Revised January 2018

FAQs: The Strengthen Opioid Misuse Prevention (STOP) Act of 2017

NCMB has received numerous calls and emails from licensees seeking guidance about various provisions of the state's new opioids law, the STOP Act. NCMB staff cannot definitively state how the Board may ultimately interpret the law. The FAQs below are meant to offer the current informal opinions of the Board staff.

Topics included in this document include:

Consultation before prescribing

Q: The STOP Act requires that, effective July 1, 2017, PAs and NPs practicing in pain clinics "consult" with their supervisors before prescribing any Schedule II or Schedule III opioid or narcotic. This provision took effect July 1, 2017. How does NCMB define a "consultation" between a physician assistant or nurse practitioner and his or her supervising physician?

A: The Board approved a draft rule in September that clarifies that consultations may occur either in person or by electronic means. The proposed rule broadly defines "consultation" as an interaction between supervisee and supervisor that provides the supervisor enough information to determine whether the prescription is medically indicated. The proposed rule must be finally approved by the NC Rules Review Commission. Read the full text of the proposed rule and send comments/feedback to the Board at Rules@ncmedboard.org

Q: How is "pain clinic" defined in the STOP Act so PAs or NPs know whether they practice in one?

A: The STOP Act defines a pain clinic as "a facility that primarily engages in the treatment of pain by prescribing narcotic medications or advertises in any medium for any type of pain management services." This definition would not normally include recognized hospice or palliative care practices which may, as a part of their usual practice, provide palliative care for pain. Nor would a family practice that offers pain management as part of a full scope of general internal medicine services.

Drugs affected by STOP Act provisions

Q: What medications are subject to the provisions of the STOP Act?

A: The STOP Act applies to all "targeted controlled substances". This is a term coined by the law to indicate all Schedule II and Schedule III opioids or narcotics, specifically those listed in N.C. Gen. Stat. § 90-90(1), (2) and 90-91(d). The specific medications are listed below.

N.C. Gen. Stat. § 90-90(1)

Any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, unless specifically excepted or unless listed in another schedule:

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium and opiate, excluding apomorphine, nalbuphine, dextrorphan, naloxone, naltrexone and nalmefene, and their respective salts, but including the following:

    1. Raw opium.
    2. Opium extracts.
    3. Opium fluid extracts.
    4. Powdered opium.
    5. Granulated opium.
    6. Tincture of opium.
    7. Codeine.
    8. Ethylmorphine.
    9. Etorphine hydrochloride.
    10. Hydrocodone.
    11. Hydromorphone.
    12. Metopon.
    13. Morphine.
    14. Oxycodone.
    15. Oxymorphone.
    16. Thebaine.
    17. Dihydroetorphine.

b. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph 1 of this subdivision, except that these substances shall not include the isoquinoline alkaloids of opium.

c. Opium poppy and poppy straw.

d. Cocaine and any salt, isomer, salts of isomers, compound, derivative, or preparation thereof, or coca leaves and any salt, isomer, salts of isomers, compound, derivative, or preparation of coca leaves, or any salt, isomer, salts of isomers, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocanized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

e. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy).

N.C. Gen. Stat. § 90-90(2)

Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation unless specifically exempted or listed in other schedules:

a. Alfentanil.
b. Alphaprodine.
c. Anileridine.
d. Bezitramide.
e. Carfentanil.
f. Dihydrocodeine.
g. Diphenoxylate.
h. Fentanyl.
i. Isomethadone.
j. Levo-alphacetylmethadol. Some trade or other names: levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.
k. Levomethorphan.
l. Levorphanol.
m. Metazocine.
n. Methadone.
o. Methadone - Intermediate, 4-cyano-2-dimethylamino-4, 4/y- diphenyl butane.
p. Moramide -Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid.
q. Pethidine.
r. Pethidine - Intermediate - A, 4-cyano-1-methyl-4/y-phenylpiperidine.
s. Pethidine - Intermediate - B, ethyl-4-phenylpiperidine-4-carboxylate.
t. Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
u. Phenazocine.

v. Piminodine.

w. Racemethorphan.

x. Racemorphan.

y. Remifentanil.

z. Sufentanil.

aa. Tapentadol.

N.C. Gen. Stat. § 90-91(d)

Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof unless specifically exempted or listed in another schedule:

1. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium.
2. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
3. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit with a four-fold or greater quantity of an isoquinoline alkaloid of opium.
4. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
5. Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
7. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
8. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

Q: Are Ritalin and other medications used to treat Attention Deficit Hyperactivity Disorder (ADHD) considered "targeted controlled substances" and, thus included in the electronic prescribing and mandatory CSRS use provisions of the STOP Act?

A: No. Targeted controlled substances are Schedule II and III ***opioids and narcotics*** per the North Carolina Controlled Substances Act, specifically those listed in N.C. Gen. Stat. § 90-90(1), (2) or 90-91(d). Ritalin and other stimulants are listed in N.C. Gen.

Stat. § 90-90 (3) and, thus, are not considered targeted controlled substances under the STOP Act.

Q: Is Tussionex (hydrocodone syrup) subject to the 5- and 7-day limits?

A: No. The STOP Act prescribing limits apply only to initial prescriptions for acute and post-surgical pain. As Tussionex/hydrocodone syrup is not prescribed for acute pain, the limits do not apply. However, it is widely recognized that hydrocodone syrup is a frequently misused/abused opioid. Prescribers are urged to exercise caution when prescribing this medication. Prescribers should examine their use of this medication, consider shorter courses when prescribing and discuss non-prescription adjunctive therapies (vaporizers/humidifiers, hydration, etc.) with their patients.

Effective dates

Q: What are some of the effective dates of STOP Act provisions that directly affect prescribers?

A: Some key dates are:

July 1, 2017 - Opioid prescribing consultations between PAs/NPs and supervising Physicians

January 1, 2018 - Limitations on prescriptions for acute pain

January 1, 2020 - Mandatory electronic prescribing of Schedule II/III opioids

NOT YET ESTABLISHED - Mandatory use of NC CSRS prior to prescribing Schedule II/III opioids. This provision will not be in effect until NC DHHS completes system improvements and technical upgrades.

NC CSRS provisions

Q: How should the prescriber determine three month intervals for the purpose of periodically reviewing the 12-month NC CSRS prescription history of a patient who is continuing on Schedule II or Schedule III opioids or narcotics? (Mandatory use of NC CSRS will not be in effect until system upgrades are completed – date TBD)

A: NC DHHS will determine this through the NC Controlled Substances Reporting System (NCCSRS), as the STOP Act identifies NC DHHS as the agency that will audit prescribers for compliance with this provision. The most obvious option is to review the 12-month prescription history three months after the initial prescription is written (review of the 12-month history prior to the initial prescription is also required).

However the prescriber chooses to calculate the three month period, it seems important that the required review be performed before issuing another prescription for the targeted controlled substance. It might also be beneficial to be consistent and use the same method each time.

Q: How are prescribers going to manage the additional work involved with conducting NC CSRS queries and reviewing results in order to comply with the STOP Act provisions related to mandatory use of the prescription monitoring system?

A: There is no question that complying with mandatory NC CSRS use provisions will create additional work for prescribers and their staff. However, here are some points to keep in mind:

- Provisions related to mandatory registration for and use of NC CSRS do not have a firm effective date, so prescribers will have time to plan and prepare. The provisions will not go into effect until NC DHHS makes technical upgrades to NC CSRS in order to make the system more user-friendly, improve reporting capabilities, provide inter-state connectivity with other Prescription Drug Monitoring Systems, and connect to the statewide health information exchange. Mandatory CSRS registration and use provisions become effective once the State Chief Information Officer confirms the required upgrades to NC CSRS are fully operational within the Department of Information Technology and the system is connected to the statewide health information exchange.
- NC CSRS allows prescribers to register delegates (nurses, non-clinician medical office staff) who can run queries on behalf of the prescriber. This allows the prescribers to share the workload with other members of the health care team.

Q: My hospital/practice EHR has lots of prescribing information regarding patients and is connected to state/national prescribing information. May I check that information in lieu of an NC CSRS query?

A: No. To fulfill the requirement of the law, it is necessary to review the patient's prescription history with NC CSRS. Additionally, most EHR systems have limitations related to availability of information from other systems, access to prescriptions obtained outside of insurance coverage, etc.

Prescribing limits

Q: How does the STOP Act limit opioid prescribing and when do these limits go into effect?

A: Effective Jan. 1, 2018, the STOP Act establishes limits on *initial* prescriptions for acute pain and post-surgical pain to a 5-day supply and a 7-day supply, respectively.

Q: Is it permissible for the prescriber to authorize additional pain medication if the patient's pain persists after the initial 5- or 7-day prescription is exhausted?

A: Yes, a prescriber may authorize additional pain medications if he or she determines more medication is clinically indicated after the initial supply has been exhausted.

Q: Do I need to physically see the patient back in the office in order to renew/refill the prescription or to issue a new prescription for a different amount and/or different drug?

A: Not necessarily. "Follow up consultation" may not require an in-person visit for the same issue before a refill/renewed prescription or a new prescription may be authorized, depending on the specific circumstances. In some instances (e.g. when symptoms of infection are reported by the patient, or when a patient reports worsening pain or other symptoms that are not indicative of healthy recovery) the prescriber may need to see the patient in person. Prescribers should determine these situations in a manner consistent with current accepted standards of care and good medical practice. In situations where an in person consultation is not indicated, a patient might submit a request for a prescription for the same pain via phone or online portal. The patient or patient representative would still need to come to the office to pick up Schedule II prescriptions unless the practice has the capability to e-prescribe controlled substances.

Q: Is it acceptable to issue a new prescription sooner than five or seven days if the patient did not tolerate the initial prescription?

A: Yes, as long as the issuance of the new prescription is consistent with good medical practice and the rationale is documented.

Q: Is it acceptable to prescribe *less* than a five or seven-day supply of opioids?

A: Yes, as long as the decision to prescribe less than a five or seven-day supply is consistent with good medical practice. The *CDC Guideline for Prescribing Opioids for Chronic Pain*, for example, recommends prescribing opioids no more than three days for acute pain and five days for post-surgical pain. The Board recognizes that such guidelines may not meet the needs of all patients.

Q: How will the 5- or 7-day limits on initial prescriptions for acute and post-operative pain apply to patients who are being discharged from an inpatient hospital or nursing home AND who received opioid pain medication during their hospitalization?

A: The STOP Act specifically exempts prescribers who order or administer Schedule II/III opioids in a hospital, nursing home, hospice facility, or residential care facility from the 5- and 7-day limits on initial prescriptions for pain. However, prescribers for these patients must comply with the limits at discharge. NCMB interprets the Act's intent to be that no patient treated for acute pain in an outpatient setting (e.g. at home) receive an initial or hospital discharge prescription that exceeds the limits stated in the law. If the patient requires additional treatment for the pain after the initial 5- or 7-day hospital discharge prescription runs out, then a subsequent prescription may be issued by the prescriber, consistent with good medical practices.

Q: Is it appropriate to give the patient, at the time of the initial prescription, an additional prescription for a targeted controlled substance that does not permit the prescription to be filled until seven days after the initial prescription?

A: No. The STOP Act states "Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription for a targeted controlled substance." (Emphasis added) This language requires the prescriber to decide, based on the circumstances at a later time, whether it is necessary to continue opioid therapy.

Q: Does the STOP Act place any limits on how much pain medication may be initially prescribed to a patient for the treatment of chronic pain?

A: No. The STOP Act limits only initial prescriptions for acute pain and post-surgical pain. There are no limits on the amount of medication that can be prescribed to treat chronic pain in a new or established patient, although any treatment recommended should be consistent with current accepted standards of care. The prescriber would be obligated to comply with the STOP Act provision that calls for a mandatory review of the patient's 12-month prescription history with NC CSRS before authorizing any prescription for chronic pain. Periodic CSRS reviews should be conducted every three months after the initial prescription for a Schedule II or Schedule III opioid or narcotic is written, for as long as the patient continues on the medication.

Q: How does the STOP Act define "acute pain"?

A: "Acute pain" is "pain from disease, accident, intentional trauma, or other cause that is expected to last for three months or less". This includes post-operative pain and pain generated from injuries of all types.

Q: Does pain from a fracture fall under post-operative pain (7 days) or acute pain (5 days)?

A: It is the Board's opinion that fracture care, regardless of whether there was actual surgery involved, should be considered a surgical procedure (it is billed as such). Therefore, a patient with a fracture could receive an initial prescription for up to 7 days of pain medication.

Q: Do the 5- and 7-day limits on initial prescriptions for acute or post-operative pain still apply if the patient being treated is also a chronic pain patient?

A: Yes, the 5- and 7-day limits apply – to the initial prescription for acute or post-operative pain. A prescriber treating acute or post-operative pain for a patient with chronic pain should consider all clinical information he or she has about the patient in selecting pain medications, dosage, and medication scheduling consistent with good medical practices. Referral for consultation with a pain specialist may be required to assist with medication selection, dosing, and management.

Suggest additional FAQs

Question not on our list? Suggest additional FAQs by emailing news@ncmedboard.org