



# NCDQS QAS Inspections and Accreditation

ENSURING CONSISTENT QUALITY THROUGH  
RECOGNIZED INSPECTION STANDARDS

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# NCDQS – A Partner in Pharmacy Supply Chain Compliance

## Request

- ▶ The Board is requested to permanently recognize NCDQS as an approved provider for QAS inspections and accreditation for Virtual Manufacturers, Wholesale Distributors, and Third-party Logistics Providers.

## Background

- ▶ Temporary acceptance of NCDQS inspections during COVID-19 ensured regulatory continuity under emergency orders.

## Purpose and Benefits

- ▶ Permanent acceptance ensures continuity, predictability, and administrative efficiency without reducing oversight or standards.

## Board Authority Preservation

- ▶ The request maintains full Board discretion over permitting and enforcement. Aligns with peer states



# BACKGROUND: COVID EMERGENCY ACCEPTANCE

## **Emergency Regulatory Adaptation**

Minnesota accepted NCDQS inspections during COVID-19 to overcome travel and staffing challenges.

## **Validation of NCDQS Standards**

NCDQS met Minnesota's inspection quality, qualifications, and reporting integrity standards during the emergency.

## **Expiration Rationale**

NCDQS approval expired due to procedure, not performance.

## **Permanent Acceptance Proposal**

Reinstating acceptance formalizes NCDQS as a proven compliance partner



# WHO IS NCDQS?

## Mission and Founding

NCDQS was founded in 2017 to promote drug quality and supply security through education and transparency.

## Independence and Objectivity

NCDQS does not provide consulting services to avoid conflicts of interest and maintain unbiased inspection activities.

## Educational Compliance Approach

NCDQS focuses on educating regulated entities about standards to enhance understanding and strengthen patient protection.

## Focus on Modern Oversight

NCDQS addresses unique business models like virtual manufacturers and 3PLs relevant to contemporary distribution and an evolving pharmaceutical supply chain.



# WHO WE SERVE

- ▶ Manufacturers and Wholesalers of
  - ▶ Rx & OTC Drugs
  - ▶ Medical Devices
  - ▶ Listed Chemicals
- ▶ Virtual Manufacturers and Wholesalers
- ▶ Medical Gas Manufacturers and Wholesalers
- ▶ Third-Party Logistics Providers
- ▶ Reverse Distributors



# INSPECTOR QUALIFICATIONS AND INDEPENDENCE

## **Inspector Qualifications**

Inspectors are licensed pharmacists with over ten years of relevant industry experience, ensuring expert knowledge.

## **Mentorship and Training**

New inspectors undergo mentorship-based onboarding by shadowing seasoned inspectors to ensure consistent professionalism and judgment.

## **Compensation Structure**

Flat fee per inspection removes financial incentives to prolong inspections or upsell, supporting impartial evaluations.

## **Conflict of Interest Policy**

Robust conflict-of-interest policy requires disclosure of any prior relationships to maintain inspection independence.



# NCDQS INSPECTION MODEL AND STANDARDS

## **Alignment with National Standards**

QAS inspections align with national Board of Pharmacy standards and adapt to evolving laws and industry practices.

## **Focus on Quality and Security**

The model emphasizes both regulatory compliance and supply chain integrity to ensure quality and security.

## **On-site and Unannounced Inspections**

Inspections are conducted in person, with unannounced visits for facilities with product on site to maintain regulatory surprise.

## **Efficient Scheduling for Nonresident Facilities**

Facilities without product on site are scheduled to optimize resources while meeting regulatory expectations.



# Operational Efficiency and Transparency

## Efficient Inspection Process

Inspections are completed within weeks, usually in a single day by one inspector, reducing disruption.

## Transparent and Fair Fees

Fees are flat, disclosed upfront with no hidden travel costs, promoting fairness and transparency in the process.

## Secure and Verifiable Reports

Inspection reports are locked, geo-tagged with GPS coordinates, and maintain auditable records.

## Color-Coded Compliance Status

Compliance is indicated by color codes, enabling quick risk assessment and focused review by Board staff.



Compliant

Partially Compliant

Non Compliant

# INTERNAL QUALITY CONTROLS

## **Quality Assurance Mechanisms**

NCDQS uses internal audits to ensure every inspection report complies with established policies and standards.

## **Peer-Review Process**

Findings are discussed with inspectors and revised only if inaccuracies are confirmed, promoting consistency.

## **Regulatory Confidence**

Internal audits reduce follow-up questions and support confident decisions by Boards of Pharmacy.



# NCDQS QAS Alignment with Minnesota BOP Rules

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MN Regulatory Domain	Corresponding NCDQS QAS Inspection Focus
<b>Personnel &amp; Supervision</b>	Licensure verification, roles, responsibilities, oversight structure
<b>Policies &amp; Procedures</b>	Written SOP review for distribution, security, recalls, complaints
<b>Drug Security &amp; Storage</b>	Facility security, access controls, temperature management
<b>Recordkeeping</b>	Transaction records, traceability, retention practices
<b>Complaints &amp; Recalls</b>	Documented processes and execution readiness

# STATE ADOPTION OF NCDQS QAS IS GROWING

## Widespread State Acceptance

Numerous state Boards of Pharmacy accept NCDQS QAS inspection reports.

- ▶ CO, IA, KS, MD, MS, NE, NH, SC, SD, TN

## Aligning Regulatory Cohorts

Minnesota aligns with other jurisdictions recognizing the need for qualified third-party inspections in complex supply chains.



# NCDQS ACCREDITATION

## 3-Year Accreditation Program Scope

QAS accreditation offers extra assurance for higher-risk or complex entities through a structured program beyond inspections.

## Review and Compliance Checks

The process includes thorough policy reviews, legal compliance, industry best practices, and background checks of personnel and finances.

## Standards and Independence

Accreditation standards are nationally-oriented, updated continuously, and non-consultative to ensure independence.



# CLOSING REQUEST AND NEXT STEPS

## **Request for Permanent Approval**

The Board is asked to formally and permanently recognize NCDQS as an approved provider for QAS inspections and accreditations for Minnesota licensees.

## **Support and Assurance**

NCDQS offers pharmacist-led, conflict-free, transparent inspections to ensure regulatory rigor and patient safety.

## **Collaboration and Next Steps**

NCDQS is ready to support the MN Board of Pharmacy with ride-alongs, report reviews, and ongoing dialogue to ensure alignment.



THANK YOU

WE WELCOME YOUR  
QUESTIONS

[WWW.NCDQS.ORG](http://WWW.NCDQS.ORG)

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