Schedule II Drug Program – Law Component

Analyzing State and Federal law and rules as they apply to the authority to prescribe schedule II drugs.

Mary Jane Maloney MSN APRN - Past President, OAAPN

Schedule II Law Component

- Pain Management Organizations 10 minutes
- Federal Rule 10 minutes
- Ohio Revised and Administrative Codes 30 minutes
- Pharmacy Board
- Medical Board
- Ohio Revised and Administrative Codes 60 minutes
- Board of Nursing

Relevant Organizations which focus on Pain Management

[Logos of relevant organizations]
American Pain Society

• Started in 1977.
• Vision: A world where pain prevention and relief are available to all people.
• Current Position Statements available
  • Assessment and Management of Children with Chronic Pain – June 2012
  • Interdisciplinary Pain Management
  • APA Response to FDA Opioids REMS Educational Blueprint – December 2011
  • Optimizing the Treatment of Pain in Patients with Acute Presentations – December 2010.
  • Continuing Education Available – approved by ANCC
• www.ampainsoc.org

Ohio Pain Initiative – non-profit organization located in Columbus, Ohio

• Over a million Ohioans suffer from chronic pain
• The under-treatment of pain is a significant and continuing problem for tens of thousands of Ohioans.
• Pain suffers should have access to appropriate and effective pain management.
• Position Statement available at www.ohiopaininitiative.org
• Analgesic Tables for Downloading – Great Resource
  • Opioid Comparisons
  • Recommended starting doses for children and adults< 50kg body weight
  • Principles for Using Opioids Effectively
  • Miscellaneous Opioid Related Analgesics
  • Co-Analgesics
  • Management of Opioid Side Effects

American Academy Of Pain Management

• Founded in 1988 – largest organization on pain management in the nation and only one which embraces an integrative care model.
• Has Journal: The Pain Practitioner
• Monthly E-newsletter: Pain Management News and Research
• ON line CE Education for physicians and APRNs
• Offers credentialing exam as an intra-disciplinary pain practitioner – Brochure on line.
• aapainmanage.org
American Society of Pain Management Nurses

- Founded in 1990
- Position Papers (may be downloaded):
  - Male Infant Circumcision Pain Management
  - Pain Assessment in the Patient unable to Self-Report
  - Guidelines for Monitoring for Opioid Induced Sedation and Respiratory Depression
  - Use of Placebos in Pain Management
  - Procedural Sedation in Emergency Care Settings
  - Authorized and Unauthorized (PCA by Proxy) Use of Analgesia Infusion Pumps
- www.aspmmn.org

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January 2013 Topics

Opioid Diversion: How, Where, and What Can We Do About It?
Effective Strategies in Managing Breakthrough Pain
Do all substance abusers present with the same behaviors of abuse patterns?

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Federal Rule

- DEA’s Practitioner’s Manual
- Important excerpts:
  - Registration requirements
  - Prescription Requirements
    - Schedule II substances
    - Schedule III-V
DEA Registration

- Every person/entity that handles controlled substances must be registered with DEA or be exempt by regulation from registration.
- The DEA registration grants practitioners federal authority to handle controlled substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located. When federal law or regulations differ from state law or regulations, the practitioner is required to abide by the more stringent aspects of both the federal and state requirements. In many cases, state law is more stringent than federal law, and must be complied with in addition to federal law. Practitioners should be certain they understand their state as well as DEA controlled substance regulations.
- To obtain a DEA Registration # application, DEA may be contacted at:
  - www.DEAdiversion.usdoj.gov (DEA Diversion Internet Web Site)
  - NOTE: Check your current DEA # to ensure it is updated to include Schedule II drugs.

DEA Registration

- Registration Renewal:
  - Practitioner registrations must be renewed every three years.
- Termination of Registration:
  - The practitioner who is no longer involved in activities with respect to controlled substances must send the DEA a letter to the nearest DEA field office. Along with the notification of termination of registration, the practitioner should submit a Certificate of Registration to the nearest DEA field office.
- Practitioner’s Role of a Hospital’s DEA Registration Number:
  - Practitioners are licensed, registered, or otherwise regulated professionals who are permitted to prescribe controlled substances to patients in the hospital or otherwise administer, dispense, or otherwise handle controlled substances under the authority of the hospital. Hospital staff and practitioners must be properly identified when acting on behalf of the hospital. The hospital or institution under whose control a practitioner is acting must be identified in the journal and, where necessary, on the prescription.
  - Practitioners are authorized to do so by the state in which they practice.
  - The hospital or institution may require that the practitioner be bonded if the hospital law, state law, or the hospital regulations so require.
  - Terminating or discontinuing a hospital’s DEA registration number:
  - If the hospital or institution terminates or discontinues a hospital’s DEA registration number, the practitioner must return the unused portion of the characteristic code to the nearest DEA field office.
- Note: If you practice outside of the hospital, i.e., another/ non-hospital practice, you will need another DEA Number or not prescribe controlled substances.

DEA: Prescription Requirements

- A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).
- A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the practitioner’s name and address, the practitioner’s lawful name, address, and DEA registration number. The prescription must also include:
  1. drug name
  2. strength
  3. dosage form
  4. quantity prescribed
  5. duration for use
  6. number of refills (if any) authorized
- A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual signature or number must be designated by the practitioner to prepare prescriptions for the known practice of the patient. The prescription must be written in such a form that it cannot be altered.
- The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.
- Note: We will talk about additional State requirements later.
DEA: Prescription Requirements

**Who May Issue**
1. A prescription for a controlled substance may only be issued by a physician, dentist, podiatric, veterinarian, or nurse practitioner, or other licensed practitioner who is:
   - Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice
   - Registered with the DEA

2. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the direction or control of the hospital.

**Purpose**
- Prescriptions for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.
- The practitioner is responsible for the proper dispensing and dispensing of controlled substances. In addition, the practitioner must ensure that the person to whom the prescription is issued is licensed to prescribe or dispense controlled substances.
- The practitioner must ensure that the prescription is issued for a legitimate medical purpose and is supported by a legitimate and authorized research.

- A prescription may not be issued in order to transfer the controlled substance to another person.

**Legal Basis**
- (Ohio Rev. Code § 3719.04)(b)
- (Ohio Rev. Code § 3719.07)(a)(1)

**Schedule II Substances**
- Schedule II controlled substances require a written prescription which must be signed by the practitioner. There is no federal time limit within which a Schedule II prescription must be filled after being signed by the practitioner.
- While some states and many insurance carriers limit the quantity of controlled substance dispensed to a 30-day supply, there are no specific federal limits to the quantities of drugs dispensed via a prescription. For Schedule II controlled substances, an oral order is only permitted in an emergency situation. When Schedule II substance ordered in an emergency situation ORAL, the prescriber may only order for 30 days. (Ohio)

**Refills**
- Writing on prescription for REFILLS for a controlled substance listed in Schedule II is prohibited (Title 21 U.S. Code § 829(a)).

**Issuance of Multiple Prescriptions for Schedule II Substances**
- An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided that the following conditions are met:
  1. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
  2. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filed immediately) indicating the earliest date on which a pharmacy may fill each prescription.
  3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

- The issuance of multiple prescriptions is permissible under applicable state laws.
DEA: Prescription Requirements

- Prescriptions must be dated with the date WRITTEN.
  - DO NOT Post date prescriptions!
- It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances.
- May write for a Schedule II substance for 90 days in OHIO except for opioids.
  - Will discuss opioid restrictions later.
- Individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

DEA: Faxing Schedule II Scripts

- Facsimile Prescriptions for Schedule II Controlled Substances
  - A prescriber may transmit a Schedule II prescription to the pharmacy by facsimile. The original Schedule II prescription must be presented to the pharmacist for review prior to the actual dispensing of the controlled substance.
    - Why would you do this?
      - To decrease time at the pharmacy for the patient.
      - Some EMRs do not allow for electronic transmission of controlled substances.
  - In an emergency, a practitioner may call-in a prescription for a Schedule II controlled substance by telephone to the pharmacy, and the pharmacist may dispense the prescription provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (30 days). The prescribing practitioner must provide a written and signed prescription to the pharmacist within seven days. Further, the pharmacist must notify DEA if the prescription is not received.
DEA: Faxing Schedule II Scripts

- Exceptions for Schedule II Facsimile Prescriptions
- The facsimile of a Schedule II prescription may serve as the original prescription as follows:
  1. A practitioner prescribing Schedule II controlled substances to be compounded for the direct administration to a patient by a pharmacist. Intramuscular, intravenous, intra-synovial injection or intra-epidural injection may initiate the prescription. However, the pharmacist will consider the facsimile prescription as "written prescription" and the practitioner will consider the facsimile prescription as "written prescription", and the pharmacist will follow all normal requirements of a legal prescription must be followed.
  2. A practitioner prescribing Schedule II controlled substance for residents of Long-Term Care Facilities (LTCF) may transmit a prescription by facsimile. The practitioner’s agent may also transmit the prescription to the pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy.
  3. A practitioner prescribing a Schedule II narcotic for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XIX or a hospice program which is licensed by the state may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner or the practitioner’s agent may also transmit the prescription to the pharmacy. The practitioner or agent will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription.

Ohio: Board Of Pharmacy - OARRS

OAC 4731-11-11 (Pharmacy) OARRS
Ohio Automatic RX Reporting System - established in 2006
- A tool to assist healthcare professionals in providing better treatment for patients with medical needs while quickly identifying drug seeking behaviors.
- Can assist in assuring that a patient is getting the appropriate drug therapy and is taking their medication as prescribed.
- Prescribers, pharmacists and officers of law enforcement whose primary mission involves enforcing prescription drug laws can register for an OARRS account.
- Registered prescribers may also permit delegates to register for an OARRS account to request Prescription History Reports on prescriber’s behalf. Any person in the office may be a delegate – HIPAA applied.

Ohio: Board Of Pharmacy - OARRS - Definitions

- (2) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.
- (3) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber’s patients for use outside the prescriber’s practice setting. APRNs may not furnish controlled substances.
- (4) "Protracted basis" means a period in excess of twelve continuous weeks.
- (5) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including:
  (a) Controlled substances in schedules II, III, IV, and V, and
  (b) All dangerous drug products containing tramadol.
Ohio: Board Of Pharmacy - OARRS

• (B) If APRN believes or has reason to believe that a patient may be abusing or diverting drugs, the APRN shall use sound clinical judgment in determining whether or not the reported drug should be prescribed to the patient under the circumstances.

• (1) To assist in this determination, the APRN shall access OARRS and document receipt and assessment of the information received if the patient exhibits the following signs of drug abuse or diversion:
  • (a) Illegally selling prescription drugs;
  • (b) Forging or altering a prescription;
  • (c) Stealing or borrowing reported drugs;
  • (d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;
  • (e) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;
  • (f) Having been arrested, convicted or received diversion, or intervention in lieu of conviction for a drug related offense while under the APRN’s care;
  • (g) Receiving reported drugs from multiple prescribers, without clinical basis; or
  • (h) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient’s use of illegal or reported drugs.

Ohio: Board Of Pharmacy - OARRS

• (2) Other signs of possible abuse or diversion which may necessitate accessing OARRS include, but are not limited to the following:
  • (a) A known history of chemical abuse or dependency;
  • (b) Appearing impaired or overly sedated during an office visit or exam;
  • (c) Requesting reported drugs by specific name, street name, color, or identifying marks;
  • (d) Frequently requesting early refills of reported drugs;
  • (e) Frequently losing prescriptions for reported drugs;
  • (f) A history of illegal drug use;
  • (g) Sharing reported drugs with another person; or
  • (h) Recurring emergency department visits to obtain reported drugs.

Ohio: Board Of Pharmacy - OARRS

• (C) An APRN who holds a CIP and prescribes a reported drug to a patient following review of an OARRS report, and determines, based on the OARRS report that the patient may be misusing reported drugs, shall first consult with the collaborating physician prior to personally furnishing or prescribing a reported drug at the patient’s next visit.

• Following review of OARRS report information, the APRN who holds a CIP shall document receipt and assessment of the information in the patient’s record, including any consultation with the collaborating physician that occurred based on the OARRS report information.
Ohio: Board Of Pharmacy – OARRS – Lots of Documentation

- An APRN who holds a CIP and utilizes reported drugs to treat a patient on what the APRN has reason to believe will be a protracted basis shall, at minimum, review an OARRS report, and document receipt and assessment of the information in the patient's record:
  - At the beginning of treatment; and
  - At least once annually after treatment begins
- In requesting OARRS reports according to this rule:
  - Initial reports requested shall cover a time period of at least one year
  - Initial reports requested shall cover a time period of at least one year
- In the event an OARRS report is not available prior to writing a prescription for a reported drug or personally furnishing the reported drug, the APRN shall document in the patient record why the OARRS report was not available.
- This rule does not apply to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code. May be wise to do so based on family circumstances.

Ohio: Board Of Pharmacy – How to Register for OARRS

- How to register in OARRS:
  1. Go to OhioPMP.gov
  2. Click on “register” and follow instructions
  3. Print your application and get it notarized
  4. Forward with copies of required certificates to Ohio Board of Pharmacy address found on application.
    - Driver’s License
    - COA and CtP
- Note: OARRS is behind by 3-4 weeks in listing of controlled substances!

Ohio Board of Pharmacy Prescription Format: OAC4729-5-13

- (B) No prescriber shall write and no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:
  1. The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.
  2. The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, or preprinted.
  3. The quantity has been written both numerically and alphabetically. Example: 30 (thirty)
Ohio Board of Pharmacy

Format: Manner of Issuance OAC 4729-5-30

- (A) If preprinted, there is only one drug and strength combination printed on the form.
- (B) If a board approved electronic prescription transmission system is used to fax a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The faxed order must come directly from the prescriber’s office.

Note: All controlled substances must be written on tamper proof paper.

Ohio Board of Pharmacy: Prescription

Format: Manner of Issuance OAC 4729-5-30

- (8) All prescriptions issued by a prescriber shall:
  - (1) Be dated as of and on the day when issued.
  - (2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber.
  - (3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.
  - (4) Indicate the full name and residential address of the patient.
  - (5) Indicate the drug name and strength.
  - (6) Indicate the quantity to dispense.
  - (7) Indicate the appropriate and explicit directions for use.
  - (8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.131 of the Revised Code. A prescription marked “Refill P.R.O.” or some similar designation is not considered a valid refill.
  - (9) Not authorized: any refills on a Schedule II controlled substances prescription.

Ohio Board of Pharmacy: Prescription

Format: Manner of Issuance OAC 4729-5-30

- (10) Authority refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.
- (11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances. No refills for substances subject to an exemption pursuant to section 4729.131 of the Revised Code.
- (12) Identify the trade name or generic name of the drug(s) in a compounded prescription.
- (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient’s choice.
- (14) For prescriptions issued to a patient by a prescriber, be:
  - (1)动手 signed or the drug issued by the prescriber to the patient, as he/she would sign a check or signature card
  - (2) Issued in compliance with rule 4729-2-01(H) of the Administrative Code.
- (15) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to section 3719.04 of the Revised Code.
- (16) Issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority. These rules do not apply to controlled substances prescribed by a prescriber in accordance with federal law for those persons who are authorized to prescribe controlled substances under Title 21, section 825 of the administrative code.

APRNs are being designated for not writing OPI on prescriptions.
Ohio Board of Pharmacy: Prescription Format: Manner of Issuance OAC 4729-5-30

- Faxing
  - (3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:
    - (a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.
    - (b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.
    - (c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code.
  - (4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber’s agent shall not be considered a valid prescription.
  - (5) The facsimile of the prescription must include header information identifying the origin of the facsimile.

- Electronic Health Records
  - (f) A prescription may be transmitted by means of a board approved electronic prescription transmission system provided that:
    - (1) The system requires positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.
    - (2) The computer data is retained for a period of three years at the prescriber’s office.
    - (3) An electronic prescription transmission system meeting the requirements of 21 C.F.R. 1311 for both controlled substance and non-controlled substance prescriptions shall be considered approved by the state board of pharmacy.
  - NOTE: Not all EHR’s will allow electronic transmission of controlled substances.

Board of Medicine: ORC 4731.052

Administrative rules for management of chronic pain with controlled substances.

- (1) “Controlled Substance” has the same meaning as in section 4729.01 of the Revised Code.
- (2) ”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. “Chronic pain” does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.
Board of Medicine: ORC 4731.052
Administrative rules for management of chronic pain with controlled substances.

• (C) When a physician diagnoses an individual as having chronic pain, the physician may treat the pain by managing it with controlled substances drugs in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. The physician shall maintain a record of all of the following:
  • (1) Medical history and physical examination of the individual;
  • (2) The diagnosis of chronic pain, including signs, symptoms, and causes;
  • (3) The plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment;
  • (4) The dates on which controlled substances were prescribed, furnished, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the controlled substances prescribed, furnished, or administered;
  • (5) A copy of the report made by the physician or the physician to whom referral for evaluation was made under this division.

Board of Medicine: OAC 4731-11-03
Schedule II controlled substance stimulants.

• (A) A physician shall not utilize a schedule II controlled substance stimulant for any purpose except:
  • (1) The treatment of narcolepsy, idiopathic hypersomnia, and hypersomnias due to medical conditions known to cause excessive sleepiness;
  • (2) The treatment of abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), and/or related disorders of childhood;
  • (3) The treatment of drug-induced or trauma-induced brain dysfunction;
  • (4) The differential diagnostic psychiatric evaluation of depression;
  • (5) The treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants and MAO inhibitors;

Board of Medicine: OAC 4731-11-03
Schedule II controlled substance stimulants.

• (6) As adjunctive therapy in the treatment of the following:
  • (a) Chronic severe pain;
  • (b) Closed head injuries;
  • (c) Cancer-related fatigue;
  • (d) Fatigue experienced during the terminal stages of disease;
  • (e) Depression experienced during the terminal stages of disease; or
• (f) Intractable pain, as defined in rule 4731-21-01 of the Administrative Code. "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, by the responsible physician that no treatment or cure is possible or for which the expected success is negligible. "Intractable pain" does not include pain experienced by a patient with a terminal condition.
• (g) Intractable pain does not include the treatment of pain associated with a progressive disease that, in the normal course of progressions, may reasonably be expected to result in a terminal condition.
• (B) A physician shall not utilize a schedule II controlled substance stimulant for purposes of weight reduction or control.
Board of Medicine: OAC 4731-11-03
Schedule II controlled substance stimulants.

• (C) A physician may utilize a schedule II controlled substance stimulant when properly indicated for any purpose listed in paragraph (A) of this rule, provided that all of the following conditions are met:
  
  1. Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance stimulant to be utilized.
  
  2. The physician shall not utilize any schedule II controlled substance stimulant when he knows or has reason to believe that a recognized contraindication to its use exists.
  
  3. The physician shall not utilize any schedule II controlled substance stimulant in the treatment of a patient who he knows or should know is pregnant.
  
  4. Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician’s directions, the physician shall reassess the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use. The physician shall actively monitor such a patient for signs and symptoms of drug abuse and drug dependency.

Board of Medicine: OAC 4731-11-09
Prescribing to persons not seen by the physician.

• (A) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

• NOTE: This applies to APRNs.

Board of Medicine: OAC 4731-11-09
Prescribing to persons not seen by the physician.

• (F) Paragraphs (A) and (B) of this rule do not apply to or prohibit if:
  
  1. The provision of controlled substances or dangerous drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians;
  
  2. The provision of controlled substances or dangerous drugs by a physician to a person who the physician has accepted as a patient, if the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment;
  
  3. The provision of controlled substances or dangerous drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals, in accordance with protocols approved by the state board of pharmacy pursuant to rule 4729-5-01 of the Administrative Code; or
  
  4. The provision of controlled substances or dangerous drugs by a physician who is a medical director or hospice physician of a hospice program licensed pursuant to Chapter 3712 of the Revised Code, to a patient who is enrolled in that hospice program.
Board of Nursing: OAC 4723-8-04 Standard care arrangement for a certified nurse-midwife, certified nurse practitioner, and clinical nurse specialist.

- (12) For nurses with a current valid certificate to prescribe, the following quality assurance provisions shall be included (in the ICA):
  - (d) A procedure for the nurse and the collaborating physician, or a designated member of a quality assurance committee, composed of physicians, of the institution, organization, or agency where the nurse has practiced during the period covered by the review, to conduct a periodic review, at least semiannually, of:
    - A representative sample of all prescriptions written by the nurse; and
    - A representative sample of all Schedule II prescriptions written by the nurse.
  - (g) For the nurse to comply with the requirements of rule 4723-9-12 of the Administrative Code related to a patient’s OARRS report, consultation with the collaborating physician prior to prescribing based on the OARRS report and signs of drug abuse or diversion described in paragraph (b) of rule 4723-9-12, and documentation of receipt and assessment of OARRS report information in the patient’s record.

Board of Nursing: OAC 4723-9-07 Certificate to Prescribe Renewal

- A) To renew a certificate to prescribe, (APN) shall submit:
  - (1) A completed renewal application on a form specified by the board;
  - (2) Documentation satisfactory to the Board of having completed during the previous two years at least twelve hours of additional continuing education in advanced pharmacology, as provided in section 4723.485 of the Revised Code, which includes instruction that is specific to controlled substances, or, if the certificate has been held for less than a full renewal period, at least six hours of approved continuing education in pharmacology as provided in section 4723.485 of the Revised Code, which includes instruction specific to controlled substances;
  - Comment: Suggest a specific CE on controlled substances.
  - Note: The 12 hours of pharmacology CE are in addition to the 24 hours of CE required for RN/COA renewal.
Board of Nursing: OAC 4723-9-07 Certificate to Prescribe Renewal

- In addition to other requirements of this rule, all nurses who hold a certificate to prescribe issued by the board prior to the effective date of rule 4723-9-13 of the Administrative Code are required with that rule on or before August 13, 2012, in order to renew their certificate to prescribe.

- So all CTP holders who want to renew, whether they plan on prescribing Schedule 2 drugs or not, must take required six-hour Schedule 2 course and provide documentation.

Board of Nursing: OAC 4723-9-09 Standards of prescribing for nurses with a certificate to prescribe.

- (A) A nurse who holds a current valid certificate to prescribe may prescribe a drug or therapeutic device provided the prescription is in accordance with:
  1. The nurse’s standard care arrangement;
  2. The scope of practice in the nurse’s specialty area;
  3. The requirements of the formulary as set forth in section 4723.50 of the Revised Code; and

- (B) The nurse’s prescriptive authority shall not exceed the prescriptive authority of the collaborating physicians, including but not limited to, any restrictions imposed on the physician’s practice by action of the United States drug enforcement administration or the state medical board.

- Example: CP is Family Practice – APN may not prescribe chemotherapy

- (C) A nurse who holds a current valid certificate to prescribe shall prescribe in a valid prescriber-patient relationship. This may include, but is not limited to:
  1. Obtaining a thorough history of the patient;
  2. Conducting a physical or mental examination of the patient;
  3. Rendering a diagnosis;
  4. Prescribing medication, ruling out the existence of any recognized contraindications;
  5. Consulting with the collaborating physician when necessary; and
  6. Properly documenting these steps in the patient’s medical records.

- Comment: No “Sidewalk” prescribing.

Board of Nursing: OAC 4723-9-09 Standards of prescribing for nurses with a certificate to prescribe.

- (D) Acceptable and prevailing standards of safe nursing care require that a nurse maintain detached professional judgment in the treatment of family members.
  1. A nurse holding a current, valid certificate to prescribe shall not prescribe any drug or therapeutic device to family members unless:
     a. The nurse is able to exercise detached professional judgment in reaching diagnostic or therapeutic decisions;
     b. The prescription is in accordance with the nurse’s scope of practice and standard care arrangements; and
     c. The prescription is documented in the patient’s record.
  2. A nurse holding a current, valid certificate to prescribe shall not prescribe controlled substances for a family member.
  3. For the purposes of this rule, “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.
Board of Nursing: OAC 4723-9-9 Standards of prescribing for nurses with a certificate to prescribe.

1. A nurse holding a current valid certificate to prescribe a controlled substance shall apply for, and obtain, the United States drug enforcement administration registration prior to prescribing any controlled substances, except if not required to do so as provided in rule 4729-31-15 of the Administrative Code.

2. A nurse holding a current valid certificate to prescribe shall not prescribe any drug or device to perform or induce an abortion.

3. All drugs and therapeutic devices shall be prescribed in accordance with the standard care arrangement and Chapter 4723 of the Revised Code and rules of the board.

4. A nurse holding a current valid certificate to prescribe may prescribe drugs for purposes other than food and drug administration (FDA) indications when both of the following apply: (OFF LABEL USE)

   (1) The prescribing is in accordance with provisions of the formulary established pursuant to section 4723.50 of the Revised Code; and

   (2) The prescribing is consistent with the standard care arrangement required by section 4723.431 of the Revised Code.

5. A nurse holding a current valid certificate to prescribe shall satisfy all requirements for prescribing set forth in rule 4729-5-30 of the Administrative Code, and shall include the nurse's prescriber number on each prescription.

6. A nurse holding a current valid certificate to prescribe shall satisfy all the standards and procedures for review of OASIS reports as defined and set forth in rule 4723-9-12 of the Administrative Code. (Effective: 02/01/2012)

Board of Nursing: OAC 4723-9-10 Formulary

1. Established by the Committee on Prescriptive Governance and available on Board of Nursing website: www.nursing.ohio.gov

2. The committee on prescriptive governance (CPG) shall review the formulary for additions or deletions at least once a year.

3. **APN may prescribe a patient a Schedule 2 drug ONLY if the following are the case:**

   a. A patient has a terminal condition.

   b. Terminal condition (ORC 2123.01) means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a declarant or other patient's attending physician and one other physician who has examined the declarant or other patient, both of the following apply:

   - There can be no recovery.

   - Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

   c. Collaborating Physician initially prescribed substance for patient.

   d. The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, twenty-four hour period.

Board of Nursing: OAC 4723-9-10 Formulary

These restrictions do not apply if prescription is issued from any of the following locations:

1. Hospitals

2. Any entity owned or controlled in whole or part by hospital or by entity that owns or controls in whole or part one to more hospitals

3. Health care facility operated by Department of Mental Health or Department of Developmental Disabilities

4. Nursing Home

5. County Home or District Home operated under ORC 5155 that is certified under Medicare and Medicaid

6. Hospice Program defined under ORC 3712.01

   a. Hospice care program means a coordinated program of home, outpatient, and inpatient care and services that is operated by a person or public agency and that provides the following care and services to hospice patients, including services as indicated below to hospice patients’ families, through a medically directed interdisciplinary team, under interdisciplinary plans of care established pursuant to section 3712.06 of the Revised Code, in order to meet the physical, psychological, social, spiritual, and other special needs that are experienced during the final stages of illness, dying, and bereavement.

   b. Comment: Regardless of Site APN's can prescribe Schedule II drugs for Hospice Patients.
Board of Nursing: OAC 4723-9-10 Formulary

- Community Mental health facility as defined by ORC 5122.01
- Ambulatory Surgical Facility
- Free standing Birthing center as defined by ORC 3702.51
- FQHC
- FQHC look a like
- Health Care Office or facility operated by ODH or board of health of city/general health district
- Physician owned offices/practices

3. 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 division (C)(2) of this section.

Board of Nursing: OAC 4723-9-10 Formulary.

1. A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may personally furnish to a patient a sample of any drug or therapeutic device included in the types of drugs and devices listed on the formulary, except that all of the following conditions apply:

   1. The amount of the sample furnished shall not exceed a seventy-two hour supply, except when the minimum available quantity of the sample is packaged in an amount that is greater than a seventy-two hour supply, in which case the packaged amount may be furnished.
   2. No charge may be imposed for the sample or for furnishing it.
   3. Samples of controlled substances may not be personally furnished.

2. A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may personally furnish to a patient a complete or partial supply of a drug or therapeutic device included in the types of drugs and devices listed on the formulary, except that all of the following conditions apply:

   1. The clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall personally furnish only antibiotics, antifungals, antiparasitics, antiepileptics, antidepressants, antipsychotics, antiasthmatics, antihistamines, antihypertensives, antidiabetics, anticoagulants, antiretroviral drugs and devices used in the treatment of asthma, and drugs used in the treatment of dyslipidemia.
   2. The clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not furnish the drugs and devices in locations other than a health department 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, a federally funded comprehensive primary care clinic, or a nonprofit health care clinic or program. [Sample: College Health Clinic]

3. For purposes of interpreting the formulary, the following definitions shall apply:

11. "Physician consultation" means a nurse holding a current, valid certificate to practice may review the medication after direct communication with the collaborating physician regarding a particular patient and documenting the consultation in the patient record. Once the medication is initially authorized by the collaborating physician, a nurse holding a current valid certificate to prescribe may continue, modify, or discontinue the medication without further consultation.

12. "Physician initiation" means the collaborating physician is required to have personally examined and evaluated the patient before therapy is indicated in accordance with rule 4731:11-09 of the Administrative Code. Following discussion with the collaborating physician, the initial order or prescription may be written by an advanced practice nurse holding a current valid certificate to prescribe. Once therapy has been initiated, the advanced practice nurse may continue, modify, or discontinue the medication without further consultation.
Formulary lists all sites

APRNs are not allowed to prescribe an opioid for the treatment of drug addiction (Federal Law). Example: Suboxone
Barbiturates are to be prescribed within an institution only.

(B) In addition to the requirements set forth in rule 4723-9-08 and rule 4723-9-09 of the Administrative Code, if a nurse who holds a current valid certificate to prescribe believes, or has reason to believe, that a patient may be abusing or diverting drugs, the nurse shall use sound clinical judgment in determining whether or not a reported drug should be prescribed or personally furnished to the patient.

(1) In making this determination, the nurse shall not personally furnish or prescribe a reported drug without first reviewing a patient's OARRS report if the patient exhibits the following signs of drug abuse or diversion: Refer to ORC 4731-11-11 (Pharmacy) OARRS Slides

All APNs who hold a CTP certificate including an externship certificate, prior to the effective date of this rule must obtain six contact hours of instruction specific to schedule II controlled substances on or before August 31, 2013 in order to be eligible to renew their certificate to prescribe, and present documentation satisfactory to the BON of having completed the instruction.

To meet this requirement the course of instruction must:
- Be approved by the board or an BON provider, like the ONA.
- Be at a minimum six hours in length.
- Applicants must submit documentation of successful completion to the board in the form of an original certificate, issued by the provider of the course of instruction that includes:
  - Name of the attendee
  - Title of Program
  - Date of Program
  - Name of the provider and BON approve #
  - Verification of completion of at least six hours each of sixty minutes in duration.

Board of Nursing will determine what proof is necessary to provide for CTP renewal.
So what is next?

- Removal of site restrictions.
- Removal of three-to-one ratio when prescribing
- APRN to supervise all hours (Direct/Indirect) for CtP externship
- Removal of PI/PC from formulary
- Delegation of immunizations, etc to non-licensed personnel
- Expansion of sample medications
- *Become a member and be part of the force to remove barriers for APRN full scope of practice.*