GUIDANCE TO PHARMACISTS ON IMPLEMENTATION OF THE STRENGTHEN OPIOID MISUSE PREVENTION ("STOP") ACT

The North Carolina General Assembly has passed, and the Governor has signed into law, the Strengthen Opioid Misuse Prevention ("STOP") Act. The STOP Act is an effort to combat the opioid abuse and misuse epidemic. The STOP Act makes changes to the laws governing controlled substance prescribing, controlled substance dispensing, and the North Carolina Controlled Substance Reporting System ("CSRS"). This FAQ guidance discusses those changes.

* * *

1. Why did the Board of Pharmacy pass this law?

   The Board of Pharmacy did not pass this law. The North Carolina General Assembly passed it, and the Governor signed it into law.

2. Does the STOP Act affect the practice of pharmacy?

   Yes, in a number of ways.

3. Does the STOP Act make changes to pharmacists' ability to dispense naloxone, including by standing order?

   No. Although the STOP Act includes a new provision that authorizes certain governmental and non-governmental organizations to distribute naloxone, it does not change existing authority for pharmacists to dispense naloxone, including pursuant to the statewide standing order. For more information on the statewide standing order and pharmacist participation, see www.naloxonesaves.org and http://www.ncbop.org/faqs/Pharmacist/faq NaloxoneDispensing.htm

4. Does the STOP Act make changes to laws governing the prescribing and dispensing of all controlled substances?

   No. The STOP Act makes changes to laws governing the prescribing and dispensing of "targeted controlled substances" and to "controlled substances included in G.S. 90-93(a)(1)a."

5. What is a "targeted controlled substance"?

The STOP Act defines a "targeted controlled substance" as "any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d)."

The controlled substances included are as follows:

G.S. 90-90(1) & (2). This statutory section includes Schedule II controlled substances that are opioids or opioid derivatives. It does not include Schedule II amphetamine derivatives, barbiturate derivatives, or nabilone derivatives. You may review the list here: http://www.ncbop.org/LawsRules/Statutes.pdf

G.S. 90-91(d). This statutory section includes Schedule III controlled substances that are combination products containing opioids or opioid derivatives. It does not include other Schedule III controlled substances. You may review the list here: http://www.ncbop.org/LawsRules/Statutes.pdf

6. What is a "controlled substances included in G.S. 90-93(a)(1)a"?

G.S. 90-93(a)(1)a defines Schedule V controlled substances to include *"*any compound, mixture or preparation containing an of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic alone . . . Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams."

This includes promethazine with codeine Schedule V products.

7. Does the STOP Act make changes to the way "targeted controlled substances" are prescribed?

Yes.

8. What are those changes?

Electronic Prescribing Required for "Targeted Controlled Substances" Effective January 1, 2020, all "targeted controlled substances" must be prescribed electronically unless an exemption applies.

Effective January 1, 2024, prescriptions for controlled substance included in G.S. 90-93(a)(1)a must be prescribed electronically. Note, however, that this electronic prescribing requirement "does not apply to any product that is sold at retail without a prescription" as allowed by North Carolina law.

The general exemptions to the electronic prescribing include: when a non-pharmacist authorized to do so by law dispenses directly to an ultimate user; orders to administer a targeted controlled substance in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential care facility; practitioner experiencing a technical failure or other circumstance preventing electronic transmission; prescription to be dispensed by a pharmacy located on federal property; a veterinary prescription.

Importantly, the STOP Act specifies that a dispensing pharmacist who receives a non-electronic prescription for a "targeted controlled substance" that otherwise is valid and for a legitimate medical purpose is **not** required to verify that an exemption to the electronic prescribing requirement applies.

Limitations on Initial Prescriptions for a "Targeted Controlled Substance" to Treat "Acute Pain" or "Post-Operative" Pain. Effective January 1, 2018, a prescriber may not prescribe more than a five-day supply of a "targeted controlled substance" upon an initial consultation for "acute pain." The STOP Act defines "acute pain" as "pain, whether resulting from disease, accident, intentional trauma, or other cause, that the practitioner expects to last for three months or less. The term does not include chronic pain or pain being treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for substance use disorder."

Similarly, effective January 1, 2018, a prescriber may not prescribe more than an initial seven-day supply of a "targeted controlled substance" for post-surgical procedure acute pain relief. The STOP Act defines a "surgical procedure" as one "performed for the purpose of structurally altering the human body by incision or destruction of tissues as part of the practice of medicine." Surgical procedure also includes diagnostic or therapeutic treatment of conditions "by use of instruments such as lasers, ultrasound, ionizing radiation, scalpels, probes, or needles that cause localized alteration or transportation of live human tissue . . . ."

The STOP Act does not prohibit prescribers from issuing additional prescriptions for acute pain or relief of post-operative acute pain upon "any subsequent consultation forthe same pain."

Importantly, however, the STOP Act specifies that a pharmacist who receives a prescription for greater than a five- or seven-day supply of a "targeted controlled

substance" is **not** required to verify that it is a prescription to treat something other than "acute pain" or "post-operative acute pain relief."

Of course, pharmacists must always exercise professional judgment to determine whether any controlled substance prescription was issued for a legitimate medical purpose in the ordinary course of medical practice.

Physician Assistant and Nurse Practitioner Consultation Requirements for "Targeted Controlled Substance" Prescriptions. Effective July 1, 2017, the STOP Act requires PAs and NPs to personally consult with their supervising physician before prescribing a "targeted controlled substance" for a patient being "treated by a facility that primarily engages in the treatment of pain by prescribing narcotic medications or [that] advertises in any medium for any type of pain management services" or if the therapeutic use of the "targeted controlled substance" will or is expected to exceed 30 days.

Pharmacists will recall that Medical Board rules already limit PAs and NPs to prescribing a 30-day supply of Schedule II and Schedule III medications. See 21 NCAC 32S.0212 (PAs); 21 NCAC 32M.0109 (NPs). PAs and NPs may authorize refills on a 30-day supply of a Schedule III medication as permitted by law.

Plainly, pharmacists are in no position to determine whether a PA or NP has complied with the consultation requirement in the STOP Act. Pharmacists are reminded, however, that when the exercise of professional judgment raises concerns about the validity of a PA's or NP's prescription for a "targeted controlled substance" (or any other prescription), consulting with the supervising physician is a good step toward resolving such concerns.

8. Does the STOP Act create requirements for the disposal of "targeted controlled substances"?

Yes, but in limited circumstances. Effective July 1, 2017, any "hospice or palliative care provider who prescribes a targeted controlled substance to be administered to a patient in his or her home for the treatment of pain as part of in-home hospice or palliative care" must "provide oral and written information to the patient and his or her family regarding the proper disposal of such targeted controlled substances."

This information-providing requirement does not fall on pharmacists or pharmacies, but, rather, to a provider who "prescribes" a "targeted controlled substance." Even so, pharmacies that serve in-home hospice or palliative care patients are likely to receive questions about proper disposal, and those pharmacies are encouraged to consider whether and to what extent their performing take-back services is practical. More information about DEA requirements for taking back controlled substances is here: http://www.ncbop.org/faqs/Pharmacist/faq DrugTakeBack.htm

9. Does the STOP Act make changes to the CSRS?

Yes. Before detailing those changes, though, pharmacists will recall that the Board of Pharmacy does not administer the CSRS. The Drug Control Unit of the North Carolina Department of Health and Human Services administers the CSRS. Pharmacists with questions or concerns about operation of the CSRS are encouraged to contact Kristen Weisberg, 919-715-2067 or John Womble, 919-715-2033.

10. What changes to pharmacy CSRS reporting does the STOP Act make?

Effective September 1, 2017, the STOP Act requires that pharmacies report all required information for any controlled substance dispensed (not just "targeted controlled substances") to the CSRS "no later than the close of the next business day after the prescription is delivered." Pharmacies are "encouraged" to report such information "within 24 hours after the prescription was delivered."

Also effective September 1, 2017, the STOP Act authorizes the Department of Health and Human Services to fine pharmacies who do not report information into the CSRS as required by law "within a reasonable period of time after being informed by [DHHS] that required information is missing or incomplete." The STOP Act establishes a series of escalating fines and caps them at $5,000 per year.

The STOP Act requires the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services to "adopt rules to implement [this section] that include factors to be considered in determining the amount of the penalty to be assessed." Pharmacists are strongly encouraged to review and comment upon any proposed rules noticed by the Commission.

Again, pharmacists with immediate questions about these provisions should contact the Drug Control Unit: Kristen Weisberg, 919-715-2067 or John Womble, 919-715-2033.

11. Does the STOP Act require pharmacists to register for access to the CSRS?

Yes, with a limited exception. The STOP Act requires that "within 30 days after obtaining an initial or renewal license to practice pharmacy," a pharmacist "shall demonstrate to the satisfaction of the North Carolina Board of Pharmacy that he or she is registered for access to the [CSRS]."

The STOP Act exempts a pharmacist from the CSRS registration requirement if the pharmacist is "employed in a pharmacy practice setting where a Schedule II, III, or IV controlled substance will not be dispensed."

As a condition of renewing a pharmacist license for 2018 (and in future years), a pharmacist must attest either: (a) that he/she has registered for CSRS access; or (b) that he/she is employed in a pharmacy practice setting where a Schedule II, III, or IV controlled substance will not be dispensed from a North Carolina-based facility or to North Carolina-resident patients.

The STOP Act provides that "a violation [of the CSRS registration requirement] may constitute cause for the Board of Pharmacy to suspend or revoke the license."

Any pharmacist who does not already have a CSRS access registration should immediately apply for one. Pharmacists can access a simple, on-line application here: https://www.ncdhhs.gov/divisions/mhddsas/ncdcu/csrs#csrs4

Please note: The STOP Act requires individual pharmacists to register for CSRS access. A pharmacy's link to the CSRS for purposes of reporting required controlled substance dispensing data is not a substitute for each individual pharmacist's registration.

12. Does the STOP Act require pharmacists to review CSRS information prior to dispensing a "targeted controlled substance"?

Yes, in some circumstances.

The STOP Act provides that a dispenser "shall review" a CSRS report on a patient "for the preceding 12-month period and document this review" when any of the following circumstances exist:

(1) The dispenser has a reasonable belief that the ultimate user may be seeking a targeted controlled substance for any reason other than the treatment of the ultimate user's existing medical condition.

(2) The prescriber is located outside of the usual geographic area served by the dispenser.

(3) The ultimate user resides outside of the usual geographic area served by the dispenser.

(4) The ultimate user pays for the prescription with cash when the patient has prescription insurance on file with the dispenser.

(5) The ultimate user demonstrates potential misuse of a controlled substance by any one or more of the following:

(a) Over-utilization of the controlled substance.
(b) Requests for early refills.
(c) Utilization of multiple prescribers.
(d) An appearance of being overly sedated or intoxicated upon presenting a prescription.
(e) A request by an unfamiliar ultimate user for an opioid drug by a specific name, street name, color, or identifying marks.

Each of these circumstances is a typical "red flag" indicating potential misuse or abuse of a controlled substance. Additional resources are available here: http://www.ncbop.org/faqs/Pharmacist/faq_RedFlagsCS.html and http://www.ncbop.org/faqs/DrugDiversionPocketcard.pdf

The STOP Act also provides that if a pharmacist "has reason to believe that a prescription for a targeted controlled substance is fraudulent or duplicative," then the pharmacist "shall withhold delivery of the prescription until the [pharmacist] is able to contact the prescriber and verify that the prescription is medically appropriate."

Finally, pharmacists should note that prescribers of "targeted controlled substances" are required to register for CSRS access, to review a 12-month CSRS report for any patient prior to issuing an initial prescription, and to review the patient's CSRS report every three months that the targeted controlled substance "remains a part of the patient's medical care."