

NC BOARD OF PHARMACY INSPECTION PROCESS

1. Inspections of pharmacy permits and Durable Medical Equipment (DME) provider permits with the NC Board of Pharmacy will be conducted by the Board's inspectors/investigators.
2. Inspections of pharmacy and DME permits will be conducted either as part of an investigation of a complaint or as a "stand-alone" inspection established by the schedule below:
 - A. Any pharmacy or DME permit being investigated pursuant to a complaint shall have a full inspection performed during the investigation if an inspection has not been completed within the past six (6) months. An inspection form shall be completed by the investigator/inspector and filed as directed below.
 - B. Stand-alone inspections of pharmacy and DME permits shall be conducted on the following schedule:
 1. **Full Retail Pharmacy & DME Permits** – at least once every four (4) years.
 2. **New Full-Service Pharmacy Permits and New DME Permits** – newly opened pharmacies and DME facilities will be inspected within the first year of permitting.
 3. **Re-registration of pharmacy permits**- For new physical location will be inspected within one year of the re-registration date.
 4. **Limited Service Permits** – Inspected pursuant to complaint only. If however, an LSP compounds prescription drugs, it will be inspected within the first year of permitting and it shall be inspected on the schedule that corresponds to the type of compounding activities that occur at the LSP (see below).
 5. **Non-Sterile Compounding Pharmacies**- Inspected at least once every four (4) years.
 6. **Sterile compounding**- Inspected at least once every eighteen (18) months.
 7. **Nuclear Pharmacies**- Inspection at least once every eighteen (18) months

3. All inspections shall be conducted using approved online database forms covering all laws (federal and state), rules (federal and state), and other standards that apply to the products and services of the inspected facility.
4. Inspectors will record and discuss any violations found with either the pharmacist manager, staff pharmacist, or on-duty person-in-charge of the DME at the conclusion of the inspection.
5. Once an inspection of a facility is completed, a copy of the inspection form will automatically be e-mailed to the pharmacist-manager, or DME person-in-charge, and to the Investigations/Inspections Coordinator. If during the inspection **severe and/or significant deficiencies are identified by the Investigator or Inspector that could affect the health and safety of the public**, a request for a Corrective Action Plan will be documented on the inspection report.
6. The Director of Inspections will review the inspection for completeness and if any further follow-up or investigative action needs to be taken. The Director of Inspections will complete this review through the database and move the inspection from pending status to reviewed status.
7. The pharmacist-manager of the pharmacy or the person-in-charge of the DME facility shall provide a written response in the form of a Corrective Action Plan (CAP) regarding **severe and/or significant deficiencies identified during the inspection**, including specific corrective action taken, within thirty (30) days of the inspection. Once the response is received, it shall be reviewed by the Inspector or Investigator for compliance. The Inspector or Investigator will upload the response into the database under the inspection and mark that the corrective action plan has been received. The **pharmacy or DME facility shall be re-inspected within ninety (90) days, to assure the deficiencies have been corrected**. If, upon re-inspection, the deficiencies and non-compliance issues have not been corrected, then Board staff shall open an investigative case on the pharmacy or DME facility.
8. If significant deficiencies and/or severe public safety issues are identified during an inspection, Board staff may immediately open an investigation case on the pharmacy or DME facility.
9. Inspection lists will be continually updated and tasked to the inspectors through the online database. Any past-due inspections will be highlighted in red, and any inspection due within thirty (30) days will be highlighted in orange.
10. Inspection reports will be reviewed quarterly by the Director of Inspections to ensure inspections are being conducted in an accurate, timely manner consistent with this policy.

Inspectors will be notified of any “Past Due” inspections that need to be completed immediately. The results of this quarterly review will factor into the inspector’s yearly evaluation.

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