Guidance for Inspection Types Accepted for Non-Resident Facilities

Approved by Kansas State Board of Pharmacy: April 27, 2023
Last Updated: March 17, 2023

I. Purpose
   a. The purpose of this guidance is to provide nonresident facilities with a list of acceptable inspections for new facility applications and renewals.

II. Statutory Authority
   a. K.S.A. 65-1643d; 65-1655; 65-1655a; K.S.A. 65-1655b
   b. K.A.R. 68-7-12a; K.A.R. 68-14-4

III. Guidance
   a. Requirements:
      i. Nonresident Pharmacy – every 18 months (K.A.R. 68-7-12a(a)(3))
      ii. Outsourcing Facilities – Initial registration inspection within prior 2 years (K.S.A. 65-1655b(7)
         1. After initial registration – inspection every 3 years (K.S.A. 65-1655b(e)
      iii. Distributors, Manufacturers, and Third-Party Logistics/3PL – every 3 years [K.S.A. 65-1643d(f); 65-1655(f); 65-1655a(f)
   b. Nonresident Pharmacy:
      i. Home State (inspection form must designate "Pharmacy")
         1. Satisfactory inspection K.A.R. 68-7-12a(3)
      ii. NABP – VPP
   c. Distributor:
      i. Home State (inspection form must designate "Distributor" or "Wholesale Distributor")
      ii. NABP – VAWD or DDA accreditation; Supply Chain Inspection
      iii. FDA – Report classification only (NAI, VAI, OAI). Only submit full report if requested by Board.
         1. NAI
         2. VAI- Must send a statement of action taken to correct observations
         3. OAI- Must send a statement of action taken to correct observations
      iv. NCDQS (accepted only if home state never inspects)
   d. DSCSA-Exempt Distributor (non-prescription, API, medical gas, veterinary):
      i. Home State (inspection form must designate "OTC Distributor" or something similar)
      ii. NABP- Supply Chain Inspection (not accepted for medical gas)
      iii. NCDQS (accepted only if home state never inspects)
   e. Medical Gas Distributor or Manufacturer:
      i. Home State
      ii. FDA
   f. Virtual Distributor:
      i. Home State (inspection form must designate "Virtual Distributor")

ii. NABP- Supply Chain Inspection (not accepted for medical gas)
iii. NCDQS (accepted only if home state never inspects)

g. Durable Medical Equipment:
   i. Home State (inspection form must designate "DME" or "Durable Medical Equipment")
   ii. NABP – Supply Chain Inspection or DMEPOS
   iii. CMS List: approved list found at the following website: MEDICARE NEW DEEMED ACCREDITATION ORGANIZATIONS FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) (cms.gov)
      1. List of approved accreditation organizations:
         a. ACHC - Accreditation Commission for Health Care, Inc.
         b. ABC - American Board for Certification in Orthotics & Prosthetics, Inc.
         c. BOC - Board of Certification/Accreditation International
         d. CARF - Commission on Accreditation of Rehabilitation Facilities
         e. CHAP- Community Health Accreditation Program
         f. HQAA - HealthCare Quality Association on Accreditation
         g. NABP - National Association of Board of Pharmacy
         h. The Compliance Team, Inc.
         i. TJC - The Joint Commission

h. Manufacturer:
   i. Home State (inspection form must designate "Manufacturer")
   ii. NABP – Supply Chain Inspection (if supplementary)
   iii. FDA–Report classification only (NAI, VAI, OAI). Only submit full report if requested by Board.
      1. NAI
      2. VAI- Must send a statement of action taken to correct observations
      3. OAI- Must send a statement of action taken to correct observations

i. Virtual Manufacturer:
   i. Home State (inspection form must designate "Virtual Manufacturer")
   ii. NABP – Supply Chain Inspection
   iii. NCDQS (accepted only if home state never inspects)

j. Manufacturer of Device(s):
   i. Home State (inspection form must designate "Manufacturer")
   ii. MDSAP
      1. The approved list may be found under "Auditing Organizations", "AO ability to conduct MDSAP audits" at the following website: Medical Device Single Audit Program (MDSAP) | FDA
         a. The inspection covers the requirements of ISO 13485:2016
      2. List of FDA approved providers with US location:
         a. bsi – BSI Group America, Inc. – Herndon, VA

b. Dekra – Dekra Certification B. V. –Concord, CA
c. IN – Interkek Testing Services NA – Lowell, MA
d. GMED – G-MED – Bethesda, MD
e. NSAI – National Standard Authority of Ireland – Nashua, NH
f. TUV USA - TUV USA, Inc. (TUV NORD Group) – Salem NH
g. UL – UL Medical and Regulatory Services UL, LLC – Northbrook, IL and Fremont, CA

k. Third-Party Logistics/3PL:
    i. Home State (inspection form must designate "3PL or Third-Party Logistics")
    ii. NABP – Supply Chain Inspection
    iii. FDA – Report classification only (NAI, VAI, OAI). Only submit full report if requested by Board.
        1. NAI
        2. VAI- Must send a statement of action taken to correct observations
        3. OAI- Must send a statement of action taken to correct observations
    iv. NCDQS (accepted only if home state never inspects)

l. DSCSA-Exempt Third-Party Logistics/3PL (non-prescription, API, medical gas, veterinary):
    i. Home State (inspection form must designate "OTC 3PL" or something similar)
    ii. NABP – Supply Chain Inspection
    iii. NCDQS (accepted only if home state never inspects)

m. Outsourcing Facility:
    i. Home State (inspection form must designate "Outsourcing or Outsourcer")
    ii. FDA
        1. New application - within 24 months of initial registration application
        2. Renewal – within previous 3 years
        3. Result of Inspection – Report classification only (NAI, VAI, OAI). Only submit full inspection report if requested by Board.
            a. NAI
            b. VAI- Must send a statement of action taken to correct observations
            c. OAI- Must send a statement of action taken to correct observations
    iii. NABP – satisfactory inspection within previous 3 years of application or current renewal; Supply Chain Inspection (if supplementary)

IV. Acronyms

a) DDA: Drug Distributor Accreditation

b) DMEPOS: Durable Medical Equipment, Orthotics, and Supplies
c) FDA: Food and Drug Administration
d) MDSAP: Medical Device Single Audit Program
e) NABP: National Association of Boards of Pharmacy
f) NAI: No Action Indicated – No further information needed
g) NCDQS: National Coalition for Drug Quality and Security
h) OAI: Official Action Indicated- Submit 483 with facility responses to observations
i) VAI: Voluntary Action Indicated- Submit 483 with facility responses to observations
j) VAWD: Verified Accredited Wholesale Distributor
k) VPP: Verified Pharmacy Program Inspection

Note: Any facility that is attempting to renew their registration but it unable to acquire one of the above inspections should review the Board's Guidance Document on Facility Renewals without Inspections.