

Here and now: Inspectional processes and COVID-19 updates

FDA's Compounding Quality Center of Excellence Virtual Conference: Working Together for Patient Safety

National Association of Boards of Pharmacy (NABP)

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What is NABP?

NABP is the independent, international, and impartial nonprofit association that assists its member boards of pharmacy in their efforts to protect the public health by offering programs to promote a safe drug supply and safe pharmacy practices for the benefit of patients.

NABP provides the boards of pharmacy with the information and resources they need to make informed decisions regarding the regulation of pharmacists, pharmacies, and other drug- and device-related facilities such as manufacturers, repackagers, distributors, third-party logistic providers (3PLs) and 503B outsourcing facilities.

NABP has provided service to the Boards of Pharmacy for 116 years beginning in 1904.



What is NABP? (continued)

NABP represents the member boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the associate members in the Bahamas, and all 10 Canadian provinces.

Services provided by NABP to support the public health protection mission of Boards of Pharmacy:

- Pharmacist licensure exams
- Maintenance of Model State Pharmacy Act and Model Rules
- Communication and training on current pharmacy- and drug-related issues for Board of Pharmacy Executive Directors, Members, and Compliance Officers
- Accreditation and Inspection of Pharmacy and Distribution Facilities





NABP Pharmacy Programs



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NABP Accreditation and Inspection Services

Pharmacy Accreditations (since 1999)

- Digital Pharmacy (formerly known as VIPPS)
- DMEPOS
- Community
- Specialty
- Compounding
- Home Infusion





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NABP Accreditation and Inspection Services (continued)

Pharmacy Inspections

- Known as Verified Pharmacy Program (VPP)
- Began in 2013 following NECC
- Practice Areas
 1. General Pharmacy
 2. Non-sterile Compounding (USP 795)
 3. Sterile Compounding (USP 797)
 4. Nuclear Pharmacy



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NABP Drug Distributor Programs



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Drug Distributor Accreditations and Supply Chain Inspections

Drug Distributor Accreditation – Business Models

- Outsourcing Facilities
- Drug Manufacturers
- Wholesale Distributors
- Third Party Logistic Providers (3PLs)
- Reverse Distributors
- Virtual Manufacturers and Wholesalers





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Supply Chain Inspections – Eligible Businesses

- Prescription drug wholesale distributors
- Prescription medical device distributors
- Active pharmaceutical ingredient (API) distributors
- API repackagers
- Repackagers of finished prescription drugs
- Veterinary prescription drug distributors
- Reverse distributors
- Sample distributors
- Investigational drug distributors
- Manufacturers
- Virtual distributors and manufacturers
- Third-party logistics providers (3PLs)



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Supply Chain Inspections (continued)

- Inspections are not Pass or Fail
- States determine a facility's compliance based on the findings
- Inspections are conducted within 8 weeks of application (or less)
- Facility receives a copy of report and can respond
- Process applies to Pharmacy Inspections as well





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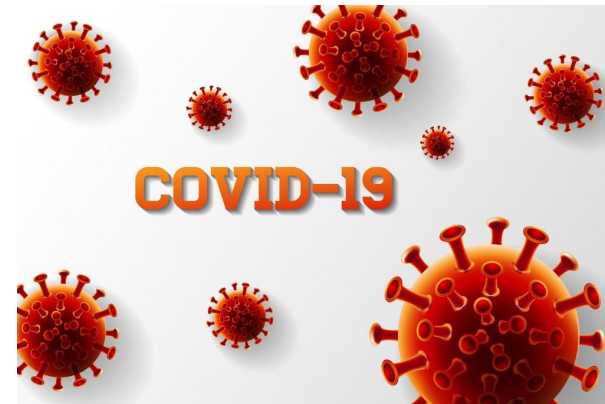
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NABP – Impact of COVID-19 on Surveys and Inspections

March 19, 2020 – NABP suspended Accreditation and Inspection Surveys

Resumed limited visits in early August

- Many factors on which visits are dependent
- States where visits cannot be made due to numbers of cases
- Company policies may prohibit outsider visits
- Visits have been cancelled due to new outbreak





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State Licensing and Inspections of 503Bs



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State Licensing of 503B Facilities

21 States have a license specific to 503B
Outsourcing Facilities

9 States license 503B Outsourcing Facilities as
Manufacturers

3 States license 503B Outsourcing Facilities as Drug
Wholesale Distributors

5 States license in-state 503B Outsourcing Facilities
as manufacturers and out-of-state 503B Outsourcing
Facilities as Drug Wholesale Distributors





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503B – State licensing status of 503B Outsourcing Facilities

State	Resident 503B a) Outsourcing Facility b) Manufacturer c) Pharmacy d) Wholesale Dist	Nonresident 503B a) Outsourcing Facility b) Manufacturer c) Pharmacy d) Wholesale Dist	Note
CA, DE, FL, IA, ID, KY, MA, MS, MO, NV, NM, NY, NC*, ND, OH, OK, SC, SD, TN, VA, VT,	a)	a)	NC* – Dept of Ag
AL, AZ, GA, ME, MN, NJ, OR, PA* WV	b)	b)	
CO, IL, PA*, TX, WA	b)	d)	PA*- NR Mfr (sales force) or List 1
IN*, MI,	c)	c)	IN*- if also a 503A
AR, LA*, MT	d)	d)	LA* - LA Board of Drug Distributors
AK, CT, Guam, HI*, MD, NE, NH, PR, RI, UT, WI, WY	None	None	HI* - NR Pharmacy license



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State Inspections of 503B Outsourcing Facilities

Focus of States on 503B Inspections

NABP – Current focus of 503B inspections and accreditations of 503B Outsourcing facilities

Findings of State and NABP Inspections and Accreditations





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Status of State Inspections

- Virtual Inspections
- Critical needs
- Complaint investigations
- 1/2 onsite and 1/2 desktop
- By pharmacy request
- Announced to ensure access





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Thank you