



December 23, 2022

Kimberly Anderson, Chief Legal Officer
Ohio State Medical Board
30 E. Broad St., 3rd Floor
Columbus, OH 43215

Sent via Email to Medical Board at: Kimberly.Anderson@med.ohio.gov

RE: Rules 4731-11-03, 4731-11-04, 4731-11-09

Dear Ms. Anderson:

Thank you for the opportunity to comment on Rules 4731-11-03, 4731-11-04, and 4731-11-09.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region's professional medical association and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing over 6,000 physicians and medical students from all the contiguous counties in Northern Ohio. We are proud to be the stewards of Cleveland's medical community of the past, present, and future.

The mission of the Academy of Medicine of Cleveland & Northern Ohio is to support physicians in being strong advocates for all patients and to promote the practice of the highest quality of medicine. With that in mind, we offer the following comments.

Rule 4731-11-03: Proposed Language: B(1)b

(1) Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician shall perform all of the following:

(a) Obtain a thorough history;

(b) Perform an appropriate physical examination and mental status examination of the patient;

We do not believe it is necessary for a physician to perform a “mental status examination,” and furthermore it is not clear what would be needed to meet this requirement. If the physician has concerns about the patient's mental status, their concerns would be considered in the regular course of treatment and when obtaining the patient's history, as already required in this rule.

Rule 4731-11-04: Proposed Language 2(e)

(2) The prescriber shall complete and document the findings of all of the following:

(e) Assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.

A physician should always take into account and record obvious signs of alcohol or drug abuse in the patient’s medical record; however, we believe it is inappropriate to ask physicians to attest to the patient’s freedom from drugs and alcohol, as sometimes it is not apparent during a single patient assessment if said patient is free from the use of such substances. In addition, “freedom from” is not clearly defined, leaving it open for interpretation error. Lastly, stating the patient has “freedom from” these substances without proof could lead the physician open to potential liability issues.

Rule 4731-11-04: Proposed Language 3(a)

(3) The prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity upon ascertaining or having reason to believe any one or more of the following:

(a) The patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the prescriber physician related to the patient's use of drugs or alcohol

Again, we are concerned with interpretation issues in this section. “Propensity for alcohol or drug abuse,” could be subjective. We recommend eliminating or replacing this verbiage for assessing a patient’s history of potential drug or alcohol abuse. Additionally, in many cases it would be impossible for the physicians to know if the patient has made false or misleading statements regarding alcohol use without further testing.

Rule 4731-11-04: Proposed Language: 4(b)(c)

(b) For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction. The prescriber shall document the patient's weight loss or maintenance in the record.

(c) The prescriber shall document the patient's progress with the treatment plan.

We recommend the board strike line (b). Line (c) seems sufficient to ensure that the physician is documenting and assessing the patient's progress. Line (b) places an arbitrary 5% goal on patients that may not be appropriate for all patients to meet. Each individual patient should be assessed individually and not be subjected to arbitrary limits on their care and treatment.

Rule 4731-11-04: Proposed Language 5 (a)(c)

(5) The prescriber shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:

(a) That the patient has made any false or misleading statement to the prescriber relating to the patient's use of drugs or alcohol;

(b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;

(c) That the patient has not responded by achieving less than 5% weight reduction after three months while under treatment with a controlled substance or controlled substances;

Again, we are concerned with the "false or misleading" statement language in 5(a) and the arbitrary 5% in 5(c).

Rule 4731-11-09: Proposed Language 9 (E)

(1) The medical record of a new patient indicates that the patient is receiving hospice or palliative care;

(2) The patient has a substance use disorder, and the controlled substance is FDA

approved for and prescribed for medication assisted treatment or to treat opioid use disorder.

(3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition;

We find that these exemptions are medically appropriate and thank the board for their inclusion.

Rule 4731-11-09: Proposed Language 4 (A)

(a) The physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;

We recommend the removal of the 3-day requirement. If the patient is truly in an emergency, then the physician should determine the required length of treatment. Additionally, there may be circumstances, such as a physician office or hospital closure or a holiday weekend where there is reason to extend the prescription beyond three days.

Rule 4731-11-09: Proposed Language G

Nothing in this rule shall be construed to imply that one in-person physician or physician assistant examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.

We find the language in this section unclear and ask for further clarification on the intent behind its insertion.

Thank you again for the opportunity to provide comment.

A handwritten signature in black ink, appearing to read "Gerard Isenberg MD". The signature is written in a cursive style with a large initial "G".

Gerard Isenberg, MD
President, AMCNO