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Drug Supply Chain Security Act Update

The Drug Quality and Security Act was signed into law on November 27, 2013. Title II of this law, the Drug Supply Chain Security Act (DSCSA), introduced several important requirements and controls to the drug supply chain intended to improve security in 2015. (Starting on January 1, 2015, trading partners of a dispenser could only be authorized trading partners, as defined by the DSCSA.) The final phase of the DSCSA, due in November 2023, has a goal to establish an electronic, interoperable system to identify and trace prescription drugs from manufacturing through dispensing, as product is distributed within the United States.

Key features of this federal law include the addition of a "product identifier" to be affixed to every pharmaceutical package (lowest level of sale to a dispenser) in both machine-readable and human-readable formats. The product identifier consists of the combination of the National Drug Code (NDC) (expressed in GS1 standards as a global trade item number), a serial number, the expiration date, and the lot number. The machine-readable format is a GS1 DataMatrix, a two-dimensional (2D) "barcode," that encodes all four of the required data elements. Whereas the primary driver for adding the product identifier is to make a drug product more difficult to counterfeit, this DataMatrix presents the pharmacist with some significant data capture opportunities. Previously, only the NDC could be scanned as part of the receiving and dispensing operations. Now, with a single scan of this "2D barcode," four very important bits of information can be instantly captured upon receiving and/or when dispensing a product to a patient. Consider the possible improvements to inventory management and electronic patient record systems that are on the horizon. Not only is it a more efficient means of data recording, but human error is effectively eliminated for this record keeping.

Other aspects of the DSCSA currently in place include the passing of "T3" data with every transfer of ownership of a pharmaceutical product. T3 is short for:

- transaction information: descriptive data about the product,
- transaction history: prior transactions going back to the original sale, and
- transaction statement: a legal statement required by trading partners promising compliance with all aspects of the DSCSA law.

Pharmacies must now receive T3 data with every delivery of product and retain this data for a minimum of six years. The requirement for T3 data helps to ensure that products are coming from a reputable source and have not been diverted, essentially adding a significant level of control to the supply chain.

T3 data and the affixing of product identifiers also provide a basis for investigation when Food and Drug Administration (FDA) or a trading partner identifies suspicious activity or product in the supply chain. The DSCSA imposes legal responsibility for several activities on dispensers if notified of suspect product by FDA or a trading partner:

- A quarantine process for the product under investigation
- A thorough investigation, including the T3 data
- Notification to FDA within 48 hours when a product is found to be illegitimate
- Prompt notification if the product is cleared
- Investigation records retention for at least six years

A key point on the DSCSA timeline is November 27, 2020. On that date, all dispensers are required by law to ensure additional compliance with the following:

- No product can be received from upstream suppliers unless it is affixed with a product identifier.
- Any investigations of suspect product must include verification of the product identifiers (ensuring that

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USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

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the product identifier is what was affixed by the original manufacturer or repackager).

So, what is the final stage of the DSCSA for implementation on November 27, 2023? FDA must still publish a guidance document describing the final requirements that are yet to be determined. However, the law states that the ultimate solution must include the ability to exchange transaction information and the transaction statements in a secure, interoperable, electronic manner. Also, transaction information in 2023 must include the product identifier for the product being transferred.

Prescription Copy and Transfer – Do the Right Thing!

Patients may request a copy of their prescription for their records and they may wish to transfer their prescriptions to another pharmacy. The rules regarding this action can be referenced in New Jersey Administrative Code (N.J.A.C.) 13:39-7.7 Copies of Prescriptions and/or Patient Profile and 13:39-7.8 Transfer of Prescriptions Between Pharmacies.

13:39-7.7 Copies of Prescriptions and/or Patient Profile

a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions and/or patient profile. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY." For purposes of this section, for requests for prescriptions that are one year or less from the original date of filling, "immediately" shall not exceed 24 hours. For all other prescriptions, "immediately" shall not exceed 72 hours.

b) Presentation of a prescription marked "COPY—FOR INFORMATION ONLY" or a labeled prescription container shall be for information purposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last dispensing pharmacy to transfer the prescription . . .

13:39-7.8 Transfer of Prescriptions Between Pharmacies

a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy, the registered pharmacist-in-charge, and the pharmacist who receives the request for transfer shall immediately comply with the patient's request. For purposes of this section, "immediately" shall not exceed four hours.

Except as provided in the case of controlled substances (see below),

b) . . . a prescription may be transferred between pharmacies, consistent with this section, for one year from the date the prescription was written, provided refills of the prescription are available.

c) A prescription for a Schedule II controlled substances may not be transferred.

d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies . . . A prescription for a Schedule III, IV or V controlled substance that has been transferred shall not be transferred a second time. This prohibition shall not apply to the transfer of such prescriptions between pharmacies engaged in central prescription handling . . . and to pharmacies that share a real-time, online database . . .

Practice Good Record Keeping!

The New Jersey State Board of Pharmacy regulations contain specifics on how to manage, handle, and store patient records and documentation. The following refers to N.J.A.C. 13:39-7.6 Required Records and Documents.

"A pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s), or extern(s) performing the component functions of" prescription:

- ♦ intake,
- ♦ processing,
- ♦ fulfillment, and
- ♦ dispensing

". . . as defined in N.J.A.C. 13:39-4.19, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern . . ."

As per N.J.A.C. 13:39-4.19(d)3,

. . . All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling,

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> the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail. The audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but the off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations[.]

The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)3 is not required to be, but may be, recorded in the audit trail. 13:39-6.15(a)3 states the following demographic information for the patient profile regarding the patient:

- name
- address
- telephone number
- age
- date of birth or age group (infant, child, adult)
- gender
- allergies
- idiosyncrasies of the patient
- any medical conditions that may relate to drug utilization

As described in N.J.A.C. 13:39-7.6(c),

> Computer systems employed for audit trail documentation shall be designed to identify and document the unique and secure identifier for all pharmacists, pharmacy technicians, interns and externs who utilize the system. Computer systems that automatically generate the unique and secure user identifier of a pharmacist, pharmacy technician, intern or extern without requiring an entry by the responsible party are prohibited.

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