.F.R. § 1317.15(d)).

3. During the Relevant Time Period, Stericycle failed to keep complete and accurate records of its handling of controlled substances as required by law (21 C.F.R. §§ 1305.03, 1317.05).

4. During the Relevant Time Period, Stericycle's unregistered facilities and the SPAK DEA transportation network generally lacked adequate security to store controlled substances in compliance with regulations promulgated under the CSA (21 C.F.R. §§ 1301.71, 1301.72) and multiple diversions occurred as a result. Stericycle reported several diversions but also failed to report thefts and significant losses on multiple other occasions as required by regulation (21 CFR § 1301.74(c)).

E. Stericycle acknowledges and admits to the facts as stated in Appendix A hereto, as well as in the Statement of Facts included as Attachment A to the Deferred Prosecution Agreement entered into between Stericycle and the United States Attorney's Office for the Eastern District California on March 24, 2026 (the "DPA").

F. The United States alleges that, through the acts described in Paragraphs D and E and in Appendix A hereto, Stericycle has committed multiple violations of the CSA, including 21 U.S.C. § 842(a)(2) and 21 U.S.C. § 842(a)(5). The conduct discussed in Paragraph D and E and in Appendix A is referred to herein as the "Covered Conduct."

G. The settlement memorialized in this Agreement is neither an admission of liability by Stericycle nor a concession by the United States that its civil claims are not well-founded.

H. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. In consideration of the obligations of the Parties set forth in this Settlement Agreement, Stericycle agrees to pay the sum of thirty-seven million, eight hundred and ten thousand dollars (\$37,810,000.00) (“Settlement Amount”) to the United States, none of which constitutes restitution. Stericycle shall remit the payment no later than thirty (30) days after the Effective Date of this Agreement, as defined in Paragraph 18 below, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Eastern District of California.

2. Stericycle shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the Settlement Amount.

3. Stericycle also represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the CSA throughout Stericycle’s operations, including, but not limited to, the minimum elements set forth in Attachment C to the DPA.

4. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below and conditioned upon Stericycle’s full payment of the Settlement Amount, the United States fully and finally releases Stericycle, together with its current and former parent corporations, owners, direct and indirect subsidiaries, brother or sister corporations, affiliates, divisions,

corporate members, corporate successors, and assigns of any of them from any civil or administrative monetary claim the United States currently has for the Covered Conduct under the CSA.

5. Notwithstanding the releases given in Paragraph 4 of this Agreement, the following claims of the United States are specifically reserved and are not released in this Agreement:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- d. Any liability of any individual;
- e. Any liability based upon obligations created by this Agreement.

6. Stericycle waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. Should DEA initiate any administrative action, including denial, suspension, or revocation of any DEA registration held by Stericycle based on conduct that occurs after the Effective Date of this Agreement, nothing in this Agreement shall in any way preclude DEA from introducing evidence of any historical conduct on the part of Stericycle, including conduct that gave rise to this Agreement. Should such an administrative proceeding arise, DEA is not precluded from attempting to offer such evidence as additional bases to support its

proposed administrative action. Stericycle does not waive its right to challenge any evidence offered against it in any administrative action or otherwise, except that Stericycle may not take any position or make any statement in connection with such administrative proceeding that 1) contradicts any fact stated in Appendix A hereto, or 2) contradicts the acceptance of responsibility by Stericycle set forth in the DPA or the facts described in the Statement of Facts included as Attachment A to the DPA.

8. Stericycle fully and finally releases the United States and its employees, servants, agents, agencies, and departments from any and all liability for any civil claims, demands, obligations, actions, causes of action, damages, costs, losses, attorneys' fees, interest, and expenses, including any claims for compensatory or punitive damages, which Stericycle has asserted, could have asserted, or may assert related to the Covered Conduct or the United States' investigation or prosecution thereof.

9. Stericycle hereby expressly waives all rights it may have by virtue of Section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

10. Any non-monetary obligations imposed upon Stericycle pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon Stericycle pursuant to all applicable federal, state, and local laws and regulations, including but

not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

11. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of California. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity. Furthermore, this Agreement constitutes the complete agreement between the Parties. This Agreement may not be modified unless the modification is in writing and all Parties agree to such written modification.

13. Each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

15. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Stericycle's successors, transferees, heirs, and assigns.

17. The Parties agree that this Agreement and any information about this Agreement may be released to the public.

18. This Agreement is effective on the date of signature of the last signatory to the Agreement (“Effective Date”). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

ERIC GRANT
United States Attorney

Dated: _____

By: _____

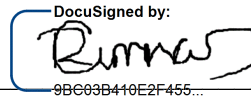
David E. Thiess
Michael D. Anderson
Adrian T. Kinsella
Assistant United States Attorneys

Counsel for the United States

STERICYCLE, INC.

Dated: April 7, 2026

By: _____

DocuSigned by:

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Rafael Carrasco
President and
authorized representative

On Behalf of Stericycle, Inc.

Dated: April 7, 2026

By: _____

Signed by:

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Terra Reynolds
LATHAM & WATKINS LLP

Counsel for Stericycle, Inc.

APPENDIX A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference in the civil Settlement Agreement between the United States of America, acting through the United States Attorney's Office for the Eastern District of California, on behalf of the Drug Enforcement Agency ("DEA"), and Stericycle, Inc. ("Stericycle"). Stericycle agrees that the information contained in this Statement of Facts, as well as in Attachment A to the Deferred Prosecution Agreement entered into between Stericycle and the United States Attorney's Office for the Eastern District of California on March 24, 2026, is true and accurate.

1. Between 2015 and 2020, Stericycle, a waste disposal company headquartered in Illinois and incorporated in Delaware, offered its customers services for regulated waste disposal. Stericycle operated various separate business units through which it received and transported regulated waste, one of which was its Environmental Solutions ("ESOL") business. ESOL was comprised of three segments: (1) Manufacturing and Industrial, (2) Healthcare, and (3) Retail. Within Stericycle's ESOL Retail segment Stericycle operated its Strong-PAK ("SPAK") DEA business, where Stericycle acted as a reverse distributor to collect expired, tainted, excess, or otherwise unneeded controlled substances and transport the controlled substances across the country for eventual destruction through a nationwide network of facilities owned or controlled by Stericycle. These included approximately 44 10-day transfer facilities ("10-days") and approximately thirteen Treatment, Storage, and Disposal ("TSD") facilities. Five of the TSD facilities in Stericycle's nationwide network were registered with the DEA to handle controlled substances at various times. These were located in Detroit, Michigan; Indianapolis, Indiana; Hatfield, Pennsylvania; Houston, Texas; and Warren, Ohio. SPAK DEA controlled substances were primarily transported to Stericycle's Indianapolis, Indiana facility, where the controlled substances were temporarily stored before being transported to third-party destruction facilities.

2. Aside from five facilities, the 10-day and TSD facilities in Stericycle's nationwide network were not registered with the DEA to handle controlled substances. These facilities were permitted to handle hazardous waste under the Resource Conservation and Recovery Act ("RCRA"), but in general were not equipped with appropriate security or personnel to handle controlled substances in a manner compliant with DEA regulations.

Legal Requirements for Reverse Distributors of Controlled Substances

3. Given the inherent risk to public health and safety associated with controlled substances, the handling of controlled substances is tightly circumscribed by the Controlled Substances Act ("CSA"). The regulatory scheme includes strict rules for registration, record-keeping, and security. These rules are designed to minimize the risk of diversion and to facilitate the prompt discovery and reporting of any diversion incidents that occur. Companies such as Stericycle that are registered with the DEA to act as reverse distributors are subject to a number of specific provisions in the Code of Federal Regulations ("C.F.R.") regarding their handling of controlled substances, including:

- 21 C.F.R. §1317.15(a), which requires registration by reverse distributors with the DEA. The

DEA only grants registrations to reverse distributors for a specific location after a thorough inspection to confirm, among other things, that adequate security is present to minimize the risk of diversion, and to obtain information regarding the individuals who will be responsible for controlled substance handling and security;

- 21 C.F.R. §1317.15(c), which requires that, upon acquiring a controlled substance, a reverse distributor shall either (1) “[i]mmediately store the controlled substance, in accordance with the security controls [required by applicable regulations], at the reverse distributor’s registered location or immediately transfer the controlled substance to the reverse distributor’s registered location for secure storage, . . . until timely destruction or prompt return of the controlled substance to the registered manufacturer,” (2) “[p]romptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer’s behalf,” or “[t]imely destroy the controlled substance in a manner authorized” by the applicable regulations;
- 21 C.F.R. § 1317.15(d), which requires reverse distributors to destroy any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt;
- 21 C.F.R. § 1301.12, which requires a registration for each principal place of business where controlled substances are manufactured, distributed, imported, exported, or dispensed;
- 21 C.F.R. § 1301.71, which requires registrants such as Stericycle to provide “effective controls and procedures to guard against theft and diversion of controlled substances”;
- 21 C.F.R. § 1301.72(a), which requires that Schedule I and II controlled substances be stored in either (1) a safe or steel cabinet when small quantities permit, (2) a vault constructed before September 1, 1971, comprised of substantial construction with a steel door, combination or key lock, and an alarm system, or (3) a vault constructed after September 1, 1971, with a number of specifications including walls, floors, and ceilings comprised of at least eight inches of reinforced concrete or other “substantial masonry,” a self-closing and self-locking gate, and an alarm and other devices designed to detect illegal entry;
- 21 C.F.R. § 1301.72(b), which requires that Schedule III, IV, and V controlled substances be stored in either a safe/steel cabinet, a vault as described above, a building with perimeter security that limits access during working hours and has security after hours, or a cage located within a building meeting a number of specifications;
- 21 C.F.R. § 1301.74(c), which requires registrants to notify their local DEA Field Division Office in writing of any “theft or significant loss of any controlled substances” within one business day of discovery of the loss or theft. Within 45 days after discovery of the theft or loss, registrants must file a DEA form, referred to as a “Form 106,” detailing the theft or loss;
- 21 C.F.R. § 1301.90, which describes the need for appropriate employee screening in order to “fairly assess the likelihood of an employee committing a drug security breach” and lists specific questions that should be included in a registrant’s “comprehensive employee screening program”;

- 21 C.F.R. § 1317.95(b)(1), which requires that, if controlled substances are transferred to a registered location for subsequent destruction, “[t]ransportation shall be directly to the registered location” and “the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur”; and
- 21 C.F.R. § 1317.95(b)(2), stating that “two employees of the transporting registrant shall accompany the controlled substances to the registered location.”

4. Registrants are also required to complete a DEA “Form 222” when taking possession of controlled substances and to complete a DEA “Form 41” when disposing of controlled substances.

Stericycle’s Handling of Controlled Substances

5. Stericycle truck drivers that picked up controlled substances from Stericycle’s retail pharmacy customers around the country were authorized to sign the DEA “Form 222s” that indicated receipt of controlled substances by Stericycle’s DEA-registered location in Indianapolis. After pickup, however, Stericycle drivers generally did not transport the drugs directly to the registered location, but to several different points through the chain of largely-unregistered ESOL facilities Stericycle owned or operated en route to eventual destruction in or near Indianapolis.

6. Stericycle’s Indianapolis facility was divided into multiple separate suites that were independently secured and staffed and were connected by locking doors. Although Stericycle listed “Suite A” in Indianapolis as the receiving registrant on the DEA “Forms 222s” that were required to be completed upon Stericycle’s receipt of controlled substances, Stericycle in fact received all controlled substances handled by its SPAK DEA business that arrived in Indianapolis first in an unregistered suite—“Suite D”—in the Indianapolis facility, before the drugs were transferred to the registered location in Suite A. Suite D was a TSD facility that was permitted to handle hazardous waste under RCRA but was not registered with DEA to allow for any receipt or storage of controlled substances.

7. Because most of the ESOL facilities Stericycle used as way stations as the controlled substances were transported through various points en route to destruction were not registered with the DEA, they were not subject to regular inspection by DEA to ensure that security was adequate and that employees were appropriately screened and properly trained in the handling of controlled substances. The unregistered locations through which Stericycle handled controlled substances included an unregistered 10-day facility in Rancho Cordova, California, within the Eastern District of California.

8. The unregistered facilities used by Stericycle’s ESOL business were often lacking in security. They were in many cases parking lots or minimally-staffed warehouses that often had little more than a surrounding chain-link fence to secure them. Some were third-party storage facilities that were not dedicated for Stericycle use and were accessible by the general public. In some cases, the facilities were unmanned.

9. At these facilities, Stericycle often stored controlled substances on unlocked trailers that were parked in the minimally-secured yards. Stericycle drivers also commonly kept controlled substances on their trucks overnight, sometimes for days at time, before offloading them at the local “10-day” facility.

10. Stericycle routinely took more than 30 days to transport SPAK DEA packages from customer pick-up to Stericycle's DEA-registered location at Suite A in Indianapolis. Controlled substances packages routinely remained at Stericycle's unregistered facilities for ten days at a time or longer before being further transferred to the next location. Stericycle often took many weeks or months to transport controlled substances across the country to Indianapolis.

11. Some Stericycle facilities had cameras, but in more than one facility the cameras were non-operational. Although ESOL employees made Stericycle managers aware on multiple occasions that trailers were not consistently locked and cameras were not working, Stericycle failed to take action to remedy these deficiencies.

12. Stericycle also transported controlled substances it picked up from pharmacy customers in cardboard boxes that lacked tamper-proof tape or security seals, which increased the possibility of theft and decreased the likelihood of detection thereof. Stericycle also routinely marked shipments of controlled substances with a hot pink "INDY" sticker that indicated the package was bound for Indianapolis and made it obvious to unscrupulous employees which boxes likely contained drugs. Stericycle did not otherwise implement effective controls or procedures to guard against theft and diversion of controlled substances.

13. The controlled substances were transferred from facility to facility by Stericycle-owned or subcontracted trucks that were driven by single drivers with no accompanying witness as required under the regulation.

14. Stericycle lacked a system for reliably tracking and auditing packages arriving in its DEA registered location in Indianapolis. In cases where packages of controlled substances could not be located for an extended period, Stericycle had a practice of using "Letters to File" to document where shipments of waste, including controlled substances, were "likely" processed, in cases where the company was not able to confirm the packages had been received and destroyed.

15. In November 2018, a Stericycle manager surreptitiously recorded a conversation with Stericycle Assistant General Counsel 1, a lawyer in Stericycle's legal department, and another Stericycle manager, in which Assistant General Counsel 1 admitted that she had "a lot of concerns about the [DEA] process itself," and that if "somebody wanted to take a whole container ... we would never know."

16. Stericycle's failure to establish a compliant system for transporting controlled substances resulted in multiple diversions during the relevant time period. Because of Stericycle's lack of security, unreliable record-keeping, and failure to consistently audit packages received in Indianapolis, it is impossible to reliably determine the full extent of the thefts that may have occurred. There were a number of instances, however, where Stericycle knew thefts had occurred as a result of security failures in its unregistered facilities. Some thefts were properly reported to the DEA and some were not.

17. Diversions that were reported to the DEA included:

- a. A diversion of hundreds of pills and patches of controlled substances from Stericycle's unregistered Birmingham, Alabama facility in September 2015, as

well as a series of diversions from multiple unregistered Stericycle facilities around the country in 2019.

- b. In June 2019, three boxes of controlled substances, including Oxycodone, Hydrocodone, were stolen from a trailer in Stericycle's unregistered Denver facility that had been left backed up to the facility's dock over the weekend, with the trailer doors open. In discussions following this incident, when a Stericycle executive suggested that it would be more secure to build a cage inside the Denver facility, a Stericycle manger responded that the facility was not permitted to store DEA waste.
- c. In September 2019, more than 1000 Oxycodone and Hydrocodone pills were stolen from Stericycle's unregistered facility in Fairburn, Georgia, again after the drugs had been left unattended and poorly secured over a weekend. Two security cameras at the facility were not functioning and had not been working for months leading up to the break-in.
- d. In October 2019, controlled substances including Buprenorphine, Morphine Sulfate, and Vicodin were stolen from Stericycle's unregistered facility in Kansas City, Missouri. The thieves accessed multiple trailers parked in the facility's yard and tampered with 40 boxes of controlled substances, some of which were completely emptied.

18. In several other instances of theft or significant loss, Stericycle failed to file a Form 106 with the DEA as required.

19. Although a number of Stericycle employees and managers, including Stericycle Assistant General Counsel 1, were aware of regulatory issues with the ESOL transportation process and its lack of adequate security, neither were remedied prior to Stericycle's sale of the ESOL business on April 6, 2020.

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