Guidance for Inspection Types Accepted for Non-Resident Facilities

Approved by Kansas State Board of Pharmacy: July 11, 2024
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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 – 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
        1. The inspection covers the requirements of ISO 13485:2016

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 – operational inspection only:
i. 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
ii. 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.