

**21 NCAC 46 .2604            RECORDS**

(a) All orders and records for devices and medical equipment shall conform in all pertinent respects with Board Rules .2301 through .2305 of this Chapter and shall be maintained at the dispensing site. In addition to the requirements of those rules, the serial numbers for all devices dispensed and all medical equipment delivered to outpatients shall be preserved as part of the records; provided, that this requirement shall not apply to disposable devices and medical equipment.

(b) All prescriptions and refill orders for devices and medical equipment shall be maintained at the dispensing site for at least three years.

(c) All device and medical equipment permit holders shall maintain a file copy of every item sold or rented with a serial number or tracking number or code in compliance with FDA Medical Device Tracking requirements.

*History Note:*     *Authority G.S. 90-85.3(e),(ll),(r); 90-85.6; 90-85.22;*  
                          *Eff. October 1, 1990;*  
                          *Amended Eff. April 1, 1999; September 1, 1995;*  
                          *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
                          *2017.*