

## 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. 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 Retail Pharmacies** – newly opened pharmacies will be inspected within the first year of permitting.
    3. **Limited Service Permits** – Inspected pursuant to complaint only. If however, an LSP compounds prescription drugs, it shall be inspected on the schedule that corresponds to the type of compounding activities that occur at the LSP (see below).
    4. **Sterile compounding/High risk pharmacy permits** – Annually.
    5. **Medium Risk Compounding Pharmacies** – Every two (2) years.
    6. **Low Risk Compounding Pharmacies** – Every four (4) years.
3. All inspections shall be conducted using approved checklists and forms covering the laws, rules, Code of Federal Regulations, and requirements relevant to 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 be e-mailed to the pharmacist-manager, or DME person-in-charge, and to the Investigations/Inspections Coordinator.
6. Once the form is e-mailed to the Investigations/Inspections Coordinator, the data will be entered into the Board database including the: the date of inspection, identity of the inspector, violations noted, case number (if applicable) and whether any follow-up is required.
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 **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. On a quarterly basis, each inspector will be issued a list of all active pharmacy/DME permits due for an inspection within that calendar year. The list will include the last date the permit was inspected and the date by which the next inspection must occur. The list will be updated quarterly to assure accurate inspection due dates.
10. Inspection queries will be reviewed quarterly by the Director of Investigations or Associate Director of Investigations 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. Results of this quarterly review will factor into the inspector’s yearly evaluation.