Controlled Substance Reporting Rule: Implications for Advanced Practice Nurse Prescribers

Bobby Lowery, PhD, FNP-BC, FAANP
Education and Advanced Nursing Practice Consultant
North Carolina Board of Nursing
blowery@ncbon.com

June 29, 2016

Controlled Substance Reporting Rule: Implications for Advanced Practice Nurse Prescribers

Introduction

Opioid abuse has reached epidemic levels with tremendous public safety implications. With almost 16,000 deaths in the US resulting from an overdose of prescription narcotics, public health officials, policy makers and regulators must evaluate public safety measures for authorized clinicians who prescribe controlled substances (Alexandre G.C. & Gielen, 2016; Centers for Disease Control and Prevention, 2015).

The North Carolina Board of Nursing (NCBON) has a rich history of protecting the public through the regulation of nursing practice (NCBON, 2015b). The NCBON's history of regulatory excellence is extended through administrative support of the midwifery joint committee (MJC); the regulatory body responsible for the regulation of nurse midwifery in NC.

The NCBON and the MJC have adopted new, ***parallel reporting rules*** in accordance with North Carolina Session Law 2013-152 Section 3. This rule enables regulatory boards to receive ***confidential reports*** from the Department of Health and Human Services (DHHS) regarding prescribers who exceed established thresholds in prescribing controlled substances (NCGA, 2013). The reports will include identified prescribers 1) who fall within the top one percent of those prescribing 100 milligrams of morphine equivalents (MME's) per patient per day; 2) those prescribing 100 MME's per patient per day in combination with any benzodiazepine and who are within the top one percent of all controlled substance prescribers by volume, or 3) those prescribers who have had two or more patient deaths in the preceding 12 months due to opioid poisoning. These reporting rules will impact nurse practitioners (NPs) and certified nurse

midwives (CNMs); advanced practice registered nurse (APRN) prescribers approved to prescribe controlled substances in NC. The relevant rule changes are noted in table 1 with 21 NCAC 36 .0815 and 21 NCAC 33 .0110 impacting NPs and CNMs respectively.

Point of Care Impact

It is essential that authorized prescribers maintain and apply current evidence in controlled substance prescribing practices. Knowledge of controlled substances that are prescribed and may have potential for abuse or inappropriate use is essential as noted in figure 1. Section 12F.16.(a) of NC Session Law 2015-241 requires licensing boards regulating authorized prescribers of controlled substances and health agencies within state government to adopt a standardized policy for the use of opiates for the treatment of pain (NCMB, 2015). The NCBON's Policy for the Use of Opiates for the Treatment of Pain, which parallels the policy of the North Carolina Medical Board, can be found on the NCBON website at http://www.ncbon.com/myfiles/downloads/use-of-opiates-policy.pdf (NCBON, 2016). Utilization of 21 NCAC 36 .0815 and 21 NCAC 33 .0110 will provide additional tools to enhance APRNs' safe, evidence-based opioid management in diverse practice settings.

Advanced Practice Registered Nurses provide safe, effective healthcare, including evidence-based opioid management. With the implementation 21 NCAC 36 .0815 and 21 NCAC 33 .0110, questions have arisen regarding the impact of these rules at the point of care when evidence-based management for select client populations may routinely result in an authorized prescriber being reported to their regulatory board. Some of the most common point of impact questions posed by APRNs are addressed in table 2.

When evidence-based controlled substance management appropriate to the clinical management of a specific client exceeds the recommended threshold, documentation of consultation with the primary supervising physician and interprofessional colleagues with expertise appropriate for controlled substance management and inclusion of controlled substance prescribing parameters in the collaborative practice agreement ensures public protection through due diligence by the APRN (Lowery & Privette, 2016).

Conclusion

Opioid and prescription drug abuse is a public health issue, exacting an enormous human and economic burden of suffering in the U.S.A. Authorized APRNs who prescribe controlled substances are key leaders in ensuring the safe, evidence-based management of chronic pain and opioid management. When appropriate clinical management requires levels of opioids or other controlled substances that are beyond the recommended thresholds, documentation of appropriate consultation, inclusion of prescribing parameters in the collaborative practice agreement, and quality improvement documentation will ensure optimal safety for the public and clinicians, alike. The NCBON remains a leader and partner for APRNs and the public; extending the history of public protection through evidence-based regulation and guidance in opioid management.

References

Alexandre G.C., F., S., & Gielen, A. e. (2016). *The prescription opioid epidemic: An evidence-based approach.* (Public Health No. 2015). Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. Retrieved from http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf. (Opioid Epidemic)

Centers for Disease Control and Prevention. (2015). Understanding the epidemic: Prescription drug overdose. Retrieved from http://www.cdc.gov/drugoverdose/epidemic/index.html

Lowery, B. & Privette, K. (2016). Public protection through opioid prescription monitoring and reporting: A new era in evidence-based nursing regulation. *Nursing Bulletin, 12(2),* pp. 12-15. http://epubs.democratprinting.com/publication/?i=293073#{"issue_id":293073,"page":12}

NCBON. (2016). Policy for the use of opiates for the treatment of pain. Retrieved from http://www.ncbon.com/myfiles/downloads/use-of-opiates-policy.pdf

NCBON. (2015b). Mission, vision and values. Retrieved from http://www.ncbon.com/dcp/i/board-information-mission-vision-and-values

NCGA, (2013). Session Law 2013-152. Senate Bill 222. An Act to revise the North Carolina Controlled Substance Reporting System Act, as Recommended by the Child Fatality Task Force. Retrieved from http://www.ncleg.net/Sessions/2013/Bills/Senate/PDF/S222v4.pdf

NCMB. (2015). NCMB's opioid prescribing policy to be broadly adopted statewide: policy for the use of opiates for the treatment of pain. Retrieved from http://www.ncmedboard.org/resources-information/professional-resources/publications/forum-newsletter/notice/ncmbs-opioid-prescribing-policy-adopted-as-statewide-standard

Table 1

APRN Role	**Nurse Practitioners**	**Certified Nurse Midwives**
Administrative Code	21 NCAC 36 .0815 **Reporting Criteria**	21 NCAC 33 .0110 **Reporting Criteria**
Rule	(a) The Department of Health and Human Services ("Department") may report to the North Carolina Board of Nursing ("Board") information regarding the prescribing practices of those nurse practitioners ("prescribers") whose prescribing: (1) falls within the top one percent of those prescribing 100 milligrams of morphine equivalents ("MME") per patient per day; or (2) falls within the top one percent of those prescribing 100 MME's per patient per day in combination with any benzodiazepine and who are within the top one percent of all controlled substance prescribers by volume. (b) In addition, the Department may report to the Board information regarding prescribers who have had two or more patient deaths in the preceding 12 months due to Opioid poisoning. (c) The Department may submit these reports to the Board upon request and may include the information described in G.S. 90-113.73(b).	(a) The Department of Health and Human Services ("Department") may report to the North Carolina Midwifery Joint Committee ("MJC") information regarding the prescribing practices of those certified nurse midwives ("prescribers") whose prescribing: (1) falls within the top one percent of those prescribing 100 milligrams of morphine equivalents ("MME") per patient per day; or (2) Falls within the top one percent of those prescribing 100 MME's per patient per day in combination with any benzodiazepine and who are within the top one percent of all controlled substance prescribers by volume. (b) In addition, the Department may report to the MJC information regarding prescribers who have had two or more patient deaths in the preceding 12 months due to Opioid poisoning. (c) The Department may submit these reports to the MJC upon request and may include the information described in G.S. 90-113.73(b).

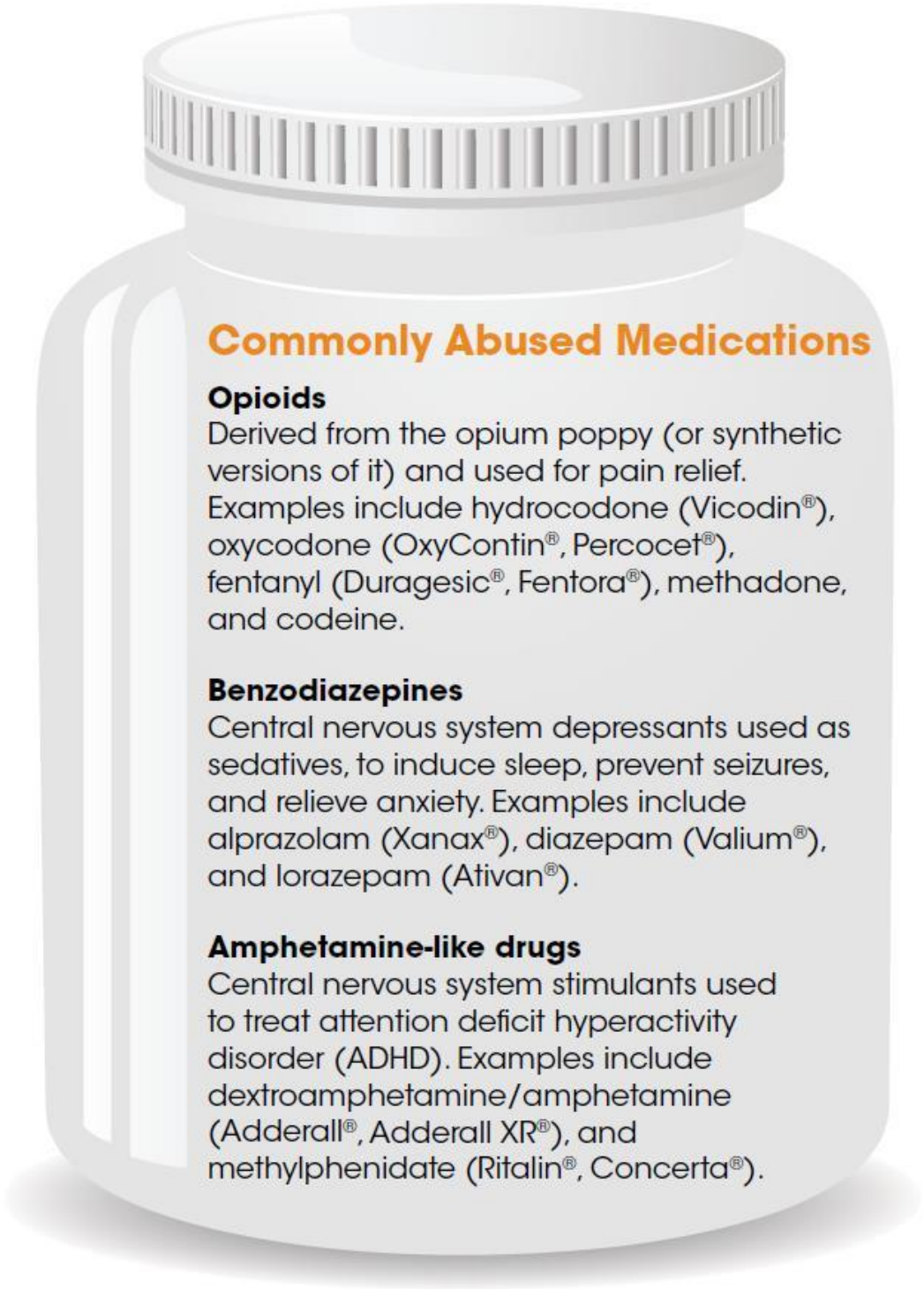
	(d) The reports and communications between the Department and the Board shall remain confidential pursuant to G.S. 90-113.74. *History Note: Authority G.S. 90-113.74; 19*	(d) The reports and communications between the Department and the MJC shall remain confidential pursuant to G.S. 90-113.74. *History Note: Authority G.S. 90-113.74*
Effective Date	April 1, 2016	May 1, 2106

Table 2

Point of Impact Question	Public Protection Measures
If an APRN is reported based on the reporting criteria, is this information published on the NCBON website?	**No.** The reports and communications between the Department and the Board shall remain confidential pursuant to G.S. 90-113.74.
What happens if an APRN is reported to the regulatory board based on the reporting criteria?	**An Investigatory process will be initiated.** When the Board receives a complaint a determination is made as to whether or not the Board has jurisdiction and whether or not reported allegation(s) violate existing laws or regulations that govern a nurse's practice. Detailed information on the investigatory process can be found on the NCBON website at http://www.ncbon.com/dcp/i/discipline-compliance-investigation-resolution-investigatory-process .
For APRNs who prescribe moderate to high dose opioids what are the proposed monitoring procedures?	**Evidence-based controlled substance management:** The monitoring and reporting will be done through the Department of Health and Human Services (DHHS), therefore, The NCBON, MJC, and NCMB cannot provide any information at this time concerning the specific proposed monitoring procedures.
If an APRN is audited does the NCBON have standard language that should be documented so that it is obvious that the NP and supervising MD are aware of dosing and patient is lucid and functional on opioid regimen?	**Evidence-based controlled substance management**: The NCBON does not have standard language that should be documented. As a client-safety and professional practice measure, it is highly advised that these cases be ***reviewed collaboratively*** with your supervising physician prior to prescribing initial or ongoing doses above 100mg (or equivalent) per day OR for cases in involving prescribing 100 MME's per patient per day in combination with any benzodiazepine (see figure 1) should be **documented** in client record. Periodic, regular review of these cases as part of the NP/CNM Supervising Physician Quality Improvement Process is also strongly advised. In this way, if a report is received by the NCBON and/or Medical Board, the NP/CNM would be immediately notified and you would be able to provide

	both client records and quality improvement documentation requested for expert review. The goal of the Rule is to identify inappropriate opioid prescribing, and this documentation would provide evidence of carefully considered, monitored, and appropriate prescribing.
APRNs working in hospice or palliative care settings may be disproportionately impacted by this reporting rule because of the large volumes of controlled substances used in evidence based management. Will this impact my license or approval to practice?	**Evidence-based controlled substance management:** The Board recognizes that the use of opiates in end of life and palliative care may present unique benefits and risks. Concepts and guidelines presented in the Policy for the use of opiates for the treatment of pain will be useful and generally apply to the use of opiates for end of life and palliative care. However, the Board's Position Statements on end of life and palliative care take precedence over information presented in the guidance.
What is the impact of this rule for APRNs who work at large tertiary, academic centers managing clients with severe, debilitating chronic pain who have failed all aggressive and interventional treatment regimens and may require large dose opioids to keep clients functional?	**Evidence-based controlled substance management:** If prescribing practices are evidence-based; in line with local and national prescribing standards; and based on current, ongoing, well documented client-specific assessments that demonstrate the need for large dose opioids; this evidence would be taken into consideration in the evaluation of any reported case.
What about clients who are transferred to us on high dose opioids and despite aggressive attempts at tapering their opioid load, they are unable to do so and function rapidly declines?	**Evidence-based controlled substance management:** If the client's history and current status are clearly documented; prescribing practices are evidence-based; in line with local and national prescribing standards; and based on current, ongoing, well documented client-specific assessments that demonstrate the need for continued high dose opioids; this evidence would be taken into consideration in the evaluation of any reported case.

Figure 1


Commonly Abused Medications
Opioids
Derived from the opium poppy (or synthetic versions of it) and used for pain relief. Examples include hydrocodone (Vicodin®), oxycodone (OxyContin®, Percocet®), fentanyl (Duragesic®, Fentora®), methadone, and codeine.
Benzodiazepines
Central nervous system depressants used as sedatives, to induce sleep, prevent seizures, and relieve anxiety. Examples include alprazolam (Xanax®), diazepam (Valium®), and lorazepam (Ativan®).
Amphetamine-like drugs
Central nervous system stimulants used to treat attention deficit hyperactivity disorder (ADHD). Examples include dextroamphetamine/amphetamine (Adderall®, Adderall XR®), and methylphenidate (Ritalin®, Concerta®).