AGENDA

Committee on Prescriptive Governance (CPG)

March 5, 2018
10 AM – 4 PM

THE MISSION OF THE OHIO BOARD OF NURSING IS TO ACTIVELY SAFEGUARD THE HEALTH OF THE PUBLIC THROUGH THE EFFECTIVE REGULATION OF NURSING CARE.

The Committee on Prescriptive Governance shall develop a recommended exclusionary formulary that specifies the drugs and therapeutic devices that a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner cannot prescribe or furnish. A recommended exclusionary formulary shall not permit the prescribing or furnishing of any drug or device prohibited by federal or state law.

1. Call to Order
   a. Welcome
   b. Introductions

2. Review/Approval of October 16, 2017 Meeting Minutes

3. Rules: Acute Pain (in effect 1/1/2018) and Resources

4. New proposed draft Rules: Medication Assisted Treatment; Use of Opioid Analgesics to Treat Chronic Pain

5. Review new approved FDA drugs

6. Practice Inquiry: Prescribing HCG for weight loss

7. CARA 2016

8. Remaining 2018 meetings: July 23 and October 29

9. Other

Adjourn
Committee on Prescriptive Governance (CPG)
DRAFT MINUTES
October 16, 2017, 10:00 a.m.

Members Attending: Sherri Sievers, Chair, DNP, APRN-CNP, Chair; Kristine A. Scordo, PhD, APRN-CNP; Richard Edgin, MD; Katherine Clark, DO; Barbara Douglas, APRN-CRNA

Members Absent: Richard Bakker, MD, PhD; Megan Keller, PharmD, R.Ph

Board Staff Attending: Lisa Emrich; Anita DiPasquale; Chantelle Coles-Neal

Guests Attending: Keeley Harding, APRN; Michele Staton, Byers, Minton, & Associates

Call to Order
Sherri Sievers, Chair, noted a quorum was present and called the meeting to order at 10:01 a.m. She welcomed those in attendance, and asked the CPG members to introduce themselves.

Review/Approval of May 15, 2017 Meeting Minutes
Kristine Scordo moved to approve the minutes as submitted, seconded by Richard Edgin. The motion passed.

Rules: OAC Chapters 4723-8; 4723-9; and 4723-14 and Acute Pain Prescribing
Chair S. Sievers asked Lisa Emrich to provide an update on the proposed revised rules. L. Emrich noted that the Board values comments regarding proposed rule revisions from all Board committees and advisory groups and will continue to seek comments from the CPG, although HB 216 revised the charge of the CPG.

L. Emrich summarized the proposed revisions to Chapters 4723-8, Advanced Practice Registered Nurse Certification and Practice; 4723-9, Prescriptive Authority; and 4723-14, Continuing Education, and noted the revisions are primarily based on HB 216. In addition, changes were made to the standards of prescribing related to the prescriber patient relationship, requested by the Ohio Association of Advanced Practice Nurses. The rules were filed with the Joint Committee on Agency Rule Review on October 12, 2017.

L. Emrich provided an update about the prescribing provisions for acute pain in Rule 4723-9-10, OAC, as proposed after the May 2017 CPG meeting. In May, when the CPG reviewed Rule 4723-9-10, the rule, as well as the rules of the Medical and Dental Boards, all limited prescribers to a 30 MED per day average.

After the CPG meeting, the Medical Board changed its proposed rule to allow the "treating physician" to exceed the 30 MED per day average for patients whose acute pain is a result of crushing bone and tissue injuries, major orthopedic surgery, severe burns, and amputations. The exception was included with the requirement that the treating physician be held "singularly accountable" for the decision to exceed the 30 MED per day average. It was noted that the purpose of the rules, as discussed with the Governor’s Opiate Task Force, is to address the opioid epidemic, reduce the number of opioids in the community, and hold the physician ultimately responsible for prescribing if this exemption is used.
All of the boards’ acute pain rules became effective on August 31, 2017. After the effective date, the Nursing Board learned the Medical Board was interpreting its rule to apply to physician assistants (PAs). When the Board confirmed the exception applied to PAs, the Board believed that if it did not propose to revise the rule, APRN practice would be restricted and patient care would be negatively impacted. Therefore, the Nursing Board immediately contacted the governmental stakeholders to seek agreement that the same exception would apply to APRNs. Agreement was reached the evening of September 12, 2017, prior to the 8:30 a.m. September 13, 2017 Board meeting. At the Board meeting, the Board members reviewed and approved the proposed change and agreed to make the exception effective as soon as possible, January 2018.

L. Emrich explained the proposed Nursing Board rule is an expansion of practice for APRNs, however the rule cannot contravene the language of the Medical Board rule. The Nursing Board rule includes the language of treating physician and singularly accountable, because it is the terminology used in the Medical Board rule. The Nursing Board rule language is also based on the statutory requirement that an APRN must have a collaborative relationship with the physician and a standard care arrangement (SCA).

L. Emrich provided an example for APRNs whose practices include rounding and discharging patients. If APRNs believe these patients may need the 30 MED per day average exception to control acute pain, APRNs would add the patients’ treating physicians to the SCA, if not already listed. The SCA also needs to specify when the APRN would consult with the treating physician prior to issuing a prescription that exceeds the 30 MED average and include a statement regarding the singular accountability of the treating physician.

Dr. Richard Edgin stated the Medical Board received a significant number of comments and concerns from physicians regarding their acute pain rule and its impact on physician practice, especially orthopedic surgeons. The physicians are concerned because they believe the 30 MED average exemption is not enough to treat acute surgical pain. Dr. Edgin stated he would have preferred more discussion regarding the clinical exceptions, the criteria needed to identify and document the exceptions, and clarification of terms that were used in the Medical Board rule. He stated the Medical Board is working to provide clarification.

Chair S. Sievers stated that she believes the proposed Nursing Board rule is unclear to APRNs because of the singularly accountable language. Even if the language is added to the SCA, it remains unclear because APRNs have a collaborative, not a supervisory relationship with the physician. PAs are required to have a supervisory relationship with supervising physicians who are liable for PAs’ practice. She stated she believes there are no legal ties within the APRN’s collaborative relationship to make the physician accountable for the APRN’s prescribing practice. She stated attorneys at her institution are reviewing the matter, and physicians are clarifying this with the Medical Board. Dr. Edgin agreed it could present an unclear situation with respect to liability.

Dr. Katherine Clark stated APRNs within her healthcare system contacted her directly with their concerns of disparity with PAs, and she is now concerned with the timeline of when the revised rule would be effective to provide parity for the APRNs.

K. Scordo stated that during the discussion at the Advisory Committee on Advanced Practice Registered Nursing (Advisory Committee) meeting, it was noted the treating physician who entered into the collaborative agreement with the APRN might not necessarily be the physician overseeing the
patient's discharge. APRNs work simultaneously with multiple physicians without entering into SCAs with every physician. The term treating physician is confusing and not necessarily applicable to practice. She recommended the use of "treating practitioner." However, she noted, as discussed with the Advisory Committee, the Nursing Board cannot change this without being in conflict with the Medical Board rule.

L. Emrich reported the Advisory Committee recommended the proposed language be revised to state that the SCA must comply with Rule 4731-11-13, OAC, the Medical Board rule, which would replace the language of treating physician and singularly accountable. The Advisory Committee also recommended that the Board seek clarification of the terms used from the Medical Board. Chair S. Sievers reported that the Board would hold the public rules hearing on November 15, 2017.

**Review New Approved FDA drugs and Recommended Exclusionary Formulary**

After reviewing new drugs approved by the FDA through September 2017, K. Scordo moved that none of the new drugs be added to the Exclusionary Formulary. B. Douglas seconded the motion. The motion passed. K. Scordo moved to recommend that the Board re-approve the current Exclusionary Formulary as adopted by the Board in May 2017. Dr. Edgin seconded the motion. The motion passed.

**Flow Chart: Prescribing**

The CPG reviewed the flow chart prepared by Holly Fischer, as requested by the CPG, regarding Rule 4723-9-10, OAC. Members commented it was helpful guidance and thanked H. Fischer. The CPG suggested embedding a hotlink to the rule, and use the term "schedule II" rather than "C-II" if there was enough space.

**Letter to NCSBN: CARA 2016**

L. Emrich referred to a letter sent to the National Council of State Boards of Nursing by the Nursing Board and summarized the Comprehensive Addiction and Recovery Act of 2016 (CARA 2016). The letter requested NCSBN's assistance to seek clarification regarding APRNs, other than NPs, being included. The Board later learned that legislation to amend CARA 2016 so that all APRNs would be included was recently introduced.

**Schedule 2018 Meetings**

The following dates for 2018 were agreed upon: March 5; July 23; and October 29

**Adjournment**

Having no further business the meeting adjourned at approximately 11:05 a.m.
4723-9-10 Formulary; standards of prescribing for advanced practice registered nurses designated as clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners.

(A) Definitions; for purposes of this rule and interpretation of the formulary, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017):

(1) "Acute pain" means pain that normally fades with healing, is related to tissue damage and significantly alters a patient's typical function, and is expected to be time-limited.

(2) "Extended-release or long-acting opioid analgesic" means an opioid analgesic that:

(a) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;

(b) Is administered via a transdermal route; or

(c) Contains methadone.

(3) "Family member" means a spouse, parent, child, sibling or other individual with respect to whom a nurse's personal or emotional involvement may render the nurse unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.

(4) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.

(5) "ICD-10-CM medical diagnosis code" means the disease code in the most current international classification of diseases, clinical modifications published by the United States department of health and human services.

(6) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code, and means a controlled substance that has analgesic pharmacological activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.

(7) "Minor" has the same meaning as in section 3719.061 of the Revised Code.
(8) "Morphine equivalent daily dose (MED)" means a conversion of various opioid analgesics to a morphine equivalent dose by the use of accepted conversion tables provided by the state board of pharmacy at: http://www.pharmacy.ohio.gov/MED.html https://www.ohiopmp.gov/MED_Calculator.aspx (effective 2017).

(9) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(10) "Terminal condition" has the same meaning as in section 2133.01 of the Revised Code.

(B) The committee on prescriptive governance shall establish a recommended exclusionary formulary, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017), that may specify the exclusion of therapeutic devices, individual drugs or subtypes or individual drugs.

(C) The recommended exclusionary formulary shall not permit the prescribing or furnishing of any drug or device prohibited by federal or state law, or rules adopted by the board, including this rule.

(D) The formulary established by the committee on prescriptive governance shall be available on the Ohio board of nursing web site, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017).

(E) The committee on prescriptive governance shall review the formulary, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017), for additions or deletions at least twice a year.

(F) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe any drug or therapeutic device in any form or route of administration if:

1. The ability to prescribe the drug or therapeutic device is within the scope of practice in the nurse's specialty area;

2. The prescription is consistent with the terms of a standard care arrangement entered into with a collaborating physician;

3. The prescription would not exceed the prescriptive authority of the collaborating physician, including restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board, or by the state medical board rules, including but not limited to rule 4731-11-09 of the Administrative Code;
(4) The individual drug or subtype or therapeutic device is not one excluded by the formulary, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017);

(5) The prescription meets the requirements of state and federal law, including but not limited to this rule, rule 4729-5-30 of the Administrative Code and rule 4729-5-13 of the Administrative Code;

(6) A valid prescriber-patient relationship exists. This relationship may include, but is not limited to:

(a) Obtaining a thorough relevant history of the patient;

(b) Conducting a physical or mental examination of the patient;

(c) Rendering a diagnosis;

(d) Prescribing medication, ruling out the existence of any recognized contraindications;

(e) Consulting with the collaborating physician when necessary; and

(f) Properly documenting these steps in the patient's medical records;

(7) Notwithstanding paragraph (F)(6) of this rule, the nurse may prescribe or personally furnish a drug according to section 4723.4810 of the Revised Code to not more than a total of two individuals who are sexual partners of the nurse's patient.

(8) If the patient is a family member, acceptable and prevailing standards of safe nursing care require that a nurse maintain detached professional judgment. The nurse shall not prescribe to a family member unless:

(a) The nurse is able to exercise detached professional judgment in reaching diagnostic or therapeutic decisions;

(b) The prescription is documented in the patient's record.

(9) For drugs that are a controlled substance:

(a) The nurse has obtained a United States drug enforcement administration registration, except if not required to do so as provided in rule 4729-17-13 of the Administrative Code, and indicates the number on the prescription;
(b) The prescription indicates the ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at minimum, include the first four alphanumeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and etiology (ex. M165);

(c) The prescription indicates the intended days' supply of the controlled substance prescription. The intended days' supply is calculated by dividing the total quantity prescribed by the maximum intended number of tablets or doses per day;

(d) The patient is not a family member; and

(e) The nurse shall not self-prescribe a controlled substance.

(G) Except as provided in paragraph (H) of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe a schedule II controlled substance only in situations where all of the following apply:

(1) A patient has a terminal condition;

(2) A physician initially prescribed the substance for the patient; and

(3) The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, seventy-two hour period.

(H) Subject to the requirements set forth in paragraphs (I) and (J) of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe a schedule II controlled substance, if not excluded by the formulary, located at http://www.nursing.ohio.gov/Practice-Prescribing.htm (effective 2017), if the nurse issues the prescription to the patient from any of the following locations:

(1) A hospital registered under section 3701.07 of the Revised Code;

(2) An entity owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(3) A health care facility operated by the department of mental health or the department of developmental disabilities;

(4) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code;
(5) A county home or district home operated under Chapter 5155. of the Revised Code that is certified under the medicare or medicaid program;

(6) A hospice care program;

(7) A community mental health agency, as defined in section 5122.01 of the Revised Code;

(8) An ambulatory surgical facility, as defined in section 3702.30 of the Revised Code;

(9) A freestanding birthing center, as defined in section 3702.141 of the Revised Code;

(10) A federally qualified health center, as defined in section 3701.047 of the Revised Code;

(11) A federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;

(12) A health care office or facility operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code;

(13) A site where a medical practice is operated, but only if the practice is comprised of one or more physicians who also are owners of the practice; the practice is organized to provide direct patient care; and the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner providing services at the site has a standard care arrangement and collaborates with at least one of the physician owners who practices primarily at that site; or

(14) A residential care facility, as defined in section 3721.01 of the Revised Code.

(I) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not issue to a patient a prescription for a schedule II controlled substance from a convenience care clinic even if the clinic is owned or operated by an entity specified in paragraph (H) of this rule.

(J) For the treatment of acute pain, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall comply with the following:

(1) Extended-release or long-acting opioid analgesics shall not be prescribed for the treatment of acute pain;
(2) Before prescribing an opioid analgesic, the nurse shall first consider non-opioid treatment options. If opioid analgesic medications are required as determined by history and physical examination, the prescription should be for the minimum quantity and potency needed to treat the expected duration of pain, with a presumption that a three-day supply or less is frequently sufficient;

(3) In all circumstances where opioid analgesics are prescribed for acute pain:

(a) Except as provided in paragraph (J)(3)(a)(iii) of this rule, the duration of the first opioid analgesic prescription for the treatment of an episode of acute pain shall be:

(i) For adults, not more than a seven-day supply with no refills;

(ii) For minors, not more than a five-day supply with no refills. As set forth in section 4723.481 of the Revised Code, a nurse shall comply with section 3719.061 of the Revised Code, including but not limited to obtaining the parent or guardian’s written consent prior to prescribing an opioid analgesic to a minor;

(iii) The seven-day limit for adults and five-day limit for minors may be exceeded for pain that is expected to persist for longer than seven days based on the pathology causing the pain. In this circumstance, the reason that the limits are being exceeded and the reason that a non-opioid analgesic medication was not appropriate to treat the patient’s condition shall be documented in the patient’s medical record; and

(iv) If a patient is intolerant of or allergic to an opioid medication initially prescribed, a prescription for a different opioid medication may be issued at any time during the initial seven-day or five-day dosing period, and the new prescription shall be subject to the requirements of this rule. The patient’s intolerance or allergy shall be documented in the patient’s medical record, and the patient advised to safely dispose of the unused medication;

(b) The patient, or a minor’s parent or guardian, shall be advised of the benefits and risks of the opioid analgesic, including the potential for addiction, and the advice shall be documented in the patient’s medical record; and

(c) The total morphine equivalent dose (MED) of a prescription for opioid analgesics for treatment of acute pain shall not exceed an average of thirty MED per day, except when:
(i) The circumstances set forth in paragraph (A)(3)(c) of rule 4731-11-13 of the Administrative Code exist; and

(ii) The patient's treating physician has entered a standard care arrangement with the advanced practice registered nurse that states the understanding of the physician as to when the nurse may exceed the thirty MED average, and when the nurse must consult with the physician prior to exceeding the thirty MED average. The standard care arrangement in this circumstance must comply with rule 4731-11-13 of the Administrative Code, and the advanced practice registered nurse must document in the patient's record the reason for exceeding the thirty MED average and the reason it is the lowest dose consistent with the patient's medical condition.

(K) The requirements of paragraph (J) of this rule apply to treatment of acute pain, and do not apply when an opioid analgesic is prescribed:

1. To an individual who is a hospice patient or in a hospice care program;

2. To an individual who is receiving palliative care;

3. To an individual who has been diagnosed with a terminal condition; or

4. To an individual who has cancer or a condition associated with the individual's cancer or history of cancer.

(L) The requirements of paragraph (J) of this rule do not apply to:

1. Prescriptions for opioid analgesics for the treatment of opioid addiction utilizing a controlled substance that is approved by the FDA for opioid detoxification or maintenance treatment; or

2. Inpatient prescriptions as defined in rule 4729-17-01 of the Administrative Code.

(M) Drugs approved by the FDA but not yet reviewed and approved by the committee on prescriptive governance may be prescribed, unless later disapproved by the committee on prescriptive governance, if:

1. The drug type or subtype is not excluded on the formulary, located at http://www.nursing.ohio.gov/Practice.htm (effective 2017); and

2. The collaborating physician has agreed in the standard care arrangement that the nurse may prescribe drugs approved by the FDA, that meet the criteria set forth
in paragraphs (M)(1) and (M)(2) of this rule, that have not yet been reviewed and approved by the committee on prescriptive governance.

(N) As specified in section 4723.44 of the Revised Code, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not prescribe any drug or device to perform or induce an abortion.

(O) As specified in section 4723.488 of the Revised Code, notwithstanding the requirements of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe or personally furnish naloxone.

(P) The requirements of paragraph (F)(9)(c) of this rule apply to prescriptions for products that contain gabapentin.
Effective: 1/1/2018

Five Year Review (FYR) Dates: 10/15/2020

CERTIFIED ELECTRONICALLY

Certification

12/18/2017

Date

Promulgated Under: 119.03
Statutory Authority: 3719.062, 4723.07, 4723.50
Rule Amplifies: 4723.481, 4723.486, 4723.487, 4723.488, 4723.49, 4723.491, 4723.492
Prior Effective Dates: 02/01/2002, 02/01/2003, 02/01/2006, 02/01/2008, 11/05/2012, 02/01/2016, 08/31/2017
Frequently Asked Questions

1. What are Ohio’s acute pain prescribing rules?

The Medical Board’s acute pain prescribing rules are made up of three parts:
- Rule 4731-11-01, Ohio Administrative Code (OAC), defines such terms as “acute pain,” Morphine equivalent daily dosage (MED), “opioid analgesic,” and other terms.
- Rule 4731-11-02, OAC, requires a prescription to comply with Pharmacy Board rules setting requirements for the content of a prescription.
- Rule 4731-11-13, OAC, sets requirements for the prescribing of opioid analgesics for the treatment of acute pain.

The rules apply to the prescribing of an opioid analgesic for the treatment of acute pain in an outpatient setting. The rules do not apply to the treatment of acute pain in an in-patient setting, treatment of chronic pain, treatment of a hospice patient, treatment of a palliative care patient, treatment of a person who has been diagnosed with a terminal condition, treatment of a cancer patient, or treatment of opioid addiction using a controlled substance approved for that purpose by the FDA.

Similar rules for acute pain prescribing have been adopted by the Ohio State Dental Board and the Ohio Board of Nursing.

2. What is the purpose of the rules?

The acute pain prescribing rules reflect the policy of the State of Ohio that when it is necessary to treat acute pain with an opioid analgesic, the prescription should be for the shortest number of days and lowest dosage required to treat the acute pain.

3. In what situations would a prescription be considered an “inpatient prescription”?

As defined by Rule 4729-17-01, "inpatient" means any person who receives drugs for use while within the institutional facility and "inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient. The dosage limits do not apply to treatment of pain during a patient’s hospital stay.

Institutional facility means a hospital, convalescent home, developmental facility, long term care facility, nursing home, psychiatric facility, rehabilitation facility, developmental disability facility and Level III sub-acute detoxification facility.
4. Are the acute pain opioid prescribing rules for physician assistants as well?

The rules are applicable to physician assistants for two reasons:
1. The Medical Board’s rules regarding controlled substance prescribing in Chapter 4371-11, OAC, apply to physician assistants. See, Rule 4730-2-07, OAC
2. The Physician Assistant Practice Act provides that a physician assistant may not prescribe beyond the authority of the supervising physician. A supervising physician may not authorize a physician assistant to provide prescriptive services in a way that is incompatible with the services within the physician's normal course of practice. See 4730.02(D)(2), ORC. See also 4730.21(C), ORC. Accordingly, the supervising physician may not authorize the physician assistant to prescribe for a greater number of days’ supply or greater dosage than the supervising physician may prescribe.

In addition, a physician assistant must comply with the Physician Assistant Formulary.

5. Do the rules apply to nurse practitioners?

Advanced practice registered nurses, including nurse practitioners, must comply with Nursing Board Rule 4723-9-10, OAC.

6. Do the rules apply to Ohio licensed physicians/physician assistants who don’t practice in Ohio, but do practice in another state?

No, the rules do not apply if the physician or physician assistant is not practicing under their Ohio license. For example:
- The rules are NOT applicable to an Ohio-licensed physician or physician assistant who is practicing in another state under a medical license issued by that other state.
- The rules ARE applicable to an Ohio-licensed physician or physician assistant who is based in another state but who is providing medical services via telemedicine to a patient located in Ohio. In this example, the practice occurs in Ohio under the Ohio license because the patient is located in Ohio at the time medical service is rendered.

7. I am a physician assistant (PA). Does Rule 4731-11-13 override the Physician Assistant Formulary?

No, the PA Formulary must still be followed in accordance with OAC 4731-11-13 and ORC 4730.41. A general summary of a physician assistant’s ability to prescribe scheduled drugs to treat acute pain is as follows:
OPIOID ANALGESICS OTHER THAN SCHEDULE II DRUGS:
The PA who holds a valid prescriber number and DEA registration may prescribe the opioid analgesic as authorized to do so by the supervising physician, and health care facility policy, if applicable, in compliance with the acute pain rules. This includes the ability to write for longer than a seven-day supply or dosage greater than a 30 MED average per day.

SCHEDULE II OPIOID ANALGESICS:
IN A HOSPITAL or other location specified in ORC 4730.411(B)(2) through (12): A PA who holds a valid prescriber number and DEA registration may prescribe a Schedule II drug for the treatment of acute pain in compliance with the acute pain prescribing rules, when authorized to do so by the facility’s policies and the supervising physician.

IN A MEDICAL PRACTICE OWNED BY ONE OR MORE PHYSICIANS TO PROVIDE DIRECT PATIENT CARE, WHERE THE SUPERVISING PHYSICIAN IS ONE OF THE OWNERS AND PRIMARILY PRACTICES AT THAT LOCATION:
• Prescription initiated by the PA without supervising physician involvement: A PA who holds DEA registration may only write one prescription for no more than a seven-day supply of a Schedule II opioid analgesic. The PA may not write the prescription for longer than seven days or write a second prescription to the patient.
• Prescription initiated by the physician or by the PA after consultation with the physician: A PA may write a prescription for more than a seven-day supply in compliance with OAC 4731-11-13(A)(3)(a)(iii). For subsequent prescriptions to the patient the physician assistant may not change the drug or dosage unless there is documentation in the patient record that the supervising physician approved the change(s).

8. Following a routine surgical procedure in my office, I gave the patient a three-day supply of a Schedule III opioid analgesic to treat the pain. If the patient calls to ask for another prescription because the pain has not subsided does the rule allow me to prescribe the patient another prescription for an opioid analgesic?

Yes, you would be able to write a subsequent prescription for an opioid analgesic. However, the prescription should be written for the fewest number of days and lowest dosage required to treat the pain.

9. Does the rule require that the patient come into the office before another prescription for an opioid analgesic may be written to treat their acute pain?

No, the rule does not require that the patient come into the office before receiving a subsequent prescription for an opioid analgesic. The determination of whether the patient should be seen in the office should be made based upon the medical condition or injury, the status of the patient, and other considerations for appropriate medical care.
10. What documentation is needed to support writing an opioid analgesic prescription for longer than seven days for an adult/five days for a minor or a prescription greater than 30 MED?

- When the physician or physician assistant believes that a patient needs a new, acute-pain related opioid that exceeds the 7/5 day or the 30 MED rule, the documentation should provide a rationale within the progress note that explains the justification for it. This could be brief information about the actual condition or treatment which necessitates more than the recommended MED or duration of treatment.
- The documentation should indicate whether there are known and available non-opiate alternatives, and why it has been determined not to utilize these alternatives.
- Should a patient have a known history of narcotic use, the physician or physician assistant should document the reason for acute opioid needs versus known chronic pain.
- The first four characters of the ICD-10 code should be noted in the progress note and, starting on December 29, 2017, written on the prescription.
- As per current standards, review of an OARRS report should be documented.
- Documentation of planned follow up with the patient.

11. How does the rule’s requirement to obtain adult consent before prescribing to a minor an opioid analgesic for acute pain square up with the provisions of Section 3719.061 of the Ohio Revised Code that exempt care in hospitals and certain other settings from a similar requirement?

It is not necessary to obtain written consent from an appropriate adult before prescribing an opioid analgesic to a minor in situations that are exempt from this requirement in Section 3719.061(C). However, the exemptions in that statute do not apply to the five-day limit or dosage limit. There must be compliance with the five-day limit and 30 MED average per day dosage limit provisions in Rule 4731-11-13.

12. Am I able to prescribe an extended-release or long-acting opioid analgesic to treat acute pain following a medical procedure for which the journals support that the patient will likely experience a high degree of pain?


13. Do the rules apply when a patient, who is prescribed an opioid analgesic for chronic pain, sustains an injury or undergoes surgery for which acute pain medication is appropriate?

Yes, the rules apply to all prescriptions for out-patient treatment of acute pain. Where the patient is already on an opioid analgesic for chronic pain, it is suggested that, the physician or physician
14. Do the rules allow for the prescribing of an opioid analgesic to a patient with sickle cell anemia who is already prescribed an opioid analgesic for chronic pain but who then experiences a sickle cell crisis resulting in acute pain if the combined dosage of the medication for the chronic and acute pain will be greater than 30 MED?

Yes, but the physician or physician assistant must document that exceeding the 30 MED limit is necessary based on clinical judgment and the patient’s needs and the reason the dosage is the lowest dosage consistent with the patient’s medical condition. When possible, the chronic pain prescriber should be consulted, with the results documented to support the dosage prescribed. However, the prescription for acute pain must be limited to no more than the number of days required to treat the expected duration of the pain, with the required documentation made if the number of days exceeds five for a minor or seven for an adult patient.

15. If I have written the first opioid analgesic prescription for longer than seven days (adult patient) or five days (minor patient), may a cross-covering or on-call physician or physician assistant write the patient another prescription?

Yes. A cross-covering or on-call physician or physician assistant may write the patient another prescription for an opioid analgesic to treat acute pain. However, the subsequent prescription should be written for the shortest number of days and lowest dosage required to treat the acute pain.

16. If I have written the first opioid analgesic prescription for a dosage above a 30 MED average per day, may a cross-covering or on-call physician or physician assistant write the patient another prescription for a dosage greater than 30 MED average per day?

No. Rule 4731-11-13(A)(3)(c)(iv) authorizes only the original prescriber to exceed the 30 MED average per day limit. The original prescriber should ensure that he or she is available to patients who may have a severe acute injury or condition for which the dosage may need to exceed the 30 MED. An in-person reassessment may also be necessary for patients experiencing escalating pain.
17. Are the “treating physician” and “prescribing physician” in Rule 4731-11-13(A)(3)(c) the same individual?

The language of paragraph (A)(3)(c) states that the treating physician determines, based upon prevailing standards of medical care, that the patient suffers from medical conditions, surgical outcomes, or injuries of such severity that pain cannot be managed with the 30 MED average limit. The treating physician must document in the record the reason for exceeding the 30 MED average. However, the rule then states that the only “prescribing physician” may exceed the 30 MED average and will be held singularly accountable for the prescription.

As used in 4731-11-13(A)(3)(c)(i) through (v), the term “prescribing physician” must be read to mean “treating physician.” Only the treating physician may write a prescription for a dosage above the 30 MED average per day limit. The treating physician must also write any subsequent prescriptions for the patient that are for a dosage above the 30 MED average per day limit.

18. Is there a preference between prescribing a drug containing hydrocodone or one containing oxycodone?

The acute pain prescribing rules do not specify the drugs that may be prescribed for post-surgical, out-patient usage by the patient. The rule does, however, prohibit the prescribing of long-acting or extended-release opioid analgesics for the treatment of acute pain.

18. What additional documentation is required on the prescription for an opioid analgesic for the treatment of acute pain?

Beginning December 29, 2017, all prescriptions for an opioid analgesic must include the first four characters of the ICD-10 code for the condition being treated. Also, beginning June 1, 2018 a prescription for any controlled substance, including an opioid analgesic, must also include the number of days for which the medication is being prescribed.

19. Does Rule 4731-11-13 apply to a liquid form of an opioid analgesic?

The rule does not apply to a liquid form of an opioid analgesic that is used for a purpose other than the treatment of pain. For example, the rule does not apply to the prescription of cough medications that contain an opioid analgesic.

20. Is it permissible to treat acute pain by writing an opioid analgesic prescription for seven days, but include a refill for another seven days in case the patient requires it?
No. Rule 4731-11-13 prohibits a physician or physician assistant from giving a refill on the first prescription written for the outpatient treatment of acute pain.

21. I practice at a Veterans Administration medical center or at a military facility in my capacity as an active duty member of a military service. Do I have to comply with the acute pain prescribing rules?

The acute pain rules do not apply to a physician or physician assistant while practicing at a U.S. Veterans Administration facility or while practicing at a military facility while serving on active military duty.

22. Rule 4731-11-13 provides a mechanism for prescribing a dosage greater than a 30 MED average per day and lists four types of conditions. Are these the ONLY conditions for which a dosage greater than 30 MED average per day or longer than 7/5 days may be written?

The acute pain prescribing rules reflect the policy of the State of Ohio that when it is necessary to treat acute pain with an opioid analgesic the prescription should be for the shortest number of days and lowest dosage required to treat the acute pain. However, there is also a recognition that there are situations where the pain is of such severity that it cannot be managed within the 30 MED or in 7/5 days. The four conditions listed in paragraph (A)(3)(c)(i) of Rule 4731-11-13 were provided as examples. There are many other types of conditions, surgical outcomes, or injuries for which the treating physician or physician assistant might determine, based upon prevailing standards of medical care, that an opioid analgesic with a dosage greater than 30 MED average or 7/5 days is appropriate. The Medical Board will not be creating a listing of reasons; clinical judgement and documentation should be used in those situations.

23. For purposes of Rule 4731-11-13’s language providing that the dosage may be greater than 30 MED average per day in certain situations, how are “major orthopedic surgery” or “severe burns” defined?

The rules do not define “major orthopedic surgery” or “severe burns.” The terms should be interpreted as surgery or burns of such severity that pain cannot be managed within the 30 MED average limit as determined based upon the prevailing standards of medical care.

24. If the patient’s procedure warrants more than 30 MED, what is the maximum MED per day that can be prescribed to treat post-operative acute pain?
Rule 4731-11-13 does not set a maximum MED per day that can be prescribed to treat post-operative, out-patient acute pain or other similar exceptions. For dosages greater than 30 MED average per day, the documentation must include the reason for exceeding the 30 MED average and the reason the dosage being prescribed is the lowest dosage consistent with the patient’s medical condition. Prescriptions that exceed the 30 MED average daily dosage are subject to additional review by the Medical Board.

25. If the patient's pain is anticipated to last longer than 7/5 days, what is the maximum period for which an opioid analgesic may be prescribed to treat acute pain?

Rule 4731-11-13 does not set a maximum number of days for which an opioid analgesic prescription may be written to treat acute pain in situations where the prescriber's clinical judgement determines more than 7/5 days is necessary. The number of days should always be the fewest number needed to treat the expected duration of the acute pain. The reason that the number of days exceeds seven for an adult or five for a minor and the reason why a non-opioid medication is not appropriate to treat the pain must be documented in the patient medical record. Prescriptions that exceed the 7/5 day limit are subject to additional review by the Medical Board.

26. When writing an opioid analgesic prescription to treat a hospice patient’s acute pain is it required that I note on the prescription that it is for a hospice patient?

The prescription should include the first four characters of the ICD-10 code for the condition being treated as acute pain. Starting on December 29, 2017 this information will be required on all prescriptions for opioid analgesics, and will be required on all controlled substance prescriptions starting on June 1, 2018. The ICD-10 code may indicate that the patient’s conditions is terminal or that the patient is receiving hospice care.

If a pharmacist calls concerning an opioid analgesic prescription that is written for more than 7/5 days or for a dosage greater than 30 MED average per day, it is appropriate for the prescribing physician or physician assistant to advise the pharmacist that the patient is a hospice patient.

27. How do I determine the MED equivalent of an opioid analgesic?

The Pharmacy Board has a MED calculator available on the OARRS website: ohiopmp.gov/MED_Calculator.aspx
Written Prescriptions:
Below is an example of a written prescription that complies with the Board of Pharmacy's prescription requirements:

1. Contain the manually printed, typewritten, or preprinted full name, professional title (MD, DO, DDS, etc.), and address of the prescriber. NOTE: The prescriber's address shall include the physical address of the prescriber's practice location (cannot include a P.O. box).

Dr. Terri Smith, M.D.
77 South High Street
Columbus, Ohio 43215
614-555-1234

2. Indicate a telephone number where the prescriber can be personally contacted during normal business hours.

3. Indicate the full name and residential address of the patient. The patient's residential address shall include the patient's physical street address.

Name: Eric Jones
Address: 1234 South Main Street,
Columbus, Ohio 43217

4. Indicate the quantity to dispense.

Oxycodone 5mg
Sig: Take 1 tab every 4-6 hours.
Disp: 12 / Twelve tablets
Diagnosis: M16.5
Days' supply: 3 days

5. Be dated as of and on the day when issued.

Date: 10/17/2017

6. Indicate the drug name and strength.

7. NOTE: To ensure clarity, it is recommended to avoid using abbreviations for drug names.

8. Indicate the appropriate and explicit directions for use.

9. Specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.

NOTE: A prescriber shall not authorize any refills for schedule II controlled substances.

IMPORTANT INFORMATION ON REFILLS: Prescriptions for schedule III and IV controlled substances may be refilled not more than five times in a 60-day period from the date the prescription is issued by a prescriber. Refills may be authorized for up to one year from the date of issuance for schedule V controlled substances and for prescription drugs that are not controlled substances.

10. For controlled substances only (does not apply to veterinarians):

a. The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four alphanumeric characters of the ICD-10 CM medical diagnosis code, sometimes referred to as the category and the etiology (e.g., M16.5).

b. For dentists, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American Dental Association, of the dental treatment requiring the controlled substance prescription.

11. For controlled substances only: Indicate the Drug Enforcement Administration registration number of the prescriber.

12. For controlled substances and products containing gabapentin (does not apply to veterinarians) indicate the days' supply of the prescription.

IMPORTANT: Effective December 29, 2017, a prescriber must determine at the time of prescribing the intended days' supply (minimum number of days) the prescription for a controlled substance or gabapentin should last the patient. Prescribers of “as needed” medications should consider the following:

• Patients may not need the maximum daily dose every day or may taper doses after a few days of use.

• Patients may not be consuming the medication continuously (i.e., around-the-clock).
Faxed Prescriptions

Written prescriptions authorized and signed in ink by a prescriber may be transmitted by the prescriber or the prescriber’s agent by a fax machine.

All faxed prescriptions must comply with the requirements for a written prescription and must also include header information identifying the origin of the fax.

In general, schedule II controlled substance prescriptions cannot be faxed. Exceptions to this are outlined in rule 4729-5-30 of the Ohio Administrative Code.

Electronic Prescribing

Prescribers may electronically transmit prescriptions directly to the pharmacy. Except for a manual signature, the systems must be able to transmit all the required information as required on a written prescription.

It is the responsibility of the vendor and prescriber to ensure that all prescriptions include the required information listed in rule 4729-5-30 of the Ohio Administrative Code, including the transmission of the diagnosis code.

IMPORTANT: All controlled substance electronic prescriptions are covered by the Drug Enforcement Administration’s (DEA) regulations on E-Prescribing of Controlled Substances (21 CFR 1311). Ohio permits the electronic prescribing of all controlled substance prescriptions.

NOTE: The Board of Pharmacy will no longer be approving most electronic prescription systems. For more information on this, visit www.pharmacy.ohio.gov/approval.

Electronic to Computer-Generated Faxed Prescriptions

Effective December 29, 2017, no prescriptions may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image.

There are two exceptions where a computer-generated faxed prescription is still permissible:

- If there is a temporary outage by a Board-approved third-party intermediary or the receiving pharmacy, then a computer-generated faxed prescription will be accepted.
- A closed system “e-to-fax” prescription or order transmission system approved by the Board.

For more information on this change, including what constitutes a closed system, visit www.pharmacy.ohio.gov/approval.

Prescription Format

Board of Pharmacy rule 4729-5-13 contains additional provisions on issuing a valid prescription, including:

- Written or faxed prescriptions may contain no more than three noncontrolled substance prescription orders per prescription.
- Written or faxed prescriptions may only contain one controlled substance prescription order per prescription.
- Preprinted prescriptions that contain multiple drug names or strength combinations (i.e., the prescriber must check a box) must comply with the following:
  - Cannot include controlled substances among the choices.
  - There is only one prescription order selected per form.
- Preprinted prescriptions for controlled substances must only contain one drug and strength combination printed on the form.

NOTE: There are some exceptions to the preprinted prescription requirements for hospice patients. For a complete list of the exceptions, please refer to rule 4729-5-13 of the Ohio Administrative Code.

Brought to you by:

TakeChargeOhio
Manage Pain. Prevent Medication Abuse.

For more information on safe pain management tips visit, takechargeohio.org
Rule 4723-9-10, OAC:  
CNP s, CNSs, CNMs Prescribing Opioid Analgesics for Acute Pain

Rule 4723-9-10, OAC, sets forth standards of prescribing for advanced practice registered nurses (APRNs) who are designated as clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), or certified nurse practitioners (CNPs). The rule includes the requirements for prescribing opioid analgesics for the treatment of acute pain. For the purposes of this document, APRN prescribers include CNSs, CNMs, and CNPs.

The information below provides an overview. APRN prescribers should review Rule 4723-9-10 in full, in conjunction with: Medical Board Rule 4723-11-13, OAC, the FAQ published by the Medical Board; Pharmacy Board Rules 4729-5-30 and 4729-17-13, OAC, Issuing a Valid Prescription: What Every Prescriber Needs to Know and the Pharmacy Board Morphine Equivalent Dose (MED) Calculator at: www.pharmacy.ohio.gov/MEDtable.

Prescribing Opioid Analgesics for Treatment of Acute Pain

Effective August 31, 2017, Rule 4723-9-10, OAC, limits the prescribing of opioid analgesics for acute pain by APRNs. These limits do not apply to inpatient prescriptions¹ and do not apply to prescriptions for:
- Cancer and associated conditions;
- Palliative care;
- End-of-life/hospice care;
- Medication-assisted treatment for addiction.

For all other situations, the following limits apply to opioid analgesics prescribed for treatment of acute pain:

- Extended-release or long-acting opioids shall not be prescribed;
- Non-opioid treatment options must be considered first;
- Opioids may only be prescribed following a history and physical that determines the need for the prescription;
- The patient has been advised of the benefits and risks of the opioid (including the potential for addiction) and this is documented in the patient record;
- The presumption is a three-day supply or less is frequently sufficient;
- Not more than a seven-day supply of opioids may be prescribed for adults, with no refills.
- Not more than a five-day supply of opioids may be prescribed for minors, with no refills, and only after the written consent of the parent or guardian is obtained.
- The seven-day and five-day limits may be exceeded for pain expected to persist for a longer period of time as long as a 30 MED average per day is maintained and the APRN documents in the patient record the reason for exceeding the time and why a non-

¹ See definition in Pharmacy Board Rule 4729-17-01, OAC.
opioid medication is not appropriate.

**Exception to the 30 MED Average Per Day (Effective January 1, 2018)**

The morphine equivalent dose of a prescription for acute pain cannot exceed an average of 30 MED per day, except as follows:

- The patient suffers from a medical condition, surgical outcome, or injury of such severity that pain cannot be managed within an average of 30 MED per day such as:
  - Traumatic crushing of tissue;
  - Amputation;
  - Major orthopedic surgery;
  - Severe burns.\(^2\)

- The treating physician\(^3\) for the condition has entered a standard care arrangement with the APRN.

- The APRN documents in the patient’s record the reason for exceeding the 30 MED average and the reason it is the lowest dose consistent with the patient’s medical condition.

**APRN Collaboration and Standard Care Arrangement**

- Ohio law requires that APRNs practice in collaboration with a physician or podiatrist with whom the APRN has entered a written contract called a standard care arrangement (SCA).\(^4\)

- An APRN’s prescriptive authority cannot legally exceed that of the APRN’s collaborating physician.\(^5\)

- Ohio physicians are required to comply with Medical Board Rule 4731-11-13, OAC, which prohibits physicians from exceeding the 30 MED average unless the physician is the “treating physician” for the patient’s medical condition (such as traumatic crushing of tissue, amputation, major orthopedic surgery or severe burns).

- The APRN must have a SCA with the “treating physician” in order to exceed the average 30 MED dose for treatment of acute pain.

- The SCA must document the understanding between the APRN and the treating physician as to: (a) when the APRN prescriber may exceed the 30 MED average; and (b) whether the APRN prescriber must consult with the physician prior to exceeding the 30 MED average, and if consultation is required, when it is required.

  - **Example:** An APRN has an SCA with all physicians in a facility orthopedic surgical unit, signed by the unit director or chair as the designated representative. The SCA includes an exhibit specifying conditions in which the APRN may exceed the 30 MED average following major orthopedic surgery of

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\(^2\) See Medical Board Rule 4731-11-13(A)(3)(c), OAC, which applies to physicians and physician assistants (as delegated by the treating physician).

\(^3\) See Medical Board FAQ #17 regarding “treating physician.”

\(^4\) Section 4723.431, Ohio Revised Code (ORC).

\(^5\) Section 4723.481(B), ORC.
such severity that pain cannot be managed within the 30 MED average limits as determined based on prevailing standards of medical care\textsuperscript{6}, including which conditions and circumstances require treating physician consultation, and which do not. The APRN prescriber must follow the SCA regarding the parameters set forth for prescribing and consultation.

- The SCA does not require the treating physician to supervise the APRN and does not constitute a delegation of prescriptive authority to the APRN.

Questions?
Please see www.nursing.ohio.gov or email practice@nursing.ohio.gov. As a reminder, guidelines for the treatment of chronic pain using opioids can be accessed here.

\textsuperscript{6} See Medical Board FAQ #23.
4723.51 Standards and procedures for medication-assisted treatment; adoption of rules.

(A) As used in this section:

(1) "Controlled substance," "schedule III," "schedule IV," and "schedule V" have the same meanings as in section 3719.01 of the Revised Code.

(2) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code.

(B) The board of nursing shall adopt rules establishing standards and procedures to be followed by advanced practice registered nurses in the use of all drugs approved by the United States food and drug administration for use in medication-assisted treatment, including controlled substances in schedule III, IV, or V. The rules shall address detoxification, relapse prevention, patient assessment, individual treatment planning, counseling and recovery supports, diversion control, and other topics selected by the board after considering best practices in medication-assisted treatment.

The board may apply the rules to all circumstances in which an advanced practice registered nurse prescribes drugs for use in medication-assisted treatment or limit the application of the rules to prescriptions for medication-assisted treatment issued for patients being treated in office-based practices or other practice types or locations specified by the board.

(C) All rules adopted under this section shall be adopted in accordance with Chapter 119. of the Revised Code. The rules shall be consistent with rules adopted under sections 4730.55 and 4731.056 of the Revised Code.

Added by 132nd General Assembly File No. TBD, HB 49, §101.01, eff. 9/29/2017.
Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) “Trigger Point”

Preface: These guidelines address the use of opioids for the treatment of chronic, non-terminal pain. “Chronic pain” means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. The guidelines are intended to help health care providers review and assess their approach in the prescribing of opioids. The guidelines are points of reference intended to supplement and not replace the individual prescriber’s clinical judgment. The 80 mg MED is the maximum daily dose at which point the prescriber’s actions are triggered; however, this 80 mg MED trigger point is not an endorsement by any regulatory body or medical professional to utilize that dose or greater.

Introduction

Recent analysis by the Centers for Disease Control and Prevention (CDC) shows that “patients with mental health and substance use disorders are at increased risk for nonmedical use and overdose from prescription painkillers as well as being prescribed high doses of these drugs.” Drug overdose deaths increased for the 11th consecutive year in 2010. Nearly 60% of the deaths involved pharmaceuticals, and opioids were involved in nearly 75%. Researchers also found that drugs prescribed for mental health conditions were involved in over half. These findings appear consistent with research previously published in the *Annals of Internal Medicine* that concluded that “patients receiving higher doses of prescribed opioids are at an increased risk for overdose, which underscores the need for close supervision of these patients” (Dunn, et al., 2010).

Non-Opioid Therapies First

Health care providers are not obligated to use opioids when a favorable risk-benefit balance cannot be documented. Providers should first consider non-pharmacologic and non-opioid therapies. Providers should exercise the same caution with tramadol as with opioids and must take into account the medication’s potential for abuse, the possibility the patient will obtain the medication for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the medication.

Avoid Long-Term and Co-Prescribing

Providers must be vigilant to the wide range of potential adverse effects associated with long-term opioid therapy and misuse of extended-release formulations. That vigilance and detailed attention has to be present from the outset of prescribing and continue for the duration of treatment. Providers should avoid starting a patient on long-term opioid therapy when treating chronic pain. Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects.

Press Pause

Providers can further minimize the potential for prescription drug abuse/misuse and help reduce the number of unintentional overdose deaths associated with pain medications by recognizing times to “press pause” in response to certain “trigger points.” This pause allows providers to reassess their compliance with accepted and prevailing standards of care. The 80 mg Morphine Equivalent Daily Dose (MED) “trigger point” is one such time.

Ensure Patient Safety

Providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than three continuous months should strongly consider doing the following to optimize therapy and help ensure patient safety:

- Reestablish informed consent, including providing the patient with written information on the potential adverse effects of long-term opioid therapy.
- Review the patient’s functional status and documentation, including the 4A’s of chronic pain treatment
  - Activities of daily living,
  - Adverse effects,
  - Analgesia; and
  - Aberrant behavior
- Review the patient’s progress toward treatment objectives for the duration of treatment.
- Utilize OARRS as an additional check on patient compliance.
- Consider a patient pain treatment agreement that may include: more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of pain medications, and consequences for non-compliance with terms of the agreement.
- Reconsider having the patient evaluated by one or more other providers who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(Released October 2013)
Review Treatment Plan

The 80 MED “trigger point” is an opportunity to review the plan of treatment, the patient's response to treatment, and any modification to the plan of treatment that is necessary to achieve a favorable risk-benefit balance for the patient's care. If opioid therapy is continued, further reassessment will be guided by clinical judgment and decision-making consistent with accepted and prevailing standards of care. The “trigger point” also provides an opportunity to further assess addiction risk or mental health concerns, possibly using Screening, Brief Intervention, and Referral to Treatment (SBIRT) tools, including referral to an addiction medicine specialist when appropriate.

For providers treating acute exacerbation of chronic, non-terminal pain, clinical judgment may not trigger the need for using the full array of reassessment tools.

Providers treating patients with acute care conditions in the emergency department or urgent care center should refer to the Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances Prescribing Guidelines. [http://www.healthy.ohio.gov/ed/guidelines](http://www.healthy.ohio.gov/ed/guidelines)
MEMORANDUM

To: Advisory Committee on Advanced Practice Registered Nursing (APRN Committee) Members Committee on Prescriptive Governance (CPG) Members

From: Lisa Emrich Program Manager

Subject: Medical Board Draft Outline for MAT Rules – Comment

Date: February 22, 2018

Attached is a draft outline for rules developed and distributed by the State Medical Board of Ohio regarding medication-assisted treatment (MAT) for opioid addiction. The Medical Board is requesting comments by March 8, 2018.

As members of the APRN Committee or CPG, if you have questions or comments, please contact Holly Fischer by email at hfischer@nursing.ohio.gov or 614-995-4934 by the end of business on March 7. She will resolve questions and/or compile comments and submit the information to the Medical Board by the deadline.

If you are providing comments on behalf of your employer, practice, organization, etc., rather than as an Advisory Committee or CPG member, please submit those comments directly to the Medical Board and in this case, please do not refer to yourself as a member of the APRN Committee or CPG.

If you have questions, please contact me. We appreciate your review.
Sections 4730.55 and 4731.056, Ohio Revised Code, require the Medical Board to adopt rules that establish standards and procedures to be followed by physician assistants and physicians in the use of all drugs approved by the FDA for use in medication-assisted treatment, including controlled substances in Schedules III, IV, or V. The required rules must address:

- detoxification,
- relapse prevention,
- patient assessment,
- individual treatment planning,
- counseling and recovery supports,
- diversion control, and
- any other topics selected by the Medical Board after considering best practices in medication assisted treatment.

The Board may apply the rules to all settings or limit the application of the rules to medication-assisted treatment in the office setting ("OBOT") or other practice types and locations.

The draft physician assistant rules are virtually the same as for physicians. The drafts were prepared with significant input from the Ohio Department of Mental Health and Addiction Services. The drafts are consistent with and reflect the provisions of the "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American Society of Addiction Medicine in 2013. The plan for the chapter of rules is as follows:

Rules 4730-4-01 and 4731-33-01: Definitions

Rules 4730-4-02 and 4731-33-02: Detoxification ===== To be presented in the future

Rules 4730-4-03 and 4731-33-03: Office based treatment for opioid addiction.

Information Concerning Proposed Rules 4730-4-03 and 4731-33-03

- The rules are re-writes of current Rule 4731-11-12, OAC. Current Rule 4731-11-12 will be rescinded.

- Paragraph (A) exempts physicians and physician assistants who provide OBOT in correctional facilities, hospitals, level III sub-acute detoxification facilities, and opioid treatment programs. All of the exempted practice settings are licensed by federal and/or state agencies.

- The rules require that the patient assessment cover specific areas and include specific testing. The rule also requires a treatment plan that includes patient education, urine-drug screens, a signed treatment agreement, and a plan for psychosocial treatment (arrived at in collaboration with a qualified behavioral healthcare provider).

- Treatment must be provided in accordance with a SAMHSA treatment improvement protocol or the ASAM practice guidelines.

- The rules provide that where clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider that the patient must be referred to a mental health service provider.
The rules require that a Naloxone kit or a prescription for Naloxone be provided to the patient.

For treatment with buprenorphine products:

- Subutex may only be prescribed for a pregnant patient, when converting the patient from methodone or Subutex to buprenorphine containing naloxone, or in formulations other than tablet form for indications approved by the FDA.

- There is not a prohibition against prescribing buprenorphine to a patient also prescribed other opioids, benzodiazepines, and other controlled substances. However, such prescribing must be limited to extenuating circumstances.

- For induction, the maximum dosage must not exceed eight milligrams and the patient must be seen at least once per week.

- During stabilization, the number of days for the drug is at first limited to a two-week supply, and after ninety days may not exceed a thirty-day supply.

- Diversion prevention requires such actions as pill counts and urine drug screens.

- The maximum dosage is set at twenty-four milligrams, but the rational for a dosage exceeding sixteen milligrams must be documented.

- Relapse prevention strategies must be incorporated into the treatment plan.

For treatment with Naltrexone:

- The physician assistant or physician must provide information to the patient concerning the risks of opioid overdose if Naltrexone is stopped and opioids are used.

- The rule sets dosage limits.

- Diversion prevention and relapse prevention strategies must be incorporated.

- Extended release Naltrexone (Vivitrol) may be used for the treatment of opioid dependence and/or alcohol use disorders. A maximum dosage is set.

Comment deadline: March 8, 2018

Please send comments to: Sallie Debolt, Senior Counsel
State Medical Board of Ohio
Sallie.Debolt@med.ohio.gov
A. “Office-based Opioid Treatment” means medication-assisted treatment in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of alcoholism or opioid addiction, prevention of relapse of alcoholism or drug addiction, or both.

B. “OBOT” means office-based opioid treatment as defined in this rule.

C. “SAMHSA” means the United States substance abuse and mental health administration.

D. “Medication-assisted treatment” means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of alcoholism or drug addiction, prevention of relapse of alcoholism or drug addiction, or both.

E. “OARRS” means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

F. “Qualified behavioral healthcare provider” means the following who is practicing within the scope of practice of the professional license:

1. Board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, licensed under chapter 4731. of the Revised Code;

2. Chemical dependency professional licensed under chapter 4758. of the Administrative Code;

3. Professional clinical counselor, or licensed professional counselor, or licensed independent social worker, licensed under chapter 4757. of the Revised Code;

4. Advanced practice registered nurse, licensed as a clinical nurse specialist under chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

5. Advanced practice registered nurse, licensed as a nurse practitioner under chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; or

6. Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under chapter 4732. of the Revised Code.

G. “Mental health service provider” means one of the following who is practicing within the scope of practice of the professional license:
1. Psychiatrist licensed under chapter 4731. of the Revised Code;

2. Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, and licensed under chapter 4732. of the Revised Code;

3. Professional clinical counselor, or licensed professional counselor, licensed independent social worker, licensed under chapter 4757. of the Revised Code; or

4. Advanced practice registered nurse clinical nurse specialist whose nursing specialty is mental health or psychiatric mental health, licensed under chapter 4723. of the Revised Code.
4730-4-03 Office based treatment for opioid addiction – Proposed 2-20-18

A. This rule is applicable to a physician assistant who provides OBOT, as defined in rule 4730-3-01 of the Administrative Code, except it is not applicable to a physician assistant who provides OBOT in any of the following settings:

1. State or local correctional facilities, as defined in section 5163.45 of the Revised Code;
2. A hospital, as defined in section 3727.01 of the Revised Code;
3. A level III sub-acute detoxification facilities certified by the Ohio department of mental health and addiction services;
4. An opioid treatment program certified by SAMSHA and accredited by an independent, SAMHSA-approved accrediting body;

B. A physician assistant who holds the DATA 2000 waiver issued by the substance abuse and mental health services administration shall only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise.

C. A physician assistant who provides OBOT shall abide by all federal and state laws and regulations governing the prescribing of the medication.

D. The physician assistant who provides OBOT shall perform and document an assessment that includes all of the following:
   a. A comprehensive medical and psychiatric history;
   b. A brief mental status history;
   c. Substance abuse history;
   d. Family history and psychosocial supports;
   e. Appropriate physical examination;
   f. Urine drug screen;
   g. Pregnancy test for women of childbearing age and ability;
   h. Review of the patient’s prescription information in OARRS;
   i. Testing for human immunodeficiency virus;
   j. Testing for hepatitis B;
   k. Testing for hepatitis C; and
   l. Testing for tuberculosis.

E. The physician assistant who provides OBOT shall establish and document a treatment plan that includes all of the following:
   1. The physician assistant’s rationale for selection of the specific drug to be used in the medication-assisted treatment;
   2. Patient education;
   3. The patient’s written, informed consent;
   4. Random urine-drug screens;
   5. A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant; and
   6. A plan for psychosocial treatment, pursuant to paragraph (E) or (F) of this rule.

F. The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:
a. SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at https://store.samhsa.gov/list/series?name=TIP-Series-Treatment-Improvement-Protocols-TIPS-&pageNumber=1.


G. The physician assistant who provides OBOT shall refer and collaborate with a qualified behavioral healthcare provider, as defined in rule 4730-3-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

   a. The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

   b. The treatment shall include at least one of the following interventions:

      i. Cognitive behavioral treatment;
      ii. Community reinforcement approach;
      iii. Contingency management/motivational incentives;
      iv. Motivational interviewing; or
      v. Behavioral couples counseling.

   c. The treatment plan shall include a structure for renegotiation of the treatment plan if the patient does not adhere to the original plan.

H. When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, as defined in rule 4730-3-01 of the Administrative Code, the physician assistant shall ensure that the OBOT treatment plan includes referral of the patient to a mental health service provider who has the education and experience to provide substance abuse counseling, or require the patient to participate in a mutual help program.

   a. If the physician assistant refers the patient to a mental health service provider, the physician assistant shall document the referral and the physician assistant’s maintenance of meaningful interactions with the mental health service provider in the patient record.

   b. If the patient is required to participate in a mutual help program, the physician assistant shall require the patient to provide documentation of on-going participation in the program.

I. The physician assistant who provides OBOT shall either provide a naloxone kit including the nasal atomizer or other device furnished by the physician, or a prescription for such kit.
a. The physician assistant shall ensure that the patient receives instruction on the kit’s use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

b. The physician assistant shall be exempt from this requirement if the client refuses the naloxone kit.

J. In addition to paragraphs (A) through (I) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with all of the following requirements.

1. With the exception of those conditions listed in paragraph (J)(2) of this rule, a physician assistant who treats the opioid addiction with a buprenorphine product shall only prescribe buprenorphine products containing naloxone for use in OBOT.

2. The physician assistant shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:
   a. When a patient is pregnant;
   c. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or
   c. In formulations other than tablet of film form for indications approved by the FDA.

3. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the physician assistant shall only co-prescribe these substances when there are extenuating circumstances.
   a. The physician assistant shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.
   b. The physician assistant shall document progress with achieving the tapering plan.

4. During the induction phase, except for medically indicated circumstances as documented in the medical record, the physician assistant shall start a patient on no more than eight milligrams of buprenorphine per day. The physician assistant shall see the patient at least once a week.

5. During the stabilization phase, the physician assistant shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.
   i. During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.
ii. Starting with the ninety-first day of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

6. The physician assistant shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician assistant shall also require urine drug screens or serum medication levels at least twice per quarter for the first year of treatment and once per quarter thereafter.

7. The physician assistant shall document in the medical record the rational for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

8. The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-3-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

9. The physician assistant may treat a patient using the administration of extended-release buprenorphine.

   a. The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

   b. The physician assistant shall prescribe an extended-release buprenorphine strictly in accordance with the food and drug administration’s approved labeling for the drug’s use.

   c. The physician assistant shall document in the patient record the rational for the use of the extended-release buprenorphine product.

   d. The physician assistant shall only delegate the administration of extended-release buprenorphine to a nurse licensed under chapter 4723 of the Revised Code, who is acting in accordance with the scope of practice of the professional license.

K. In addition to the requirements of paragraphs (A) through (I) of this rule, the physician assistant providing OBOT using naltrexone shall comply with all of the following requirements.

1. Prior to treating a patient with naltrexone, the physician assistant shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician assistant shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.
2. The physician assistant shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.
   
a. The dosage shall be no greater than 50 mg daily or three times weekly dosing with two 100-mg doses followed by one 150-mg dose.

b. The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

c. The physician assistant shall take steps to reduce the chances of naltrexone diversion by using the lowest effective dose, appropriate frequency of office visits, and pill counts. The physician assistant shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

d. The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

3. The physician assistant may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.
   
a. The physician assistant should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

b. The injection dosage shall be no greater than 380 mg per injection given every four weeks.

c. The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-3-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.
A. “Office-based Opioid Treatment” means medication-assisted treatment in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of alcoholism or opioid addiction, prevention of relapse of alcoholism or drug addiction, or both.

B. “OBOT” means office-based opioid treatment as defined in this rule.

C. “SAMHSA” means the United States substance abuse and mental health administration.

D. “Medication-assisted treatment” means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of alcoholism or drug addiction, prevention of relapse of alcoholism or drug addiction, or both.

E. “OARRS” means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

F. “Qualified behavioral healthcare provider” means the following who is practicing within the scope of practice of the professional license:

   1. Board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, licensed under chapter 4731. of the Revised Code;

   2. Chemical dependency professional licensed under chapter 4758. of the Administrative Code;

   3. Professional clinical counselor, or licensed professional counselor, or licensed independent social worker, licensed under chapter 4757. of the Revised Code;

   4. Advanced practice registered nurse, licensed as a clinical nurse specialist under chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

   5. Advanced practice registered nurse, licensed as a nurse practitioner under chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; or

   6. Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under chapter 4732. of the Revised Code.

G. “Mental health service provider” means one of the following who is practicing within the scope of practice of the professional license:

   1. Psychiatrist licensed under chapter 4731. of the Revised Code;
2. Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, and licensed under chapter 4732. of the Revised Code;

3. Professional clinical counselor, or licensed professional counselor, licensed independent social worker, licensed under chapter 4757. of the Revised Code; or

4. Advanced practice registered nurse clinical nurse specialist whose nursing specialty is mental health or psychiatric mental health, licensed under chapter 4723. of the Revised Code.
A. This rule is applicable to a physician who provides OBOT, as defined in rule 4731-33-01 of the Administrative Code, except it is not applicable to a physician who provides OBOT in any of the following settings:

1. State or local correctional facilities, as defined in section 5163.45 of the Revised Code;
2. A hospital, as defined in section 3727.01 of the Revised Code;
3. A level III sub-acute detoxification facility certified by the Ohio department of mental health and addiction services;
4. An opioid treatment program certified by SAMSHA and accredited by an independent, SAMHSA-approved accrediting body;

B. A physician who provides OBOT shall abide by all federal and state laws and regulations governing the prescribing of the medication.

C. The physician who provides OBOT shall perform and document an assessment that includes all of the following:
   1. A comprehensive medical and psychiatric history;
   2. A brief mental status history;
   3. Substance abuse history;
   4. Family history and psychosocial supports;
   5. Appropriate physical examination;
   6. Urine drug screen
   7. Pregnancy test for women of childbearing age and ability;
   8. Review of the patient’s prescription information in OARRS;
   9. Testing for human immunodeficiency virus;
   10. Testing for hepatitis B;
   11. Testing for hepatitis C; and

D. The physician who provides OBOT shall establish and document a treatment plan that includes all of the following:
   1. The physician’s rationale for selection of the specific drug to be used in the medication-assisted treatment;
   2. Patient education;
   3. The patient’s written, informed consent;
   4. Random urine-drug screens;
   5. A signed treatment agreement that outlines the responsibilities of the patient and the physician; and
   6. A plan for psychosocial treatment, pursuant to paragraph (F) or (G) of this rule.

E. The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

   1. SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at https://store.samhsa.gov/list/series?name=TIP-Series-Treatment-Improvement-Protocols-TIPS-&pageNumber=1.

F. The physician who provides OBOT shall refer and collaborate with a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

   1. The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

   2. The treatment shall include at least one of the following interventions:

      a. Cognitive behavioral treatment;
      b. Community reinforcement approach;
      c. Contingency management/motivational incentives;
      d. Motivational interviewing; or
      e. Behavioral couples counseling.

   3. The treatment plan shall include a structure for renegotiation of the treatment plan if the patient does not adhere to the original plan.

G. When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, the physician shall ensure that the OBOT treatment plan includes referral of the patient to a mental health service provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling, or require the patient to participate in a mutual help program.

   1. If the physician refers the patient to a mental health service provider, the physician shall document the referral and the physician’s maintenance of meaningful interactions with the mental health service provider in the patient record.

   2. If the patient is required to participate in a mutual help program, the physician shall require the patient to provide documentation of on-going participation in the program.

H. The physician who provides OBOT shall either provide a naloxone kit including the nasal atomizer or other device furnished by the physician, or a prescription for such kit.

   1. The physician shall ensure that the patient receives instruction on the kit’s use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.
2. The physician shall be exempt from this requirement if the client refuses the naloxone kit.

I. In addition to paragraphs (A) through (H) of this rule, the physician who provides OBOT using buprenorphine products shall comply with all of the following requirements.

1. With the exception of those conditions listed in paragraph (I)(2) of this rule, a physician who treats the opioid addiction with a buprenorphine product shall only prescribe buprenorphine products containing naloxone for use in OBOT.

2. The physician shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:
   
a. When a patient is pregnant;

   b. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; or

   c. In formulations other than tablet or film form for indications approved by the FDA.

3. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the physician shall only co-prescribe these substances when there are extenuating circumstances.
   
a. The physician shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

   b. The physician shall document progress with achieving the tapering plan.

4. During the induction phase, except for medically indicated circumstances as documented in the medical record, the physician shall start a patient on no more than eight milligrams of buprenorphine per day. The physician shall see the patient at least once a week.

5. During the stabilization phase, the physician shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.
   
a. During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

   b. Starting with the ninety-first day of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

6. The physician shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and
checks of OARRS. The physician shall also require urine drug screens or serum medication levels at twice per quarter for the first year of treatment and once per quarter thereafter.

7. The physician shall document in the medical record the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

8. The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01of the Administrative Code, who has the education and experience to provide substance abuse counseling.

9. The physician may treat a patient using the administration of extended-release buprenorphine.

   a. The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

   b. The physician shall prescribe an extended-release buprenorphine strictly in accordance with the food and drug administration’s approved labeling for the drug’s use.

   c. The physician shall document in the patient record the rational for the use of the extended-release buprenorphine product.

   d. The physician shall only delegate the administration of extended-release buprenorphine to a physician assistant licensed under chapter 4730. of the Revised Code or a nurse licensed under chapter 4723. of the Revised Code, when the physician assistant or nurse is acting in accordance with the scope of practice of their professional license.

J. In addition to the requirements of paragraphs (A) through (H) of this rule, the physician providing OBOT using naltrexone shall comply with all of the following requirements.

1. Prior to treating a patient with naltrexone, the physician shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

2. The physician shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

   a. The dosage shall be no greater than 50 mg daily or three times weekly dosing with two 100-mg doses followed by one 150-mg dose.

   b. The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.
c. The physician shall take steps to reduce the chances of naltrexone diversion by using the lowest effective dose, appropriate frequency of office visits, and pill counts. The physician shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

d. The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare or mental health service provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

3. The physician may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.

   a. The physician should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

   b. The injection dosage shall be no greater than 380 mg per injection given every four weeks.

   c. The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider or mental health service provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.
### New Drugs Review by CPG March 5, 2018 (October 2017 to January 2018)
(Original New Drug Applications: FDA)

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<th>Generic</th>
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<td>Axicabtagene Ciloleucel</td>
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<td>Zoster Vaccine (Recombinant)</td>
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<td>Hepatitis B Vaccine</td>
<td>Heplisav-B</td>
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#### December 2017

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**CPG Action: An "X" in this column indicates the drug was not added to the Exclusionary Formulary**
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<td>Macrilen</td>
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<td>Voretigene Neparovvec-rzyl</td>
<td>Luxturna</td>
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<tr>
<td>Lutetium Lu 177 Dotatate</td>
<td>Lutathera</td>
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**January 2018**
Board staff are receiving inquiries regarding APRN practice about prescribing Human Chorionic Gonadotropin (HCG) to patients for weight loss. This information is being provided for your review and discussion.

By way of background, the prior Committee on Prescriptive Governance reviewed this request from an APRN and in 2016, voted to designate in the Formulary that APRNs “may not prescribe” HCG for the purpose of weight loss. At that time, the CPG noted there was no evidence-based data to support that prescribing HCG for weight loss is consistent with the standards of practice.

The Formulary was later revised to the current Exclusionary Formulary, which restricts APRN prescribing only to drugs prohibited by state or federal law, so there is no longer a prohibition in the Formulary for prescribing HCG for weight loss. Board staff have been contacted again with the question of whether an APRN may prescribe HCG for weight loss. Staff have advised those inquiring, that when determining whether to prescribe a drug that is not prohibited in the Exclusionary Formulary, an APRN must consider the acceptable and prevailing standards of practice, and that currently Board staff have no evidence-based data to support that prescribing HCG for weight loss is consistent with the standards of practice.

The attached article by Asher, W., and Harper, H. (1973) was the only documentation provided by a recent inquirer to support the practice. The attached Drug Facts and Comparisons monograph notes that the American Medical Association and the American Society of Bariatric Physicians do not support the use of HCG for weight loss. At the September 2017 meeting, the State of Ohio Medical Board changed its Physician Assistant Formulary to prohibit physician assistants from prescribing HCG, noting “there is no evidence-based data to support the use of HCG in a weight loss program...” The page of the Medical Board Meeting Minutes pertaining to the discussion is also attached.

We appreciate your review. The Committee’s comments will be provided to the CPG when the question is discussed at its March 5, 2018 meeting.
Effect of human chorionic gonadotrophin on weight loss, hunger, and feeling of well-being

W. L. Asher, M.D., and Harold W. Harper, M.D.

Since Simeons (1, 2) introduced his method of treating obesity using human chorionic gonadotrophin (HCG), there has been continuing controversy concerning the effect of HCG on the program. Simeons and his followers have generally not claimed that patients eating 500 kcal daily will lose more weight when receiving HCG. They (2-4) have claimed that patients are less hungry and feel better because of the HCG and are thus more apt to remain in treatment. There have been a number of literature reports of double-blind studies (5-9) concerning the effect of HCG on weight loss. Only one (8) indicated HCG may be of more value than a placebo. However, as pointed out by Gusman (4), most investigators significantly altered Simeons' basic program. Both Simeons and his followers have vociferously maintained that strict adherence to the basics of Simeons' program is essential if HCG is to be useful.

Because of the increasing popularity of Simeons' program, it was felt further attempts should be made to assess, in a double-blind manner, not only weight loss but the degree of hunger and the feeling of well-being of patients receiving HCG or an identically appearing placebo.

Patients and methods

One of us (HH), who has an active practice using HCG in weight reduction, did the clinical work. The other (WA) prepared the protocol, labeled the vials of HCG and placebo, and analyzed the results. Forty female patients received, in a modified double-blind manner, either HCG injections or placebo injections. HCG and placebo were prepared by Glogau & Co., Chicago, Illinois, in identically appearing vials. The HCG preparation was prepared in the usual commercial manner. It contained, in addition to HCG, mannitol with monobasic and dibasic sodium phosphates as buffers. The placebo preparation consisted of mannitol with monobasic and dibasic sodium phosphates as buffers.

All patients were evaluated for weight loss and other parameters. The code was not broken until the clinical work was completed and the data had all been gathered.

Patient selection

All patients were females 18 years of age or older who had no known serious disease processes requiring significant medications. They were selected from apparently well-motivated patients desiring to enter the HCG program for weight reduction. None was selected who had previously been on Simeons' program. Also excluded from the study were patients who had received appetite suppressants or other weight medications in the 6 weeks prior to the start of the study. None had lost more than 5 lb in the 3 months prior to treatment. No patients were to receive diuretics during the study. Oral contraceptives, estrogen, or thyroid products needed to maintain a euthyroid state could be continued if the patients were receiving them prior to the start of the study. They were neither to be stopped nor started during the study period. Patients known to be pregnant were excluded from the study.

Parameters measured

Blood pressure was taken at the start and at the end of treatment with the patient in a sitting position. The patients were weighed with approximately the same amount of light clothing each day. They were questioned daily about hunger; the responses of those reporting hunger were recorded as "little," "some," or "much." Patients were also asked on each visit how they felt, and the responses were recorded as "excellent," "good," "fair," or "poor."

Injections

Three patients received injections from each vial. Numbers of the three patients to receive injections from each vial were assigned on a random basis before the vials were shipped to the clinical investigator (HH). A series of six vials, of either HCG or an identically appearing placebo, were

1 From the American Society of Bariatric Physicians Research Council, 333 West Hampden Avenue, Englewood, Colorado 80110.
2 Requests for reprints should be addressed to W. L. Asher, M.D., at the American Society of Bariatric Physicians Research Council.
3 Present address: 3959 Laurel Canyon Blvd., Suite F, Studio City, California 91606.
labeled for each trio of patients. Two series of vials, however, had only two numbers on each vial. A new vial was used each 7 days. The study material was kept refrigerated after mixing with bacteriostatic water. Injections were given while cold; at no time did the medications remain at room temperature. Patients were to return to the office 6 days each week for 36 injections (unless the desired weight was achieved prior to this). They received 125 IU of the study material intramuscularly in the upper-outer quadrant of the buttocks on each visit. Injections were discontinued on the days of heavy menstrual flow of a few patients (usually 2 or 3 days). No appetite suppressants or other medications were given. Patients were advised to use no laxatives but were permitted to use a Fleet's or Baxter enema if needed.

Patients were advised to "avoid the use of any and all cosmetics containing fats or oils." They were also to avoid skin contact with other oils or fats. Chewing gum, throat pastilles, vitamin pills, cough syrups, and alcohol were not permitted. The patients were encouraged to drink 8 to 10 glasses of water daily.

Patients were repeatedly advised that absolute adherence to the program was essential. They were told the slightest infractions would slow or stop their weight loss. "The slightest deviation from any of the details will result in utter disaster."

Diet for days of the first three injections

Patients were encouraged to eat all they wished of the foods allowed. No beverages containing caffeine were permitted during this period.

Breakfast and lunch, 1st day. Meat: (all lean) beef, veal, lamb, pork, chicken, turkey, beef or veal heart. Hard cooked eggs. Vegetables: brussels sprouts, cauliflower, green peppers, cucumbers, spinach (not canned), Swiss chard, cabbage, fresh asparagus, tomatoes, kohlrabi. Fruit: apples, oranges, and grapefruit at any time until lunch.

Afternoon of 1st day to noon 2nd day. Patients were to fast after lunch the 1st day until noon the 2nd day. There was no limit on noncaloric, noncaffeine fluids during this period.

Noon 2nd day until noon 3rd day. Patients could have only fruits and vegetables to be selected from the fruit and vegetable groups of the 1st day.

Lunch and evening meal 3rd day. Same as breakfast and lunch of the 1st day.

Diet for remainder of the study period

On the 4th day of injections, the patients were started on a low fat diet of 500 to 550 kcal (no mention was made of calories, however). They were warned "you must not make any changes or substitutions even though you may think they are an improvement or you will be utterly disappointed."

Patients were advised to keep a daily food diary and bring it with them each day. Two meals each day were to be eaten. Meals could be eaten at any

time but foods from both meals could not be eaten at the same time. For each meal, one item was to be chosen from each of four food groups, protein, vegetable, bread, and fruit.

Protein group

All meat and fish were to be weighed on a postal scale. Three and one-half ounces (raw weight) were to be eaten at each meal.

1) Meat: Chicken breast (white meat, excluding skin), chicken livers purchased raw and cooked. Veal, in the following lean cuts only: a) sirloin, b) rump roast, c) loin chop. Lean beef hearts, dried chopped beef (3.5 oz). No other beef allowed. All meats and seafoods to be prepared by fat-free cooking.

2) Seafoods: White fish, fresh or frozen, unbreaded, as the following: flat fish (sole, flounder), haddock, pollock, perch, pike, white sea bass, halibut. Shellfish: Lobster, crab, shrimp, only. Iris-brand dietetic canned Cohoe salmon, 3.75 oz (oil must be washed from top). No dried, pickled, or smoked fish, or other seafood allowed.

3) Meat substitutions: Hoop (farmer or pot) cheese, 4 oz mixed with water and seasoning. Occasionally, the whites only of six hard-cooked eggs might be taken as a protein substitute. No cottage cheese was allowed.

Vegetable group

One-half to one cup of one type of the following vegetables at each meal: asparagus, beet greens (not beets), cabbage, celery, chard, chicory, Chinese cabbage, cucumbers, dill-sour pickles (these must be unsweetened), endive, escarole, fennel, kale, lettuce salad. Mung bean sprouts, mushrooms, onions, parsley, red radishes, spinach, string beans, summer squash, tomatoes, watercress. Low calorie dressings containing no more than 1 kcal/tablespoon might be used.

Bread group

Choice of one of the following: one average size bread stick (Grissino), melba toast, Finn crisp cracker (very thin), one square of Norwegian flatbread, or one-third of an English muffin containing 75 kcal or less per muffin (actual calories must be listed on the package).

Fruit group

Choice of one: apple, orange, handful of strawberries (approximately 8 oz), one-half cantaloupe, or one-half grapefruit, one-fourth casaba or honeydew melon, ½ cup sugar-free cooked rhubarb (artificial sweetener permitted), ¼ cup of the following (fresh or waterpacked, and/or artificially

The basic 500- to 550-kcal diet was suggested by Simeons. The specific details of this and the diet for the first 3 days in toto were designed by Peter G. Lindner, M.D., and are reprinted with his permission.
sweetened): sliced peaches, apricots, gooseberries, or papaya. One cup D-Zerta gelatine dessert (other sugar-free brands allowed).

The following were also allowed at any time: 1) juice of one lemon daily for all purposes; 2) one tablespoon of milk/day; 3) salt, Lawry’s seasoning, pepper, vinegar, dry mustard powder, garlic, sweet basil, thyme or seasonings, but no oil, butter, or dressing; 4) any amount of water, black coffee or tea, dietetic soft drinks marked 2 kcal/bottle or less, and artificial sweeteners.

The diet sheet ends with “Any slight change in the above diet rules will result in downright disappointment.” The patient was also impressed that he was to lose weight each day or a reason must be found, i.e., fluid retention, dietary digressions, et cetera.

The initial workup included a medical and dietary history, physician examination, and a number of laboratory tests.

**Results**

Of the 40 patients starting this study, 17 of 20 in the HCG group and 13 of 20 in the placebo group completed 30 or more injections (Table 1). Data on all starting patients were included in the final analyses whenever possible. Final blood pressures and measurements were not obtained in patient 2 of the placebo group who left town due to a death in the family. These data were also unavailable on patients 19, 20, 25, 26, and 33 of the placebo group who dropped out of treatment early. Data concerning hunger in patients 13 and 16 were misplaced and thus not included in evaluating the degree of hunger for this group.

The mean age of the HCG group was 37.8 years (range 18 to 63) and that of the placebo group was 38.4 years (range 21 to 67). The mean height of the HCG group was 64.2 inches (range 60.2 to 70.0), whereas the placebo group had a mean height of 64.0 inches (range 58.5 to 67.5).

Weight loss data on all patients are included in Table 1. The mean starting weight was 6.3 lb greater in the placebo group than in the HCG group. This difference, however, was not significant. The mean weight loss in the HCG group was 19.96 ± 1.63 lb and 11.05 ± 1.29 lb in the placebo group (P < 0.001). The mean percentage of starting weight lost in the HCG group was 11.47 ± 0.58 and 6.77 ± 0.83 in the placebo group (P < 0.001). The mean weight loss per injection was 0.585 ± 0.044 lb in the HCG group and 0.403 ± 0.047 lb in the placebo group (P < 0.025). Fourteen patients lost 15 lb or more in the HCG group and in the placebo group five lost 15 lb or more.

The change in mean systolic and diastolic blood pressures during treatment was not significant in either group at the P = 0.05 level (Table 2). Patients 2, 19, 20, 25, 26, and 33 were excluded from analysis because of incomplete data.

In the HCG group, 76.6 ± 3.30% of the daily responses indicated little or no hunger. In the placebo group, 48.7 ± 4.44% of the daily responses indicated little or no hunger (P < 0.001) (Table 3).

Of the daily responses of patients in the HCG group, 86.5 ± 2.66% indicated they felt “good” to “excellent” as compared with 70.0 ± 3.82% of the responses in the placebo group (P < 0.001) (Table 3).

**Discussion**

The mean weight loss and the mean percentage of starting weight that was lost were significantly greater in the HCG group than in the placebo group. It seems unlikely that if both groups had followed their diets strictly there would have been a significant difference in weight loss between the groups. Advocates of this method, including Simeons (1-4) feel that with HCG the patients are less hungry and generally feel better. Responses to daily questioning regarding hunger and feeling of well-being in this study are consistent with these views. It thus seems probable that the increased weight loss of the patients on HCG was related to the fact that they followed more closely the dietary instructions than did the placebo group.

Of the four reports of double-blind studies in the literature, only the study of Lebon (8) showed a significantly greater weight loss in the HCG group than in the placebo group (P < 0.05). The results of our study were quite unexpected by the author responsible for study design because the results of our initial study were negative, as have been most double-blind studies reported in the literature.

There was strict attention given to limiting
dietary fat. Simeons (3) pointed out that American beef, which is feed lot fattened, contains much more fat than Italian beef. No beef other than beef hearts or dried chipped beef was allowed on this program. All fats were markedly restricted. Even cosmetics containing fats were curtailed, although it is difficult to see how this would affect the pro-

| TABLE 1 |
| Starting weight and weight loss |

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<th>Height, inches</th>
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<th>Loss, lb</th>
<th>Percent body weight loss</th>
<th>Loss, lb, per injection</th>
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* Difference between the HCG and placebo groups, significant at $P < 0.001$.  * Difference between the HCG and placebo groups, significant at $P < 0.025$.  
TABLE 2
Blood pressure

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<th>Mean final blood pressure</th>
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<td>Diastolic</td>
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<td>77.4 ± 1.80</td>
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<tr>
<td>Placebo</td>
<td>122.1 ± 2.87</td>
<td>79.2 ± 2.16</td>
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Patients 2, 19, 25, 26, and 33 were excluded from analysis because final blood pressures were not obtained.

<sup>a</sup> SEM.

TABLE 3
Percentage of all daily patient responses of hunger and feeling of well-being

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<th>Feeling</th>
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<td>33.1</td>
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<td></td>
<td>48.7±</td>
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Patients 13 and 16 were excluded from hunger analysis because these data were unavailable.

<sup>a</sup> Difference between HCG and placebo group, significant at P < 0.001.
<sup>b</sup> SEM.
starting patients should be included in the analyses rather than only those completing treatment, we have included all starting patients.

The placebo used in our study was as nearly like the HCG preparation as possible with only the HCG itself missing. Thus, the HCG and placebo preparations should have been essentially indistinguishable on the basis of appearance or the local sensation of the patient who received the injections.

In addition to the study reported here, we have also completed a double-blind study involving patients of four physicians using Simeons’ programs modified to varying degrees. Three of these physicians had had little or no experience with the use of HCG in weight reduction. None of their programs approached the rigidity of the program considered in detail in this report. For instance, one physician allowed some patients to administer their own HCG injections at home. One physician at times gave injections three times/week and one gave injections five times/week.

Physicians were allowed to use diets of their own choosing, as these patients were seen in the course of their regular practice. None of these four physicians insisted on the patient’s absolute attention to detail in contrast to the physician whose practice is reported here. This is particularly true in regard to the restriction of fat intake.

The dropout rate was high in all practices involved in the initial study. When weight loss was analyzed for each practice, there was no significant difference between the HCG and placebo groups in any practice. Combined data from all four practices revealed 28 patients were on HCG and 32 on the placebo. The mean number of visits in the HCG group was 18.0 and 18.5 in the placebo group (36 visits possible).

When all starting patients were analyzed, the mean weight loss in the HCG group was 6.8 lb and 6.5 lb in the placebo group. This difference in weight loss was not significant. Thus, it appears that insistence on strict adherence to details is correlated with success (even in the placebo group).

In these four studies and the study presented here only females were included. Because males tend to lose larger amounts of weight, we felt including a few males in each group was undesirable. A large enough series of males needs to be studied so the results in males can be analyzed in a statistically meaningful way.

Fleigelman and Fried (11) injected 50 IU HCG daily intraperitoneally for 7 days into rats. Controls received 0.2 ml saline. The rats were killed after 7 days. The levels of three enzymes involved in linking glycolysis to the esterification and synthesis of fatty acids were assessed. There was an 85%, 35%, and 48% reduction in the adipose tissue levels of alpha-glycero-phosphate dehydrogenase (AGPD), lactic dehydrogenase (LDH), and glucose-6-phosphate dehydrogenase (G6PD), respectively. Liver levels of G6PD and muscle levels of AGPD were also significantly reduced. These enzymes play significant roles in directing lipid synthesis. If these reductions in enzyme levels are in turn responsible for a decrease in the rate of fatty acid synthesis, a possible enzymatic basis for the finding in our present study is suggested.

The extraction method used in preparing HCG from pregnant human urine is similar to the extraction method used for the preparation of urogastrone, a hormone inhibiting gastric secretion (12, 13). These authors report HCG preparations cause inhibition of gastric secretions even when the gonadotrophic activity of HCG preparations is destroyed. Ghosh (14) reported different activity rates for gonadotrophic and antisecretory effects in rats when two purified gonadotrophin preparations were assayed. In addition, van Hell et al. (15) have presented evidence that HCG preparations may be fractionated into a number of HCG components differing from each other in biological potency, electrophoretic mobility, and sialic acid content.

It is conceivable that the activity of HCG preparations in regard to weight reduction could be related to a specific HCG fraction or fractions, or to urogastrone, or other unknown urine components extracted by this method. If this were the case, such “fat mobilizing” activity levels might vary considerably in different preparations and batches of HCG. This might in part explain the variability in results in various reports where HCG has been used.
Another possible explanation of negative results might be the loss of activity of HCG with time after mixing especially if not refrigerated. It is probable in most studies that an individual patient received injections from a single vial which, after mixing, would be a minimum of 6 weeks old by the time of the final injection.

The 500- to 550-kcal eating plan needs supplementation of certain items such as calcium to make it nutritionally complete. However, in the interest of simplicity, supplements were not included in the present study.

Whether the long-term results of weight loss using single or multiple courses of HCG injections are better than the usual dismal long-term results of weight reduction needs objective examination. It seems doubtful such would be the case unless the physician involved continued to work vigorously with the patient in the re-education of eating patterns.

The strict requirement that the patient must follow meticulously the various aspects of the program seems almost ritualistic. Whether certain aspects of this ritual are necessary for success when HCG is used remains to be seen. Proponents generally insist a minimal intake of dietary fats is necessary. The emphasis on strict attention to all details may at least motivate the patient to more careful restriction of his daily food intake.

It is interesting to note that HH’s patients who were given a placebo lost more on the average than either the HCG or placebo patients of the other four practitioners (11.05 lb versus 6.8 and 6.5 lb, respectively). It therefore appears that HCG used in a casual program of weight reduction, as it often is in a general practice, is of no value. The fact that HH’s placebo patients lost more weight in a 6-week period than most physicians’ patients do on other diets and/or medications is in itself interesting. Certainly, the psychological impact of receiving a daily injection which the patient believes in is important.

It is hoped other investigators will repeat this study. The insistence on strict adherence to a low fat, low calorie eating plan seems critical. Ideally, each patient should have six or seven individual weekly vials that would make blinding more complete than in this study. Each vial should be kept refrigerated after reconstitution with bacteriostatic water, and should not be used longer than 1 week. Patients selected should be sufficiently overweight to assure they will not reach their desired weight before the termination of the study.

**Summary**

Twenty female patients on 500- to 550-kcal diets receiving daily injections of 125 IU of human chorionic gonadotrophin (HCG) were compared with 20 female patients on 500- to 550-kcal diets receiving placebo injections. Patients in both groups were instructed to return for daily injections 6 days each week for a total of 36 injections (unless desired weight was achieved prior to this). The HCG group lost significantly more mean weight, had a significantly greater mean weight loss per injection, and lost a significantly greater mean percentage of their starting weight. The percentage of affirmative daily patient responses indicating “little or no hunger” and “feeling good to excellent” was significantly greater in the HCG group than in the placebo group. Additional investigation of the influence of HCG on weight loss, hunger, and well-being seems indicated.

We wish to acknowledge the valuable assistance of Lynne Stone who was responsible for carrying out the details of the study on a daily basis.

**References**

8. Lebon, P. Treatment of overweight patients
Human Chorionic Gonadotropin *(Natural Products Database)*

**Common Name(s)**  
HCG; Simeons diet; Simeons therapy

**Clinical Overview: Uses**  
Existing evidence does not support the use of human chorionic gonadotropin (hCG) in weight reduction, and the use of hCG for this purpose is not supported by the American Medical Association (AMA) or the American Society of Bariatric Physicians. Homeopathic preparations of hCG do not contain significant amount of the active ingredient, and clinical trials have not been conducted to provide evidence for effect. hCG is a one of the most common ancillary substances used by anabolic-androgenic steroid (AAS) users to not only enhance muscle/strength during stacking but to also reduce depressive symptoms upon AAS withdrawal.

**Clinical Overview: Dosing**  
Recommendations for dosing for indications other than those approved for hCG cannot be made because evidence to support efficacy is lacking.

**Clinical Overview: Contraindications**  
Precocious puberty, prostatic carcinoma or other androgen-dependent neoplasia, prior allergic reaction to chorionic gonadotropin, and pregnancy.

**Clinical Overview: Pregnancy/Lactation**  
hCG is contraindicated in pregnant women. Avoid use in lactation.

**Clinical Overview: Interactions**  
None well documented.

**Clinical Overview: Adverse Reactions**  
Arterial thromboembolism, headache, irritability and other CNS symptoms, genitourinary effects, and hypersensitivity have been reported.

**Clinical Overview: Toxicology**  
Defects of forelimbs and the CNS, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and hCG regimens. No mutagenic effect has been clearly established in humans.

**Source**  
hCG is prepared from the urine of pregnant women. It can also be produced via recombinant DNA/genetic modification techniques.\(^\text{Ref}\)

**History**  
In the 1950s, the endocrinologist Dr. Albert Simeons promoted the use of hCG together with an ultra-low calorie diet (500 calories per day) as a weight loss strategy in which the body would preferentially burn stored fat from the stomach, hips, and thighs without causing undesirable loss of muscle tissue, hunger, or irritability.

Following the publication of trials refuting its efficacy and including adverse events, the use of hCG fell out of favor. In 1995 the US Food and Drug Administration required labeling and advertising of hCG to state that there was no evidence of efficacy in weight reduction. Homeopathic drops and lozenges containing the "energetic imprint" of hCG have been promoted via the Internet.\(^\text{Ref}\)

**Chemistry**  
hCG is a water soluble glycoprotein hormone derived from the urine of pregnant women. It is produced by the developing embryo after
conception and later by the placenta. Ref

**Uses and Pharmacology**

The action of hCG is virtually identical to that of pituitary luteinizing hormone, although hCG appears to have a small degree of follicle-stimulating hormone activity as well. It stimulates production of gonadal steroid hormones by stimulating the testis to produce androgens and the corpus luteum of the ovary to produce progesterone. Ref Approved indications for the use of hCG are prepubertal cryptorchidism, hypogonadism, and ovulation induction. However, hCG is commonly used as an ancillary substance by AAS users for its anabolic effects and for managing AAS withdrawal symptoms. Ref

**Anabolic steroid use**

hCG has been identified in a systematic review as one of the 10 most common ancillary substances used by AAS users. Across a total of 17 studies (ie, interviews, questionnaires, cases) that included 1,258 AAS users, hCG was often used to supplement "stacking" during AAS "on cycles" in order to improve testosterone production and enhance muscle/strength as well as prevent weight loss and testicular atrophy. Upon AAS cessation, hCG was used to minimize withdrawal symptoms such as depressive symptoms. Users included legal offenders, male and female weightlifters/bodybuilders, IV drug users, and footballers across a variety of settings (ie, police stations, gyms, syringe exchange centers, online forums, prison, supplement shops, sports shops and associations). Ref

**In vitro fertilization**

Adjunctive use of low-dose hCG (200 units/day) to a gonadotropin releasing hormone antagonist protocol in women undergoing in vitro fertilization/intracytoplasmic sperm injection, failed to produce any significant difference in rates of pregnancy, fertilization, implantation, or ongoing pregnancy in a randomized controlled trial (n=137). Ref

**Obesity/weight loss**

hCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity, and it is the position of the American Society of Bariatric Physicians that hCG cannot be recommended for weight loss. Ref

**Animal data**

Animal studies are lacking for the use of hCG in obesity, and based on evidence from clinical trials, would now be redundant.

**Clinical data**

A meta-analysis of clinical trials conducted up to 1995 found no evidence of effect for hCG in weight loss, redistribution of fat, or sense of hunger or well-being, beyond that resulting from caloric restriction. Ref There have been no published quality clinical trials since the meta-analysis, and no clinical trials have been published using either homeopathic drops or lozenges. Ref

**Dosing**

Recommendations for dosing for indications other than those approved for hCG cannot be made as evidence to support efficacy is lacking. Trials used 125 units of hCG daily for 6 days out of 7 over a 6-week period for weight reduction. Ref

Homeopathic forms of hCG do not contain sufficient quantities of the active ingredient, and the efficacy of the "energetic imprint" has not been substantiated. Ref

Bioavailability of the injection is greater with intravenous delivery than with subcutaneous delivery. Ref

**RNP Pregnancy/Lactation**

Category X. hCG is contraindicated in pregnant women. Ref
It is not known whether chorionic gonadotropin is excreted in human milk. Ref

**Interactions**

hCG can crossreact in the radioimmunoassay of gonadotropins. Ref

**Adverse Reactions**

Known adverse reactions include arterial thromboembolism, CNS symptoms (eg, headache, irritability, restlessness, depression, fatigue, aggressive behavior), and genitourinary and hypersensitivity effects, as well as local effects from the injection (eg, pain, edema). Ref

The transmission of hepatitis that was historically associated with the use of jet injectors in clinics was resolved by use of single-use disposable syringes. Ref

**Toxicology**

Defects of forelimbs and the CNS, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and hCG regimens. The dose of gonadotropins used was intended to induce superovulation. No mutagenic effect has been clearly established in humans. Ref

**References**


Robb-Nicholson C. By the way, doctor. I've been trying to lose weight for a long time and nothing seems to work. What do you know about the HCG diet? Harv Womens Health Watch. 2010;17(9):8.[PubMed 20593560]


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Revision Date

- September 22, 2017

Last Updated 9/27/17

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Mr. Gonidakis - aye
Dr. Schachat - aye
Dr. Factora - aye
Dr. Edgin - aye
Dr. Bechtel - aye

The motion carried.

PHYSICIAN ASSISTANT/SCOPE OF PRACTICE COMMITTEE

REQUEST FOR REVIEW OF DRUGS

Dr. Steinbergh stated that Caitlin Jones, P.A., has made an inquiry regarding the ability of physician assistants to prescribe human chorionic gonadotropin (HCG). Ms. Jones practices in a physical medicine practice and, if permitted, would potentially be prescribing HCG as part of a medically-guided weight-loss program. Following a review of documentation and discussion by both the Physician Assistant Policy Committee and the Physician Assistant/Scope of Practice Committee, both committees voted to recommend that HCG not be prescribed by physician assistants. Dr. Steinbergh stated that there is no evidence-based data to support the use of HCG in a weight loss program and, in fact, the Drug Enforcement Administration (DEA) and the American Medical Association (AMA) Council on Science and Public Health specifically oppose this use of HCG.

Dr. Steinbergh moved to disallow the use of HCG by physician assistants. Dr. Bechtel seconded the motion. A vote was taken:

ROLL CALL:
Dr. Saferin - aye
Dr. Schottenstein - aye
Dr. Steinbergh - aye
Mr. Giacalone - aye
Dr. Soin - aye
Mr. Gonidakis - aye
Dr. Schachat - aye
Dr. Factora - aye
Dr. Edgin - aye
Dr. Bechtel - aye

The motion carried.

PHYSICIAN ASSISTANT FORMULARY

Dr. Steinbergh stated that the Physician Assistant/Scope of Practice Committee discussed moving forward with development of an alternative formulary for physician assistants in Ohio. Dr. Steinbergh stated that she has spoken with Mr. Groeber about obtaining the services of a consultant with experience in developing formularies. Dr. Steinbergh stated that formulary forms from the Cleveland Clinic and the Ohio State University Wexner Medical Center have been obtained as the possible bases for a new formulary template.
Advisory Committee on Advanced Practice Registered Nursing

DRAFT Meeting Minutes
January 29, 2018

Members Attending: Erin Keels, Chair; Latina Brooks; James Furstein; Candy Rinehart; Kristine A. Scordo; Sandra Wright-Esber; Michelle Zamudio

Members Absent: Christopher Kalinyak

Staff Attending: Betsy Houchen; Lisa Emrich; Anita DiPasquale; Holly Fischer (Present for Rules discussion); Tom Dilling; Chantelle Sunderman

Guests Attending: Keeley Harding, APRN; Jodi Ulloa, OSU School of Nursing; Judy Audas, OSANA; Christine Williams, OAAPN; Sarah Kincaid, OSU-NP Council; Lori Nicholas, Premier Health; Lori Chovanak, ONA

Call to Order and Welcome
Erin Keels, Chair, called the meeting to order at 10:00 a.m. and welcomed members and guests.

Review and Approve October 2017 Meeting Minutes
Kristine Scordo moved to approve the minutes as written and Michelle Zamudio seconded. The Committee unanimously approved the minutes.

Acute Pain Rule
Lisa Emrich reported Rule 4723-9-10, OAC, was effective January 1, 2018. Related materials are posted on the Board website and were provided to the Committee. Chair Erin Keels asked the Committee members if they were hearing from APRNs with questions on acute pain rule prescribing and if the members thought APRNs were clear about the rule. No Committee members stated they were hearing questions.

Administrative Rules

Medication Assisted Treatment
Holly Fischer stated the law requires the Nursing and Medical Boards to work together to adopt consistent Medication Assisted Treatment (MAT) rules. She asked Committee members to review draft concepts/discussion points from the Medical Board she received just prior to the Committee meeting.

H. Fischer explained the rule would include both detoxification and treatment, however the discussion points only address treatment. The treatment rule would apply to office-based treatment and exclude facilities already regulated by federal and state laws, such as correctional facilities, hospitals, or treatment providers regulated or certified by the federal government. The discussion points specify requirements such as examinations, screens, OARRs checks,
treatment planning, coordination with other providers, psychosocial plans, etc. There would be prescribing limitations and special considerations regarding types of drugs prescribed. The use of certain drugs, such as Subutex for treatment would be excluded. H. Fischer stated that detoxification would be addressed, but perhaps in a separate rule. After talking with Dr. Hurst, Medical Director of the Ohio Department of Mental Health and Addiction Services, she believes the detoxification rules could apply to correctional facilities and jails because detoxification is currently occurring in those settings. H. Fischer noted that only Clinical Nurse Specialists (CNSs) were included in the Medical Board’s discussion points as “qualified behavioral health care providers” for coordination of services. The Committee recommended that CNPs be included.

H. Fischer stated she anticipates an expedited timeframe for the rulemaking process in 2018, and asked that the Committee review the discussion points and provide recommendations and concerns to her as soon as possible. She noted that the Nursing Board members have not yet discussed the rules or reviewed the discussion points being reviewed by the Committee today.

Chair E. Keels clarified that the Nursing Board would draft rules that mirror the Medical Board rules. She asked if the Committee would have an opportunity to review the rules before they are filed so the Committee has time to review for the rule language to be congruent and acceptable for both the Nursing and Medical Boards. H. Fischer suggested the Committee could schedule an additional meeting in May to review the draft MAT rules and chronic pain rules. She stated the Medical Board plans to review MAT rule proposals in February and the Nursing Board would review them either at the March Board meeting or Board Retreat in April. She anticipates the interested party meeting will be held in May and invited all members of the Committee to attend, and the Public Rules Hearing could be held at the July 2018 Board meeting. H. Fischer responded that if members see something off base in these discussion points or if they are aware of research, best practices, or pertinent information to please send it to her. H. Fischer noted that some topics are statutorily required, as included in Section 4723.51, ORC.

Chair E. Keels asked about CARA 2016 that authorizes CNPs to be MAT prescribers. Staff reported that legislation to amend federal law to include CNSs was introduced, but NCSBN is not optimistic about its passage.

M. Zamudio stated that nursing specialty associations may have comments and H. Fischer requested Committee members to ask those groups to contact her with information, questions, protocols or guidelines. She stated members could individually contact her with comments, but she cautioned the Committee members that according to the Open Meetings Act, members should not discuss the rules via emailing each other. T. Dilling stated the Committee could track information provided to the Board through the Board website and social media and emails.

Sandra Wright-Esber stated she believes the acute pain rules reflect a lack of understanding about APRN practice but she is pleased to start early in the process to have these discussions and regarding the MAT rules, work closely with the Board so APRNs have their voice heard. She noted the issue of prescribing opioids is mainly a physician issue, not an APRN issue. Candy Rinehart stated in her experience, it seems outside entities are defining APRN practice without understanding APRN practice so she sees the value of this Committee and gathering information from others.

Chair E. Keels stated the Committee has an opportunity for input with these rules and asked if the Committee members would agree to schedule a meeting in May. A meeting was scheduled for May 14, 2018.
**Chronic Pain Rule**

H. Fischer stated GCOAT is discussing rules to address prescribing for chronic pain. The Committee was provided the 2013 GCOAT Guideline for chronic pain prescribing. She stated prior to prescribing, the rule could require consideration of non-opioid and non-medication modalities. After seven days of a 50 mg Morphine Equivalent Dose (MED) daily dose, the prescriber would consider referring the patient to a pain management specialist. After seven days of 80 mg MED daily dose, the prescriber must obtain a urine drug screen, consult with a pain management specialist, and consider consulting with an addiction medicine specialist or psychiatric specialist. H. Fischer asked the Committee to review the materials and contact her with information, protocols, questions, or concerns.

M. Zamudio and L. Brooks stated a concern regarding referrals to specialists because there is limited or a lack of reimbursement or insurance coverage and it is difficult for patients to get to appointments. They asked about having consumer and insurance company representatives involved. Tom Dilling stated there were numerous discussions and testimony concerning cost, access, and the convenience for the patient during past GCOAT meetings.

S. Wright-Esber stated that the Guideline seems to mirror the CDC guidelines and her hospital is implementing the CDC guidelines. She believes the Committee should be more involved in the early conversations in drafting the chronic pain rule to present narratives and opinions, and to provide clear language. H. Fischer asked if S. Wright-Esber would participate in meetings or conference calls if that was a possibility; she stated she would be willing to participate.

Chair E. Keels asked about the impact of medical marijuana and the treatment of chronic pain. H. Fischer stated she is a member of the Marijuana Regulatory Guidelines Committee established by the National Council of State Boards of Nursing (NCSBN) and indicated the NCSBN Committee has found inconsistent research on the effectiveness of medical marijuana for treatment of chronic pain.

S. Wright-Esber stated she had several points for Board consideration. She stated APRNs are prescribing in many areas and types of practices, such as primary care, specialty care, and rural areas. Also, CNSs need to be included. L. Brooks stated that prescribing for patients who are currently are being treated for chronic pain would also need to be addressed in the chronic pain rule. M. Zamudio asked about using the term "prescribing APRN" rather than "nurse" to eliminate possible confusion. S. Wright-Esber stated she learned at a conference that in the Netherlands there are no overdoses and there are clinics and assistance available.

Chair E. Keels thanked Board staff for informing the Committee and associations about the MAT and the chronic pain rules so there is an awareness of what is being developed. She suggested the Committee further review and discuss the draft rules for chronic pain prescribing at the May 14, 2018 meeting.

**CNP Acute and Primary Care Practice**

Chair E. Keels summarized the materials provided to the Committee. She reported that the Board met with OONE/OHA who then surveyed their members about the practice of CNPs in hospitals. The Committee was provided the survey results. In addition, Committee members received the National Organization of Nurse Practitioner Faculties (NONPF) document showing acute and primary care competencies. Chair E. Keels stated the Committee is to advise and make a recommendation to the Board and highlighted the options as to continue to follow the Consensus Model or identify alternatives to the Consensus Model. She stated the Consensus
Model outlines four roles within a population focus for which CNPs are certified for entry into APRN practice.

C. Rinehart stated she wanted to begin by discussing competencies saying she believes graduation from an APRN education program shows that APRNs have the needed competencies, and she agreed that competency is determined through national certification examinations.

S. Wright-Esber stated she believes the term "acute" must be defined because Ohio law says APRNs can care for acute conditions without defining it. She does not believe the Committee should start by discussing the two options because that is an all or nothing approach and she believes the question is how Ohio is interpreting the Consensus Model. She questioned the appropriateness of the Board regulating whether CNP practice is acute or primary care because she believes a CNP's competency and certification is relative only at entry level. She does not believe the Board should license an APRN and then regulate APRN practice which limits the APRN's ability to manage patients requiring either acute or primary care. She stated the Consensus Model is a guide and not law and application of it is not required.

K. Scordo disagreed with the need to define "acute." She stated the Consensus Model clearly delineates the population of a role through national certification. She agrees there can be overlap in the hospital setting, however she asked how could a primary care CNP have a collaborative arrangement with an intensivist. There was discussion regarding acute conditions and acute care. S. Wright-Esber stated she did not believe it would be appropriate for a primary care CNP to have a collaborating arrangement with an intensivist.

M. Zamudio read from the Consensus Model language about specialty areas saying the Board is not to regulate specialty areas. Director Houchen stated that the Board does not regulate APRN specialties because specialties are obtained after national certification and licensure. Director Houchen stated she believes that the term specialty as used in the Consensus Model is confusing, and it should not be applied to national certification and population foci. She asked the Committee members to discuss what the Committee's suggestions would be for an alternative model other than the Consensus Model.

L. Brooks stated that a primary care CNP could manage and treat an acutely ill patient within the hospital because the setting itself is not the determining factor for the population. The Committee discussed populations of patients that require care within the hospital setting and their conditions, which range from patients who can be managed by primary care CNPs to patients with conditions that should be managed by acute care CNPs.

S. Wright-Esber stated that this might be the time to raise a concern that a Committee member advertised her acute care graduate program on a social media website, and she believes the social media advertisement is a conflict of interest for the Committee member. K. Scordo responded that S. Wright-Esber was referring to a post that K. Scordo wrote because she was receiving emails asking where APRNs could return to school.

S. Wright-Esber said she was concerned about alternative motives since K. Scordo is a Committee member. K. Scordo clarified that there are no alternative motives and stated she was sorry it was interpreted that way. K. Scordo stated she called the Ohio Ethics Commission and the Ohio Ethics Commission advised her they did not view it as a conflict of interest.

S. Wright-Esber stated she is asking the Board to look into it. Chair E. Keels clarified that the conflict of interest inquiry is at the individual level, not the Committee level. Director Houchen
stated K. Scordo was advised to contact the Ohio Ethics Commission and that ethics training was provided at the last Committee meeting so all members would be aware that they should review their work and professional positions in relation to potential conflicts and contact the Ethics Commission. S. Wright-Esber stated she wanted it on the record that she did not disclose the member’s name, that the member disclosed it herself. K. Scordo responded that she volunteered the information because she has nothing to hide.

C. Rinehart suggested that the Committee look at how issues regarding CNP practice started and asked if it started because APRNs are not taking good care of people and then the issue transformed into the Board regulating where APRNs work. She stated she believes the OONE review shows that APRNs are doing well, so what is the Board hoping to achieve. Director Houchen said the Board is to protect the public and to apply the law and rules. This began when the Board was asked a question about the law and the Board responded.

S. Wright-Esber asked what acute care means because there are gray areas. L. Brooks stated that many hospitals will not hire primary care CNPs and we need to be clear about language regarding populations. L. Emrich asked that if hospital training or post-graduate training is used, whether it is standardized. K. Scordo stated that training and education provided by hospitals is not standardized. M. Zamudio stated she thinks Board is trying to determine what ARPN credentials should be and she believes post-graduate training or education should determine it. She stated that training could provide the APRN with an expanded scope of practice.

Chair E. Keels said the Board is not addressing credentialing, rather it is requiring that APRNs work within their population foci. She stated the hospital is to hire and credential based on the national certification and population focus, which determines the scope of practice.

S. Wright-Esber stated this started when the Board published an anonymous article in Momentum. L. Emrich responded the article was a Board article in a Board publication. T. Dilling noted the Committee previously discussed the history of the article, background, and purpose in detail.

K. Scordo spoke against the idea of not following the Consensus Model because it would make Ohio licensure and practice inconsistent when the purpose of the Consensus Model is to unify states and the regulation of APRNs. T. Dilling stated multiple organizations and associations developed the Consensus Model and NCSBN asked that state boards of nursing follow it. Over the years, practice has changed but the basic requirements of core education, national certification and population focus in the Consensus Model have not changed.

S. Wright-Esber stated that APRN practice has not changed and asked what are the next steps and expectation of the Board? She stated she thinks the Board has already made a decision and she disagrees with where the Board is taking this. She stated that acute illness language is used in current law. T. Dilling stated that in 2013 acute illness language was added through HB 303 at the request of the APRN association who informed the Board that it needed to be added due to reimbursement issues, not to expand the scope of practice.

Chair E. Keels agreed that the acute illness language may be confusing, but it can be clarified. She summarized saying the discussion began by identifying two choices. She stated this Committee is to advise the Board of the next steps, and she does not think the Committee is there yet, but she may be hearing agreement about some parts of the issue.

C. Rinehart asked if there was feedback from institutions and what are they were doing. Chair E. Keels stated that the Board will continue the dialogue OONE/OHA. She stated the discussion
would continue at the May 14, 2018 meeting and asked that members bring guiding definitions and concepts for discussion, review past discussions and materials including the Consensus Model, and bring their recommendations.

The Committee reviewed the *Emergency NP Specialty Certification Candidate Handbook*, noting that this certification is for a primary care CNP who wishes to specialize in the provision of primary care in the emergency department. There was discussion about NCSBN re-visiting the Consensus Model for clarification. It was noted that the NCSBN APRN Roundtable is scheduled for April 11, 2018. Committee members were directed to the NCSBN website to obtain addition information if they are interested in attending.

**APRN Practice Question/Response: HCG for Weight Loss**
L. Emrich stated the Board received a question about APRNs prescribing Human Chorionic Gonadotropin (HCG) for the purpose of weight loss. She explained that prior to implementation of the Exclusionary Formulary, the CPG revised the Formulary to specify that an APRN "may not prescribe" HCG for weight loss. With the implementation of HB 216, the Board adopted an Exclusionary Formulary and prescribing HCG for weight loss is not currently excluded. Recently the Board received a request again with a 1972 article as supportive evidence. L. Emrich explained that the question would be considered by the CPG, and asked the Committee if they would like to make a recommendation. The Committee stated it is a standard of practice issue and that APRNs should not prescribe HCG for weight loss because it is not evidence based practice, but agreed by general consensus not to recommend that prescribing of HCG for weight loss be added to the Exclusionary Formulary.

**General Information**
Director Houchen reported that 91% of APRNs completed the COA renewal/APRN license issuance process. The renewal and licensure season proceeded smoothly except an erroneous auto-generated email message was sent on January 1, 2018. She thanked the APRNs who alerted the Board, so Board staff had the opportunity to quickly provide correct information.

Uploading collaborating physician information and continuing education (CE) for APRN license renewal were discussed. APRNs will need to comply with the CE requirement for licensure renewal in 2021 using CE obtained between November 1, 2019 and October 31, 2021. The 2017 RN and APRN Workforce Reports are posted on the Board website. K. Scordo asked if future APRN reports could include the number and type of APRN national certifications. L. Emrich informed the Committee members about a *Freakonomics* podcast.

James Furstein asked the Committee to consider requiring one hour of CE to address the opioid crisis and be counted as part of the current 24 hour CE requirement for RN renewal. The Committee agreed by general consensus and the recommendation will be presented to the Advisory Group on Continuing Education for their consideration.

**Legislative Updates**
T. Dilling provided an update on HB 191, the CRNA bill. Surgeons testifying as proponents of the bill provided testimony stating a preference not to have liability as the CRNA's supervising physician, although the surgeon may be the only physician present when the CRNA is administering anesthesia. J. Furstein discussed the differences in CRNA practice between states.
Future Meetings
Meetings are scheduled for May 14, 2018; June 11, 2018; and October 1, 2018. There was additional discussion about the May meeting. C. Rinehart asked if APRNs will be reported to the Board based on their practice. Chair E. Keels stated that there could be a complaint that would be reviewed and investigated. S. Wright-Esber asked about grandfathering and Chair E. Keels stated that could be part of the recommendations brought to the next meeting.

Public Comments
Christine Williams, OAAPN, provided comments about the CRNA bill testimony regarding supervising physicians and CRNAs providing anesthesia and pre- and post-anesthesia care. She stated the Committee should be cautious in its discussions because people are interpreting the Consensus Model differently and she did not hear enough agreement by the Committee to pursue regulation based on population foci.

Adjournment
The meeting adjourned at 1:32 p.m.
Portman Announces Introduction of CARA 2.0

U.S. Sen. Rob Portman (R-OH) joined with a bipartisan group of senators to introduce the Comprehensive Addiction and Recovery Act (CARA) 2.0 that they said would increase funding authorization levels for the CARA programs enacted in 2016 and put in place additional policy reforms to help combat the opioid epidemic, including limiting opioid prescriptions to three days.

Portman co-sponsored the bill along with Sheldon Whitehouse (D-RI), Shelley Moore Capito (R-WV), Amy Klobuchar (D-MN), Dan Sullivan (R-AK), Maggie Hassan (D-NH), Bill Cassidy (R-LA) and Maria Cantwell (D-WA).

"Now that CARA has been implemented and is starting to help communities around the country, it's time to start the discussion about reauthorizing this important federal law," said Portman in a statement. "Passage of CARA was a historic moment, the first time in decades that Congress passed comprehensive addiction legislation, and the first time Congress has ever supported long-term addiction recovery. Now we have the opportunity to build on this effort, increasing funding levels for programs we know work and implementing additional policy reforms that will make a real difference in combating this epidemic. I want to thank Sen. Whitehouse and my bipartisan colleagues for their leadership and partnership on this important national effort."

The sponsors said CARA 2.0 will build on the original law by increasing the funding authorization levels for CARA's evidence-based programs to better coincide with the recent budget agreement and laying out new policy reforms to strengthen the federal government’s response to this crisis. CARA 2.0 will authorize $1 billion in dedicated resources to evidence-based prevention, enforcement, treatment and recovery programs, they said.

The bill includes the following policy reforms:

- Imposes three-day limit on initial opioid prescriptions for acute pain as recommended by the Centers for Disease Control and Prevention (CDC), with exceptions for chronic pain or pain for other ongoing illnesses.
- Makes permanent Section 303 of CARA, which allows physician assistance and nurse practitioners to prescribe buprenorphine under the direction of a qualified physician.
- Allows states to waive the limit on the number patients a physician can treat with buprenorphine so long as they follow evidence-based guidelines. There is currently a cap of 100 patients per physician.
- Require physicians and pharmacists use their state prescription drug monitoring program (PDMP) upon prescribing or dispensing opioids.
- Increases civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids.
- Creates a national standard for recovery residence to ensure quality housing for individuals in long-term recovery.

The sponsors also said the bill has the following authorization levels:

- $10 million to fund a National Education Campaign on the dangers of prescription opioid misuse, heroin and lethal fentanyl (up from $5 million in the original CARA).
- $300 million to expand evidence-based medication-assisted treatment (up from $25 million in the original CARA).
- $300 million to expand first responder training and access to naloxone (up from $12 million in the original CARA).
- $200 million to build a national infrastructure for recovery support services to help individuals move successfully from treatment into long-term recovery (up from $1 million in the original CARA).
- $20 million to expand Veterans Treatment Courts (up from $6 million in the original CARA).
- $100 million to expand treatment for pregnant and postpartum women, including facilities that allow children to reside with their mothers (up from $17.9 million in the original CARA).
- $60 million to help states develop an Infant Plan of Safe Care to assist states, hospitals and social services to report, track and assist newborns exposed to substances and their families (no authorization in the original CARA).
- $10 million for a National Youth Recovery Initiative to develop, support and maintain youth recovery support services (no authorization in the original CARA).

FDA In Brief: FDA takes new steps to help mitigate overprescribing of opioid medications as effort to reduce rates of new addiction

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Media Inquiries

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"We're taking an all of the above approach in our efforts to combat the immense public health emergency of opioid addiction. With millions of Americans misusing prescription opioids and more than 40 people dying every day from overdoses involving opioid medications, it has become abundantly clear that we need to do everything we can, along with our partners, to get ahead of this crisis," said FDA Commissioner Scott Gottlieb, M.D. “Appropriate prescribing practices and education are important steps within our statutory authority to help address the human and financial toll of this crisis. We can and must do more to arm physicians – who are the gatekeepers of prescription opioids – with the most current and comprehensive guidance on the appropriate management of pain. Many people who become addicted will first be exposed to opioids through a lawfully prescribed medication. Often it’s for an immediate-release formulation of an opioid drug. We need to do more to ensure that prescriptions are written for only appropriate purposes and durations of use. Opioids should rarely be our first resort when treating patients in pain. We must continuously reexamine how opioids are being prescribed when deemed an appropriate course of treatment. The Blueprint is one tool for achieving these goals. We’ll continue to seek feedback from a broad group of stakeholders and explore a range of approaches that, when combined with other steps we’re taking to tackle this epidemic, help ensure proper treatment for pain and better addresses the crisis of opioid addiction..

Today, the U.S. Food and Drug Administration took several important steps as part of its efforts to address the opioid epidemic by releasing a revised Blueprint (https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf) for opioid prescriber education and holding a public hearing (/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm) to explore additional frontline measures to curb overprescribing and the rate of new addiction.
The revised Blueprint contains core content for training that drug manufacturers are required to make available to prescribers. The revised Blueprint broadens content to include information on acute and chronic pain management, safe use of opioids or other non-opioid or non-drug treatments, as well as material on addiction medicine and opioid use disorders. Once finalized later this year, together with the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS), the blueprint will apply to manufacturers of both immediate-release opioid analgesics intended for use in the outpatient setting and extended release/long-acting formulations and be required to be offered, for the first time, to other health care professionals who are involved in the management of patients with pain, including nurses and pharmacists, in addition to prescribers. The revised blueprint is being released in advance to ensure these continuing educational materials and activities are made available in a timely manner.

As noted in a statement (NewsEvents/Newsroom/PressAnnouncements/ucm594443.htm) released today by FDA Commissioner Scott Gottlieb, M.D., the meeting is serving as an opportunity to receive input from a broad group of stakeholders as the FDA explores new approaches to encourage appropriate prescribing of opioid analgesics through the FDA’s REMS authorities. Among other things, the agency’s Opioid Policy Steering Committee (OPSC) is considering ways to use these authorities to augment existing prescribing and dispensing practices, such as utilizing electronic prescribing systems and interfacing with state prescription drug monitoring programs, while maintaining appropriate prescribing for patients in medical need. Discussions at the meeting, including possible packaging, storage and disposal solutions, as well as the revised blueprint being released today are in addition to broader ongoing considerations by the FDA about whether mandatory prescriber education is appropriate and how the agency would operationalize such a requirement. These, and other steps, are a part of the FDA’s commitment to take all reasonable steps to address the crisis of opioid use disorder.

For more information:

- Opioid Analgesic REMS Education Blueprint for Health Care Providers Involving in the Treatment and Monitoring of Patients with Pain (https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf)
- FDA’s Opioid Policy Steering Committee - Prescribing Intervention - Exploring a Strategy for Implementation (NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm)
- Opioid Policy Steering Committee (AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/ucm587929.htm)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.
Introduction
FDA’s Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain
(January 2018)

Background

In July 2012, FDA approved the Extended-Release and Long-Acting (ER/LA) Opioid Analgesic Risk Evaluation and Mitigation Strategy (ER/LA REMS) to ensure that the benefits of ER and LA opioid analgesics used in the outpatient setting outweigh the risks. That REMS is undergoing modification and, once approved, the new Opioid Analgesic REMS will include, in addition to ER/LA opioid analgesics, all immediate-release (IR) opioids used in the outpatient setting that are not already covered by another REMS program. The Opioid Analgesic REMS is intended to support other national efforts underway to address the misuse and abuse of prescription opioid analgesics.

As part of the Opioid Analgesic REMS, all opioid analgesic companies must provide the following:

- Education for healthcare providers (HCPs) who participate in the treatment and monitoring of pain. For the purpose of the Opioid Analgesic REMS, HCPs will include not only prescribers, but also HCPs who participate in the treatment and monitoring of patients who receive opioid analgesics, including pharmacists and nurses.
  - Education will be offered through accredited continuing education (CE) activities. These activities will be supported by unrestricted educational grants from opioid analgesic companies.

- Information for HCPs to use when counseling patients about the risks of ER, LA, and IR opioid analgesic use.

To facilitate the development of CE educational materials and activities as part of the Opioid Analgesic REMS, FDA has also revised the education blueprint — originally designed to facilitate development of CE educational materials under the ER/LA REMS. FDA has completed the revisions to the FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (FDA Blueprint), following publication of a draft version and consideration of received public comments, and is making it available in advance of the approval of the Opioid Analgesic REMS.

The revised FDA Blueprint contains a high-level outline of the core educational messages that will be included in the educational programs developed under the Opioid Analgesic REMS. The FDA Blueprint focuses on the fundamentals of acute and chronic pain management and provides a contextual framework for the safe prescribing of opioid analgesics. The core messages are directed to prescribers, pharmacists, and nurses, but are also relevant for other HCPs who...
participate in the management of pain. The course work is not intended to be exhaustive nor a substitute for a more comprehensive pain management course.

Accrediting bodies and CE providers will ensure that the CE activities developed comply with the standards for CE of the Accreditation Council for Continuing Medical Education,\(^1\)\(^2\) or another CE accrediting body, depending on the target audience’s medical specialty or health care profession.

FDA is making the FDA Blueprint, which will be approved as part of the Opioid Analgesic REMS, available on the REMS@FDA Website (www.fda.gov/REMS), where it will remain posted for use by CE providers as they develop the CE materials and activities. A list of the REMS-compliant CE activities supported by unrestricted educational grants from the opioid analgesic companies to accredited CE providers will be made available when the Opioid Analgesics REMS is approved.

### Reasons Why HCP Education Is So Important

Adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioids have emerged as major public health problems. It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as they pertain to their patients as well as from a public health perspective. The data continue to show problems associated with prescription opioid analgesics.

- In 2015, over 52,404 Americans died from drug poisonings, and of these, 24% or approximately 12,570 deaths involved opioid analgesics.\(^3\)

- Based on the 2016 National Survey on Drug Use and Health (NSDUH), an estimated 11.5 million Americans aged 12 or older misused a prescription pain reliever in the past year — with hydrocodone, oxycodone, and codeine products being the most commonly reported.\(^4\)

- The most common source of pain relievers in the 2016 NSDUH was “a friend or relative” (53%). “A physician’s prescription” was the second most common source, reported by approximately 35% of respondents.\(^5\)

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\(^5\) Ibid.
The nation is facing competing public health problems: the need to adequately treat a large number of Americans with acute and chronic pain and an epidemic of prescription opioid abuse. Described in the 2011 report by the National Academies of Science, Engineering, and Medicine (NASEM), Relieving PAIN in America, A Blueprint for Transforming Prevention, Care, Education, and Research, 6 100 million Americans suffer from common chronic pain conditions; fewer than half of Americans undergoing surgery report adequate pain relief; and 60% of Americans visiting the emergency department with acute painful conditions receive analgesics.

The increasing availability of prescription opioids since the 1990’s has been accompanied by an epidemic of opioid addiction. The Substance Abuse and Mental Health Services Administration’s National Survey of Drug Use and Health has shown that most people who use prescription analgesics “nonmedically” obtain them from friends or family, who it is believed obtained the drugs from a doctor’s prescription. 7

Some of the immediate consequences of untreated or undertreated pain include reduced quality of life, impaired physical function, and high economic costs. Chronic pain is associated with physical disability, fear, anger, depression, anxiety, and reduced ability to carry out the roles of family member, friend, and employee. It is critically important that HCPs have all the information they need to properly treat their patients and safely manage their pain. It is also critical for HCPs to understand when opioid analgesics are the appropriate treatment and how to implement best practices to ensure their patients’ safety. A 2017 report by NASEM, Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, describes the challenges of providing adequate pain management and calls for the establishment of “comprehensive pain education materials and curricula” for HCPs. 8

Having broad knowledge about how to manage patients with pain can create the opportunity for HCPs to consider all options for pain management, including nonpharmacologic and non-opioid pharmacologic options, and to reserve opioids for when non-opioid options are inadequate and when the benefits of the opioids are expected to outweigh the risks. This information can also aid HCPs in identifying and intervening when encountering obstacles that may reduce access to nonpharmacological and non-opioid medication options. Fully informed HCPs can help contribute to national efforts to address opioid addiction and reduce opioid misuse and abuse.

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FDA Education Blueprint for Health Care Providers
Involved in the Treatment and Monitoring of Patients with Pain

Purpose of the Opioid Analgesic REMS HCP Educational Effort

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, identifying risk factors for abuse and addiction
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder

In addition, HCPs will gain an understanding of current information about safe opioid practices and about current Federal\(^9\) and State regulations, national guidelines,\(^10\) and professional organization\(^11\) and medical specialty guidelines on treating pain and prescribing opioids. HCPs will also become familiar with the use of naloxone and with the importance of its availability for use by patients and caregivers both in the community and in the home.


Section 1: The Basics of Pain Management

I. THE NEED FOR COMPREHENSIVE PAIN EDUCATION

The FDA Blueprint was developed with two, competing, U.S. public health concerns in mind, (1) the large number of Americans with acute and chronic pain and (2) the epidemic of prescription opioid abuse.

1. Providing health care providers (HCPs) with a thorough understanding of the risks associated with opioids can give HCPs the opportunity to consider all pain management options, including nonpharmacologic and pharmacologic options, prescribing opioids only when non-opioid options are inadequate and when the benefits of using an opioid are expected to outweigh the risks.

2. When HCPs have information about the risks of opioid misuse and abuse, they will be better able to create opportunities for patient counseling and other strategies to reduce these risks.

II. DEFINITIONS AND MECHANISMS OF PAIN

Pain can be categorized according to its duration, underlying pathophysiology of the original insult, and whether a central sensitization component has developed. An understanding of these different categorizations can help direct therapeutic decisions.

When defining, and classifying pain, the following should be taken into consideration:

1. Biological significance of pain (survival value)
2. Relationship between acute and chronic pain
3. Distinction between nociceptive and neuropathic pain

III. ASSESSING PATIENTS IN PAIN

HCPs should be knowledgeable about how to assess each patient when initiating a pain management program. When appropriate, evidence-based, standardized scales and tools can be used to document pain characteristics and guide management decisions throughout treatment, noting the strengths and weaknesses regarding specificity and sensitivity of these scales.

Important elements of an initial assessment should include the following:

1. Patient history
2. Screening tools to evaluate the known risk factors for development of chronic pain after an acute injury or disease

3. Screening tools to evaluate the known risk factors for opioid use disorder (OUD) or abuse

4. Queries of state prescription drug monitoring programs (PDMPs)

5. Pain assessment scales/tools

6. Functional assessment scales

7. Physical examination

8. Family planning, including information about use of contraceptives, pregnancy intent/status and plans to breastfeed

9. Psychological and social evaluation

10. Diagnostic studies when indicated

Section 2: Creating the Pain Treatment Plan

A comprehensive pain treatment plan should be developed and customized to the needs of the individual patient. The treatment plan should include the types of therapies planned, the goals of treatment, and an explanation of the patient and prescriber roles and responsibilities. The goals of treatment should be based on (1) expected outcomes of pain reduction; (2) improvement in functional outcomes impaired by pain (e.g., activities of daily living); and (3) quality of life.

If HCPs encounter potential barriers to managing patients with pharmacologic and/or nonpharmacologic treatment options, such as lack of insurance coverage or inadequate availability of certain HCPs who treat patients with pain, attempts should be made to address these barriers. The overall treatment approach and plan should be well documented in the patient record, including written agreements and informed consent/patient provider agreements (PPAs) that reinforce patient-provider responsibilities and avoid punitive tones.

I. COMPONENTS OF AN EFFECTIVE TREATMENT PLAN

1. The goals of treatment, including the degree of improvement in pain and function when function has been impaired by pain

2. Possible constituents of the treatment plan, including nonpharmacologic approaches and pharmacologic therapies
3. Patient/prescriber/health care team interactions, including
   - Patient responsibilities/compliance with the plan
   - Responsibilities of the prescriber and health care team, including patient monitoring
   - Plans for reviewing functional goals
   - Use of supplemental medication for intermittent increases in pain
   - Use of PPAs

II. GENERAL PRINCIPLES OF NONPHARMACOLOGIC APPROACHES

Pain can arise from a wide variety of causes. There are a number of nonpharmacologic and self-management treatment options that have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain. Examples include, but are not limited to, psychological, physical rehabilitative, and surgical approaches, complementary therapies, and use of approved/cleared medical devices for pain management. HCPs should be knowledgeable about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a multidisciplinary approach to pain management. HCPs should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others.

III. GENERAL PRINCIPLES OF PHARMACOLOGIC ANALGESIC THERAPY

A variety of analgesics, including non-opioid and opioid medications, are available for use to manage pain symptoms. HCPs should be well informed about the range of analgesics available and the types of pain that may be responsive to those analgesics.

A. Non-opioid medications

When using non-opioid medications in pain management, HCPs should be knowledgeable about the following:
   1. Mechanism of action of analgesic effect
   2. Indications and uses for pain management
   3. Routes of administration and formulations used in pain management
   4. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
   5. Contraindications
   6. Adverse events, with emphasis on labeled warnings
   7. Drug interactions — both pharmacodynamic and pharmacokinetic

B. Opioid analgesic medications

Opioid analgesic medications can be used successfully as a component of pain management. However, opioids carry risks not present with most non-opioid analgesics, specifically the risks of addiction, abuse and misuse, which can lead to respiratory depression, overdose and death. Therefore, it is the responsibility of HCPs to be knowledgeable, not just about the presence of
such risks, but about how to weigh these risks before prescribing an opioid and about how to properly manage patients who are prescribed opioids, both for short-term and long-term use. When using opioid analgesics as part of pain management, HCPs should be knowledgeable about the following:

1. General precautions
   a. Even at prescribed doses, opioid analgesics carry the risk of misuse, abuse, opioid use disorder, overdose, and death
   b. Importance of the appropriate use of PDMPs\textsuperscript{12} and their use as a clinical decision support tool
   c. DSM-5 (R) criteria (or the most recent version) for OUD and the concepts of abuse (taking an opioid to get high) vs. misuse (taking more than prescribed for pain or giving to someone else in pain)\textsuperscript{13}
   d. The concepts of tolerance and physiological dependence and how they differ from OUD (addiction)
   e. Recognition that some opioid analgesics (e.g., Transmucosal Immediate Release Fentanyl products, some ER/LA products) are safe only for opioid-tolerant patients

2. Mechanism of action and analgesic effect

3. Types of opioids (full agonists, partial agonists)

4. Indications and uses for pain management

5. Range of opioid analgesic products available for pain management and their related safety concerns
   a. Routes of administration including oral, transmucosal, transdermal
   b. Release characteristics of immediate release (IR), extended-release (ER), long-acting (LA)
   c. Abuse-deterrent formulations (ADFs)
      • Definition of ADF based on the FDA guidance for industry, \textit{Abuse-Deterrent Opioids – Evaluation and Labeling}\textsuperscript{14}
      • Recognition that all ADFs have the same potential for addiction and overdose death as non-abuse-deterrent opioids
      • How to understand FDA-approved ADF product labeling

6. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia
   a. Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature
   b. Interindividual variability of response

\textsuperscript{13} American Psychiatric Association DSM-5-Opioid Use Disorder Diagnostic Criteria accessed April 12, 2017.
\textsuperscript{14} See FDA guidance for industry \textit{Abuse-Deterrent Opioids — Evaluation and Labeling}. accessed April 12, 2017.
c. Special populations
   • Pregnant, postpartum, breastfeeding, and neonatal opioid withdrawal syndrome
   • Renal and hepatic impairment
   • Children and adolescents
   • Genetic and phenotypic variations
   • Older adults
   • Sleep disorders
   • Common and uncommon psychiatric disorders

7. Contraindications

8. Adverse Events
   a. Medication errors
   b. Periods of greater risk for significant respiratory depression, including at treatment initiation and with dose increases
   c. Serious adverse drug reactions (including overdose and death)
   d. Labeled warnings
   e. Common adverse drug reactions

9. Drug interactions
   a. Pharmacokinetic interactions based on metabolic pathway
   b. Pharmacokinetic and pharmacodynamic interactions with alcohol
   c. Concerns with particular drug–drug interactions, including, but not limited to:
      • Benzodiazepines and other central nervous system depressants, including alcohol
      • Monoamine oxidase inhibitors
      • Antidiuretic hormone drugs

10. Key safety strategies for use with opioid medications
    a. Dosing instructions including daily maximum
    b. Safe storage to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens and to reduce risk of theft
    c. Naloxone products for use in the home to reduce risk of overdose deaths in patients and household contacts
    d. Proper disposal of used (e.g., transdermal systems) and unused opioids
    e. Pain management after an opioid overdose
    f. Driving and work safety

IV. MANAGING PATIENTS ON OPIOID ANALGESICS

HCPs should be knowledgeable about the appropriate use of opioids in patients with acute and chronic pain, including the importance of balancing potential benefits with the risks of serious adverse outcomes such as overdose and death.

A. Initiating treatment with opioids — acute pain
1. Patient selection — consider when an opioid is an appropriate option and consult the PDMP
2. Dosing — as needed vs. around-the-clock dosing, prescribing an appropriate quantity based on the expected duration of pain, i.e., the least amount of medication necessary to treat pain and for the shortest amount of time
3. Naloxone for home use — prescribe and discuss the use of naloxone products and the various means of administration
4. Screening tools for risk of abuse

B. Initiating treatment with opioids — chronic pain

1. Patient selection
   a. Differences in benefit and risk and expected outcomes for patients with chronic pain, palliative care, or end-of-life care
   b. Differences in initiating treatment in opioid nontolerant vs. opioid-tolerant patients
2. Dosing
   a. As needed vs. around-the-clock
   b. How to determine a safe initial dose
   c. Safe conversion from other opioids
3. Considerations in opioid selection
   a. IR or ER/LA
   b. Special precautions with methadone
   c. Products restricted to opioid-tolerant patients
4. When and how to use an opioid or non-opioid analgesic to supplement pain management

C. Ongoing management of patients on opioid analgesics

1. Periodic review of pain and functional goals
2. Review adverse events at each visit
   • Eliciting signs or symptoms of opioid abuse
   • Screening for endocrine function may be recommended
   • Importance of adverse event reporting and mechanisms to report
3. Review refill history/review PDMP
4. How to determine when an opioid analgesic is no longer necessary/beneficial

D. Long-term management
1. Evaluation of the patient with worsening pain for changes in underlying condition and for signs of OUD before increasing opioid dosage

2. Changing opioid medications
   - Concept of incomplete cross-tolerance when converting patients from one opioid to another
   - Concepts and limitations of the conversion charts in labeling and the limitations of relative potency or equianalgesic dosing tables in literature

3. Monitoring of patient adherence to the treatment plan, especially regarding misuse and abuse:
   - Perform medication reconciliation — recognize, document, and address aberrant drug-related behavior
   - Determine if nonadherence is due to inadequate pain management
   - Understand the utility and interpretation of urine drug testing (e.g., screening and confirmatory tests) and use as indicated
   - Screen and refer for substance use disorder treatment when concerns arise

E. How to recognize and intervene upon suspicion or identification of an OUD

HCPs should understand how to monitor patients taking opioid analgesics and identify the signs and symptoms of opioid misuse, abuse, and OUD and be knowledgeable about how to begin the process of intervention upon suspicion of an OUD.

F. When to consult with a pain specialist

HCPs should be knowledgeable about when referral to a pain management specialist is indicated, including identifying patients at high risk for OUD and patients unable to achieve adequate pain management.

G. Medically directed opioid tapering

HCPs should be knowledgeable about how to safely taper opioid analgesics, including how to recognize and manage signs and symptoms of opioid withdrawal. HCPs should be knowledgeable about the particular risks associated with tapering during pregnancy.

H. Importance of patient education

HCPs should recognize their role in reducing the risks associated with opioid analgesics through patient education at initiation of an opioid and throughout long-term management.

1. Inform patients about pain management expectations and managing pain through different pharmacologic and nonpharmacologic modalities.

2. Use the Patient Counseling Document and Medication Guide as part of discussion with patients and caregivers when prescribing opioid analgesics.
3. Counsel the patient about the following:
   a. Importance of adherence to prescribed dosing regimen
   b. Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time
   c. The risk of serious adverse events that can lead to death
   d. The risk of addiction that can occur even when product is used as recommended
   e. Known risk factors for serious adverse events, including signs and symptoms of overdose and opioid-induced respiratory depression, GI obstruction, and allergic reactions, among others
   f. The most common side effects, along with the risk of falls, working with heavy machinery, and driving
   g. When to call the prescriber (e.g., managing adverse events, ongoing pain)
   h. How to handle missed doses
   i. The importance of full disclosure of all medications and supplements to all HCPs and the risks associated with the use of alcohol and other opioids/benzodiazepines
   j. Product-specific concerns, such as not to crush or chew ER products; transdermal systems and buccal films should not be cut, torn, or damaged before use, etc.
   k. How to safely taper dose to avoid withdrawal symptoms
   l. Safe storage and disposal, risks of theft by family members and household visitors
   m. Never share any opioid analgesic with another person
   n. How and when to use naloxone products and their various means of administration
   o. Seeking emergency medical treatment if an opioid overdose occurs
   p. How to report adverse events and medication errors to FDA (1-800-fda-1088 or via http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)

V. ADDICTION MEDICINE PRIMER

HCPs should be knowledgeable about the basic elements of addiction medicine and be familiar with the definition, neurobiology, and pharmacotherapy of OUDs. In particular, stigmatizing or blaming language should be replaced with language that acknowledges that addiction, reclassified as substance use disorder\textsuperscript{15} in the revised Diagnostic Statistical Manual–V, is a disease. The term opioid use disorder\textsuperscript{16} should be used when referring to the use of opioids, rather than other substances.

It should also be noted that there may be a different approach with a patient who misuses an opioid analgesic by taking the product differently than prescribed for the purpose of managing pain, in contrast to the patient who abuses an opioid analgesic with the intent of getting high. HCPs should be familiar with the following:

\textsuperscript{15} Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (Copyright 2013). American Psychiatric Association

\textsuperscript{16} Id.
1. The neurobiology of OUD (addictive cycle)

2. Use of screening tools to identify patients at risk, based on known risk factors, and to identify patients developing signs of opioid dependence or addiction as early as possible.

3. Management of OUD, including the types of pharmacologic and nonpharmacologic treatments available and when to refer to an addiction medicine specialist.