



NABP's Verified-Accredited Wholesale Distributors® (VAWD®) Program: Protecting the Prescription Drug Supply Chain

Maintaining a secure medical supply chain is critical to the health and safety of our nation. Although the United States' medication supply chain is one of the most secure in the world, NABP witnesses firsthand ongoing threats to the integrity of this supply chain. Countering those threats requires a multifaceted approach centered around state licensure and quality assurance measures. NABP's VAWD program is a recognized quality assurance measure utilized to help ensure the integrity of the medications that are dispensed to patients.

The intrusions into the integrity of the medication supply chain include, but are not limited to, falsified transactions that are indispensable elements of drug diversion and counterfeiting schemes. These factors, coupled with emerging globalization, provide a greater opportunity for drugs to enter the supply chain through illegal means and increase the incentive for diversion and criminal networks. The security of the medication supply chain is dependent on robust and comprehensive regulations and standards that must be implemented and enforced through timely deadlines and in the best interest of the patient.

Current Status of VAWD

VAWD accreditation plays a pivotal role in preventing counterfeit drugs from entering the US drug supply: it helps protect the public from drugs that have been contaminated, diverted, or counterfeited. As of July 31, 2018, 634 facilities currently hold VAWD accreditation. All VAWD-accredited facilities are listed on NABP's website at <https://nabp.pharmacy/programs/vawd/vawd-accredited-facilities/>.

The VAWD program has been helping maintain a safe and secure drug supply for 14 years. During this time, the US drug supply has been repeatedly targeted by individuals and organizations trying to compromise the supply chain with counterfeit and diverted, substandard drugs. The VAWD program has served and continues to serve as an effective deterrent to these actions through careful review of application documentation, policies and procedures, drug sources, and detailed on-site surveys of distribution facilities. Throughout the program's history, NABP has discovered counterfeit products and fraudulent transaction histories—and we continue to see evidence of these threats today. The overwhelming success of the VAWD program occurs because of NABP's comprehensive accreditation process that uncovers these threats to the public and shields the public from harm.

How to Succeed in Obtaining VAWD Accreditation

The 634 facilities that achieved VAWD accreditation are a testament that the program works. Achieving VAWD accreditation requires that the applicant operate in compliance with all state and federal laws and regulations and comply with the VAWD criteria.

Some facilities that seek accreditation have minimal knowledge of the VAWD criteria and/or have no experience going through an accreditation process. If a facility has stalled in the VAWD process, it is likely due to a lack of transparency about their supply chain, a lack of compliant policies and procedures, and/or an inability or indisposition to implement compliant policies and procedures.

Timely, transparent, thorough, and responsive submission of all requested information (as outlined on the NABP website) throughout the accreditation process is essential to progress toward accreditation.

Significant delays and cancellations occur when applicants do not elect or are not able to meet these conditions.

Applicants must implement, maintain, and adhere to policies and procedures. Generic policies and procedures that simply restate VAWD requirements and state and federal laws are not sufficient. If the policies and procedures do not reflect the distribution practices of that facility and are not written at the site level, they will not be accepted, and applicants will be subject to cancellation.

Time it Takes to Achieve VAWD Accreditation

Typically, applicants who have prepared for VAWD succeed in earning an award of accreditation within three to six months. They do so by carefully:

- Reviewing the VAWD criteria and requirements posted on the NABP website;
- Reviewing the additional information provided by NABP in advance of application submission, such as the pre-accreditation checklists, which enable applicants to audit and self-assess their degree of readiness before applying;
- Preparing organized, complete policies and procedures and related documentation at the time of application submission, which demonstrate compliance with all state and federal rules and laws applicable to drug distribution;
- Responding in a timely manner to VAWD requests for information or clarification when received;
- Preparing clear, complete, and accurate documentation evidencing a safe supply chain, which includes attesting that the applicant is not purchasing from pharmacies or other distributors not deemed to be fully compliant with laws and regulations governing drug distribution; and
- Implementing detailed steps to prevent the receipt of suspect products, which include:
 - Vetting and knowing their vendors and sources;
 - Performing due diligence with the increasing risk within their drug supply; and
 - Providing documentation evidencing that due diligence has been performed.

Applicants are strenuously encouraged to wait to apply until they are substantially compliant with VAWD.

Applicants that are not prepared for VAWD before submission of application (as outlined above), may take much longer to complete the accreditation process and risk cancellation of their application.

Consultant Services

Some facilities may require additional assistance and coaching in order to achieve VAWD accreditation. There are a number of accreditation consultants and firms offering to provide assistance to applicants with the VAWD application process. There is no guarantee that the use of a consultant will lead to accreditation if an applicant is unwilling or unable to meet the above requirements and demonstrate program compliance.

While consultants may be used, they are prohibited from representing applicants during the application process. NABP requires that applicants work directly with VAWD staff and be able demonstrate knowledge of their processes.

As with any such service, there are qualified and unqualified service providers. VAWD applicants should carefully research prospective consultants. NABP [recommends](#) that applicants investigate the qualifications of consultants, including their knowledge, experience, and success in helping their clients achieve accreditation, which should be

verified. Some applicants that have experienced lengthy accreditation times have seen success after re-evaluating their current consultant services.

Conclusion

The VAWD program remains a critical tool to help ensure the integrity of the prescription drug supply chain. The VAWD accreditation has been earned by hundreds of facilities that:

1. Come to the accreditation process prepared;
2. Have evidenced implementation of policies and procedures that comply with the VAWD criteria; and
3. Are transparent about their supply chain.

VAWD applicants currently in the pipeline that follow similar steps will increase their likelihood of progressing through the accreditation process.