For Immediate Release  
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NCDQS Launches New Wholesale Drug Distributor Accreditation Program and a Wholesale Drug Distributor Inspection Program  

Dover, DE, September 6, 2019 -- The National Coalition for Drug Quality & Security (NCDQS) today announced the launch of two new programs for wholesale drug distributors, the Quality and Security (QAS*) Accreditation and the QAS Inspection. These national programs are important tools in protecting the prescription drug supply chain.  

With a 90-day timeline, the QAS Accreditation offers a robust accreditation process with an efficient, streamlined approach and responsive accreditation team.  

To obtain accreditation, the facility must meet or exceed the program standards (available [here](#)). We will look at the business and facility organization and leadership, policies and procedures, security, product storage environment, product handling, federal and state regulatory compliance, the quality program for distribution operations and industry best practices for securing and maintaining the integrity of prescription and non-prescription products.  

The QAS Accreditation has additional focus on:  

- Suspicious order monitoring for controlled and non-controlled substances.  
- Authentication of vendors of non-prescription products supplying items that are subject to counterfeiting, or “grey-market” products, such as diabetic test strips and OTC insulin.  
- Implementation of a quality program that addresses all aspects of the operations including product integrity issues, diversion, and reporting of any issues with authentication of vendors or customers, suspicious orders, and suspect or illegitimate product handling and investigation.  

The QAS Accreditation Program  

Upon submission of the application form and requested documents, the QAS Accreditation team will perform a document review of the submitted data and select policies and procedures, perform background checks on owners, executive officers, the designated representative (DR) and key management personnel, verify the business and facility licensure including any disciplinary actions, and schedule an on-site survey to verify security, storage conditions, performance to policies and procedures, and operations. The site survey will typically occur 4-6 weeks out from scheduling.  

QAS Accreditation staff are happy to work with applicants to identify solutions to address any items that do not meet the criteria and standards. The process is educational rather than punitive and our goal is to assist the facility in improving the quality of the operations. “I come from an independent, rural pharmacy background, and I understand the plight of small operations that do...”
not have large compliance teams to assist in improving their operations and complying with federal and state regulations. Our goal is to protect the public by working not only with the large players, but with the smaller operators to assist them in achieving the level of compliance and quality to meet the accreditation standards and ultimately protect the public,” said Denise M. Frank, BPharm, RPh, FACA, Director of Accreditation and Inspection Services for NCDQS.

The site surveyor will review items to be addressed at the conclusion of the site visit and the facility will receive an email listing the items as well as any outstanding items from the document review that have not already been addressed. Once the facility has achieved compliance to the requirements and standards, the Accreditation Board reviews and votes on the approval of the accreditation. The Director of Accreditation and Inspection Services has the authority to veto a vote to approve an accreditation if the Director has reason to believe the facility is not compliant or does not meet the requirements. If timely responses to items needing to be addressed are received from the facility during the process, the accreditation may take as little as 90 days.

The standard accreditation term is three years. If the facility has less than 6 months of distribution operations at the time of application, there is a one-year probation period (accreditation will be granted for one-year) and with successful submission of requested documentation at the end of that year, the accreditation will be extended two more years (to make the full three-year cycle).

**Why obtain accreditation?**

Wholesalers may be required to obtain accreditation as a condition of licensure in specific states, or as a requirement from their customers due to third-party payor or health care company contracts.

Accreditation also is used to differentiate a wholesaler in the marketplace as it recognizes a higher level of quality in the wholesaler operations. Obtaining products from an accredited wholesaler will help prevent pharmacies and other health care providers from receiving products that are of unknown origin and quality, have been diverted or are counterfeit, or whose integrity has been compromised by improper conditions during transportation, handling and storage. We will be working with those Boards of Pharmacy and other state agencies that license or register wholesale drug distributors to be recognized and approved to provide inspections and accreditations where it is a requirement of licensure or registration.

NCDQS will be working with those Boards of Pharmacy and other state agencies that license or register wholesale drug distributors to be recognized and approved to provide wholesale drug distributor accreditations where it is a requirement of licensure or registration. The organization will also be working with those third-party payors and health care companies that have this requirement in their contracts with pharmacies and other healthcare providers to also recognize and accept the NCDQS QAS Accreditation.

**QAS Inspection Program**

The inspection program was developed by request of several wholesale distributors facing non-resident licensure difficulties because they are unable to produce a current inspection performed by their home-state licensing agency or Board of Pharmacy.

The QAS Inspection team will perform an on-site unannounced inspection of the facility within a timeframe given to the facility when the inspection is requested. These inspections are performed
by pharmacists with training and experience in drug supply chain operations and regulations. Pharmacists are used for these inspections to allow for the acceptance of the inspection by the Board of Pharmacy. A copy of the inspection will be provided to the facility and, if requested by the facility, directly to the Board of Pharmacy or state regulatory agency.

NCDQS will be working with those Boards of Pharmacy and other state agencies that license or register wholesale drug distributors to be recognized and approved to provide inspections where it is a requirement of licensure or registration.

*prounced “case”

About NCDQS

The National Coalition for Drug Quality and Security was formed in 2018 by supply chain industry members. In addition to the Accreditation Board, NCDQS has an Advisory Board of people from the industry and compliance including those with experience in distribution, manufacturing, repackaging and relabeling, 3PL, consultants, FDA, DEA, Board of Pharmacy (member, compliance officer) as well as two members who purchase products from wholesalers. The advisory board does not make decisions but provides input on the development and maintenance of standards including best practice, emerging issues in the drug supply chain, and compliance considerations.

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