APRIL 2025

ARIZONA STATE BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Update Your Profile

In an effort to improve communications with its licensees and permittees, the Arizona State Board of Pharmacy has noticed that contact information in its system is not always current and up to date. The Board reminds you that you are required to update your personal contact information and pharmacy employer within 10 days after a change, pursuant to Arizona Revised Statutes §32-1926. Please use your online profile to update your contact information.

Be on Alert – Scam Letters and/or Phone Calls

Warning: Scammers are using letters, in addition to phone calls, to scam licensees. The Board has recently experienced an increase in the amount of reports from licensees who are receiving scam calls.

In one past incident, the imposter called the pharmacist's cell phone using a caller ID that matched the Board's phone number. The caller claimed to be a Board investigator. The imposter threatened the pharmacist, said the phone was tapped, and claimed that emails were being monitored by the Board. The caller was intimidating and manipulative and connected the pharmacist with another caller who pretended to be a Federal Bureau of Investigation (FBI) agent.

The pharmacist was sent a letter that claimed to be an official notice of suspension. This letter had Board letterhead, a State of Arizona Board of Pharmacy seal, and the licensee number and appeared to

Access the National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation® (NABPF®)

Be on Alert – Scam Letters and/or Phone Calls *(cont)*

have been **signed by the Board's executive director.**

Fortunately, this licensee contacted the Board and confirmed that they were in good standing and not part of any investigation. The licensee also provided the information contained in this alert so that the Board could notify other licensees about this imposter and scam.

Techniques used by fake callers include the following:

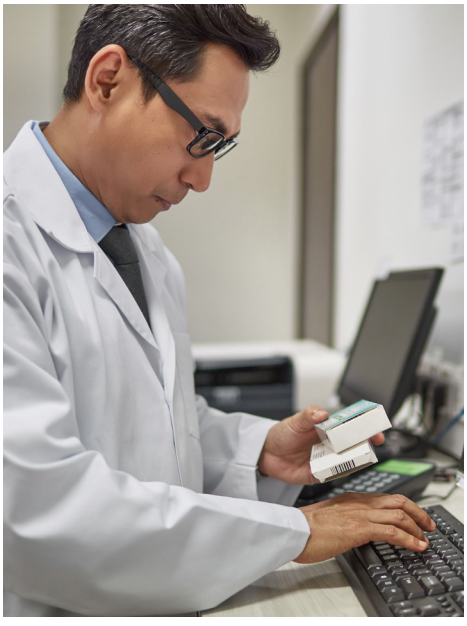
- A caller uses caller ID that shows "AZ State Board of Pharmacy" with the Board's phone number, 602/771-2727.
- The caller claims that a licensee is under investigation by the Board, Drug Enforcement Administration (DEA), FBI, or another government agency. In some cases, the caller also warns of discipline unless the licensee pays a "fine" over the phone.
- A caller warns a licensee not to report the call to anyone "or else [they] will jeopardize the investigation."
- A caller requests a licensee's cell phone number.
- A caller gives a fake callback number.

These calls are scams!
In many cases, callers are attempting to extort money or elicit sensitive, nonpublic information – bank account information, personal addresses, DEA registration numbers, etc – from licensees.

What can you do to protect yourself and your pharmacy?

Licensee security is important to the Board. Be aware of these tips:

- **If you have any doubts or questions about someone claiming – by phone or in person – to represent the Arizona State Board of Pharmacy, call the Board at 602/771-2727.**
- If a scam caller claims to represent DEA or the FBI, report the call to DEA's Extortion Scam reporting program or FBI's Internet Crime Complaint Center.
- If a scam caller's phone number appears to be a Board telephone number, report the scam using the Federal Communications Commission's consumer complaint form.



Information on Clozapine – Risk Evaluation and Mitigation Strategies

Food and Drug Administration (FDA) published the following statement regarding the risk evaluation and mitigation strategies program for clozapine:

> **February 24, 2025** - Beginning today, FDA does not expect prescribers, pharmacies, and patients to participate in the risk evaluation and mitigation strategies (REMS) program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. Information about

Information on Clozapine – Risk Evaluation and Mitigation Strategies

(cont)

severe neutropenia will remain in the prescribing information for all clozapine medicines, including in the existing Boxed Warnings.

Although the risk of severe neutropenia with clozapine still exists, FDA has determined that the REMS program for clozapine is no longer necessary to ensure [that] the benefits of the medicine outweigh that risk. Eliminating the REMS [program] is expected to decrease the burden on the health care delivery system and improve access to clozapine. FDA has notified the manufacturers that the [C]lozapine REMS must be eliminated. FDA has instructed the clozapine manufacturers to formally submit a modification to eliminate the Clozapine REMS and to update the prescribing information, including removing mandatory reporting of ANC blood tests to the REMS program.

In the coming months, FDA will work with the clozapine manufacturers to update the prescribing information and eliminate the Clozapine REMS.

Compliance Corner

2025 is already moving along quickly and so are the legal considerations of the Drug Supply Chain Security Act (DSCSA). In this installment of the Compliance Corner, we will explore what DSCSA is, who is affected, and what regulatory considerations must be met to satisfy DSCSA requirements. Also, several resources are included below to provide additional information. As always, this article should not be construed as legal advice but rather serve as an introduction to DSCSA. The Act is evolving and the information below is based on the information that was available at the time the article was written. Always consult your legal counsel on matters involving DSCSA.

What Is DSCSA?

According to the resource below, DSCSA, enacted in 2013, preempts a 50-state patchwork of pedigree requirements to create one

federal traceability framework for prescription medicines. DSCSA sets out a 10-year timeline to build an electronic, interoperable system for the exchange of transaction documentation (transaction information, transaction history, and transaction statements) to enable the tracing of prescription medicines, serialized at both the case and the smallest unit of sale, throughout the pharmaceutical supply chain. At the end of August 2023, FDA announced a one-year stabilization period. This period extended enforcement flexibility until November 27, 2024, to give supply chain partners time to stabilize data exchange, systems, and processes developed to meet the final implementation requirements of DSCSA. FDA has stated that it intends for trading partners to keep working diligently but also recognizes supply chain readiness gaps and wants to ensure that products continue to move through the supply chain.

Who Is Affected?

Any entity that is involved in the drug supply chain in the United States for human drugs is affected. This includes manufacturers, wholesalers, dispensers, and more. FDA's requirements are different for each business type. For example, manufacturers must keep a pedigree of each medication and what entity each was sold to. Wholesalers must keep records of where they receive drugs and to whom they sell drugs. Dispensers must keep records of where they receive drugs, as well. DSCSA defines a dispenser as a retail pharmacy, a hospital pharmacy, a chain pharmacy group that does not act as a wholesaler, or any other person authorized by law to dispense drugs.

What regulatory considerations must be met to satisfy DSCSA requirements?

Currently, dispensing partners are required to have three key items in place. First, dispensers must verify that the suppliers they are using are legitimate suppliers. Manufacturers and repackagers must be registered with FDA, while wholesalers and third-party logistics report to FDA and must be licensed by the state(s) where they conduct business. Second, dispensers must have and enforce policies and procedures for verifying drug suppliers, purchasing drug products, identifying and investigating suspicious drug products, and appropriate training for applicable employees. Lastly, dispensers must know where the drug pedigree records are stored and be readily able to access those records. There are resources available for anyone to gain education and tools for implementing these requirements.

Several additional requirements for manufacturers, repackagers, and wholesalers, and more information, can be found in the resources provided below.

Additionally, there have been extensions to the enforcement of DSCSA for certain trading partners. However, the three key items above must already be in place. The extensions that are in place pertain only to the electronic reporting capabilities of the entities.

For more information, see the resources below:

- FDA Resources – *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies*
- FDA Waivers and Exemptions – *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period*
- Dispenser Education Web Page – *www.dscsa.pharmacy*
- Dispenser Education Guide – Sign up at *https://pulse.pharmacy/about/sign-up/*

Disciplinary Actions and Updates – Health Boards

Disciplinary actions for the Arizona State Board of Pharmacy can be found here.

Disciplinary actions for the Arizona Medical Board can be found here.

Disciplinary actions for the Arizona Osteopathic Board can be found here.

Disciplinary actions for the Arizona State Board of Dental Examiners can be found here.

Discipline is posted under each license holder.

Board Members

- Lorri Walmsley, RPh, President
- Jeff Anderson, PharmD, RPh, Vice President
- Tarek Al Nassif, RPh, Member
- Tenille Davis, PharmD, RPh, Member
- Stephanie Spark, PharmD, RPh, Member
- Christopher Hogan, RPh, Member
- Kristen Snair, CPhT, Member
- Frank Thorwald, Member (Public)
- Les Braswell, Member (Public)

The Arizona State Board of Pharmacy News is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Kamlesh "Kam" Gandhi, PharmD - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

1110 W Washington St, Ste 260 | Phoenix, AZ 85007 | https://pharmacy.az.gov | kgandhi@azpharmacy.gov