New Policy Changes Designed to Combat the Opioid Epidemic

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Objectives

● List federal requirements regarding the prescribing and dispensing of opioids.
● Understand and apply the laws and rules related to the prescribing and dispensing of controlled substances, including opioids.
● List the main components of the Comprehensive Addiction and Recovery Act of 2016.
● Ensure access to controlled substances
● Review use of the Prescription Drug Monitoring Program’s Database.
● Discuss laws and rules related to the prescribing and dispensing of controlled substances.

Outline

Part 1
● Opioid Epidemic from Public Policy Perspective
● Congressional Response
  ● CARA 1.0 and CARA 2.0
● Regulatory Response
Part 2
● Ensure access to controlled substances for all patients with a valid prescription.
● Review use of the Prescription Drug Monitoring Program’s Database.
● Assess prescriptions for appropriate therapeutic value.
● Detect prescriptions not based on a legitimate medical purpose.
● Discuss laws and rules related to prescribing and dispensing of controlled substances.
Opioids killed more than 42,000 in 2016, or 116 people a day.
11.5 million people misused and opioid prescription in 2016

3 out of 4 people who used heroin, first misused a prescription opioid.
Currently, over 2 million Americans suffer from opioid use disorder

Only 20% receive treatment for opioid use disorder

CONGRESSIONAL RESPONSE
Comprehensive Addiction and Recovery Act (CARA)

- Signed into law July 22, 2016
- Prevention
- Treatment
- Recovery
- Law enforcement
- Criminal justice reform
- Overdose reversal
- Authorizes $181 million per year, but subject to annual approval through Congressional approval process.

CARA: Pharmacy/Prescriber “Lock-in”

- Designed to prevent prescription drug abuse under Medicare Part C and D. Beginning January 1, 2019, prescription drug plan (PDP) sponsors are permitted to establish drug management programs (DMPs) for at risk beneficiaries.
- HHS Final Rule effective 1/1/19
  - Voluntary drug management program to limit access for “at risk” beneficiaries
    - Exempted: beneficiaries who have cancer or are in hospice or LTCF
    - ALF residents not exempted, but “if a sponsor learned during case management that a beneficiary resides in an assisted living facility that does dispense drugs through a contract with a single pharmacy, then the sponsor must exempt such resident from its drug management program.”

CARA: State Monitoring Programs

- Reauthorizes National All Schedules Prescription Electronic Reporting Act (NASPER) that provides grants to state prescription drug monitoring programs (PDMPs).
- Grants support state efforts to improve their PDMPs by increasing interoperability and the use of health information technology (HIT), e-health records, health information exchanges and e-prescribing.
- Goal with enhanced PDMPs is to ensure health care providers have access to the accurate, timely prescription history information to use as a tool for the early identification for patients at risk of addiction.
CARA: Partial Fills

- Amends the Controlled Substances Act to allow for partial fills of prescriptions of Schedule II controlled substances if not prohibited by state law subject to the following requirements:
  - the prescription is written and filled in accordance with this section and Drug Enforcement Administration regulations;
  - a partial fill is requested by the patient or practitioner; and,
  - the total quantity dispensed does not exceed the total quantity prescribed.
- Any remaining portion of a partially filled prescription may be filled but must be filled not later than 30 days after the prescription was written. In an emergency situation, the remainder of the prescription may be filled not later than 72 hours after the prescription is issued.

CARA: Overdose Reversal

- Expands access to reversal agents, including naloxone.
- Makes federal grants available to states to fund programs that allow pharmacists to dispense naloxone without prescriptions.
- Encourages health care providers who prescribe opioids to simultaneously prescribe opioid overdose reversal drugs, while expanding access to opioid overdose antidote medications for caregivers of at-risk individuals.

CARA: FDA Action Plan

- FDA is required to refer all new drug applications for opioids to an FDA advisory committee.
- Before approving any labeling or labeling change for opioids intended for use in a pediatric population, the Secretary of HHS must convene an FDA Pediatric Advisory Committee to seek recommendations for the inclusion of information on drug labels.
- Required to develop an Extended Release/Long Acting Opioids Risk Evaluation and Mitigation Strategy, including recommendations regarding education programs for prescribers on opioids.
- Required to release a final version of guidance on General Principles for Evaluating the Abuse Deterrence of Generic Solid Opioid Drug Products.
CARA: Unused Medications

- The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

- Covered entities: a State, local, or tribal law enforcement agency;
- a manufacturer, distributor, or reverse distributor of prescription medications;
- a retail pharmacy;
- a registered narcotic treatment program;
- a hospital or clinic with an onsite pharmacy;
- an eligible long-term care facility; or
- any other entity authorized by DEA.

CARA 2.0 – Current Action in Congress

- Expected to pass and become law before Labor Day

- Current Status
  - House passed about 30 bills and will consolidate into single legislative package
  - Senate working on different track with their own bills
  - Should be able to reconcile and combine into single, bipartisan bill supported by both House and Senate
- Will play role in 2018 election

CARA 2.0

- Three-day limit on initial opioids for acute pain
- Requires physicians and pharmacists use their state Prescription Drug Monitoring Program (PDMP) upon prescribing or dispensing opioids
- Creates a national standard for recovery residences to ensure quality housing for individuals in long-term recovery
Prevention

- Reduce Overprescribing
  - Expand “Lock-in” programs
  - Real-time controls and point-of-sale
  - Standard pharmacy protocols for new or changed prescriptions
- Incentives for Appropriate Prescribing
  - Incorporate into Medicare Quality Star Ratings and Quality Payment Program
- Align CDC guidelines with monitoring programs for overprescribing and partner with law enforcement
- Disseminate best practices for Medicaid and other payers
Treatment

- Identify and develop solutions for treatment barriers for pain and opioid use disorder across Medicare, Medicaid, and private health plans:
  - Access to non-opioid treatment
  - Access to medication-assisted treatment
  - Access to providers in rural and low-access communities

Data Analytic Tools

- Monitor success of prevention measures related to reducing overuse and misuse
- Improve data transparency and interoperability to target safe prescribing efforts
- Analyze use patterns across CMS programs
- Support state Medicaid tracking and reporting data
Coverage

- CMS Coverage policies now ensure some form of Medication-assisted treatment across all CMS programs – Medicare, Medicaid, and Exchanges

Tracking

- Due to safe prescribing policies, the number of Medicare beneficiaries receiving higher than recommended doses from multiple doctors declined by 40% in 2017

Awareness

- CMS sent 24,000 letters in 2017 and 2018 to Medicare physicians to highlight that they were prescribing higher levels of opioids than their peers to incentivize safe prescribing practices.
Best Practices

- CMS activated over 4,000 hospitals, 120,000 clinicians, and 5,000 outpatient settings through national quality improvement networks to rapidly generate results in reducing opioid-related events.

Access

- As of June 2018, CMS approved 12 state Medicaid 1115 demonstrations to improve access to opioid use disorder treatment, including new flexibility to cover inpatient and residential treatment while ensuring quality of care.

PART 2
Objectives

- Ensure access to controlled substances for all patients with a valid prescription.
- Review use of the Prescription Drug Monitoring Program’s Database.
- Assess prescriptions for appropriate therapeutic value.
- Detect prescriptions not based on a legitimate medical purpose.
- Discuss laws and rules related to the prescribing and dispensing of controlled substances.

Mandatory Continuing Education

- All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:
  - Ensuring access to controlled substances for all patients with a valid prescription;
  - Use of the Prescription Drug Monitoring Program’s Database;
  - Assessment of prescriptions for appropriate therapeutic value;
  - Detection of prescriptions not based on a legitimate medical purpose; and,
  - The laws and rules related to the prescribing and dispensing of controlled substances.

- Complete the required course during the biennium ending on September 30, 2019.
- A 2-hour course taken every biennium thereafter.
- Course counts towards the mandatory 30 hours of CE required for licensure renewal.
- Complete required course before the end of the first biennial renewal period.
BOP Rule Revision for Pharmacists and Patients

- Rule prompted by the state board’s feeling based on testimony from the general public.
- 2002 Rule: Presumption that the prescription is not good.
- 2015 board philosophy by Michael Jackson, BPharm, CPh: Presumption that the prescription was issued for a specific purpose and is valid. Write a rule to help pharmacists confirm validity of the prescription rather than look at a prescription and find reasons not to fill it.

Pharmacist Role and Expectations

- Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment.
- Pharmacists should attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.
- Every patient’s situation is unique and prescriptions for controlled substances shall be reviewed with each patient’s unique situation in mind.
- Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice.

Definitions

- For purposes of this rule, the following definitions shall apply:
  - Valid Prescription: When it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.
  - Invalid Prescription: If the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.
  - Validating a Prescription: Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.
Controlled Substances Prescription Requirements

- Name of the prescribing practitioner
- Name, strength, and quantity of the drug prescribed
- Controlled Substance RX Requirements
- Date
- Directions for use
- Signature of prescribing practitioner on the issued day

- Electronically generated prescriptions have some requirements except:
  - Signature may be in an electronic format

Validating a Prescription

- Each prescription may require a different validation process and no singular process can fit each situation
- A concern with the validity of a prescription does not mean the prescription shall not be filled
- The pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.
General Standards for Validating a Prescription

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist’s independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

Minimum Standards Before Refusing to Fill a Prescription

1. Initiate communication with the patient or the patient’s representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber’s agent to acquire information relevant to the pharmacist’s concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program’s Database to acquire information relevant to the pharmacist’s concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to validate a prescription due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.
Drug Utilization Review

Assessment of Prescriptions for Appropriate Therapeutic Value

Prospective
- Evaluation of a patient's drug therapy PRIOR to a medication being dispensed.

Concurrent
- Ongoing monitoring of a drug therapy DURING the course of treatment with the medication.

Retrospective
- Review of a drug therapy AFTER the patient has received the medication.

Issues Commonly Addressed by Prospective DUR
- Clinical abuse or misuse
- Drug-disease contraindications
- Dosage modifications
- Drug-drug interactions
- Drug-patient precautions (i.e. age, allergies, sex, pregnancy, etc.)
- Formulary substitutions
- Inappropriate duration of treatment
Issues Commonly Addressed by Concurrent DUR
- Drug-disease interactions
- Drug-drug interactions
- Dosage modifications
- Drug-patient precautions (i.e., age, allergies, sex, pregnancy, etc.)
- Overutilization of drug
- Underutilization of drug

Issues Commonly Addressed by Retrospective DUR
- Appropriate generic use
- Clinical abuse or misuse
- Drug-disease contraindications
- Drug-drug interactions
- Inappropriate duration of treatment
- Incorrect dose/dosage form
- Use of formulary medications
- Overutilization of drug
- Underutilization of drug
- Therapeutic appropriateness
- Therapeutic duplication

Prescription Drug Monitoring Program
What is a prescription drug monitoring program (PDMP)?

According to the National Alliance for Model State Drug Laws (NAMSDL), a PDMP is a statewide electronic database which collects data on substances dispensed within the state.

The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency.

The housing agency distributes data from the database to professionals who are authorized under state law to receive the data for purposes of their profession.

Florida’s PDMP: E-FORCSE

New platform PMP SWARSE is available at: https://florida.pmpaware.net

E-FORCSE Search Criteria
E-FORCSE Example

E-FORCSE Additional Functions

- Search History Query
- Prescriber DEA Query
- Report Queue

For more information and a detailed tutorial please visit “Training Guide for Florida Practitioners and Pharmacists - Florida Department of Health Prescription Drug Monitoring Program”


HB 21
Controlled Substances

Effective date:
07/01/2018
Identity verification

- Before dispensing a controlled substance to a person not known to the pharmacist, the person picking up the prescription must present a valid photographic ID or other verification of their identity to the pharmacist.
- If the person does not have valid identification, the pharmacist may verify the person’s identity and prescription validity with the prescriber or his/her agent.
- “Proper identification” means an ID issued by state or federal government that contains the person’s photograph, printed name, and signature.

New requirements for PDMP

- Signed by Rick Scott on March 19, 2018 and will go into effect on July 1, 2018.
- Prescribers and dispensers or their designees must consult the PDMP to review a patient’s controlled substance dispensing history before prescribing or dispensing a controlled substance to a patient age 16 or older.
- Non-opioid schedule V controlled substances are exempt from checking requirements.
- If prescribers or dispensers fail to consult the PDMP, must document in the medical record/prescription record why they did not consult the system and they shall not prescribe or dispense greater than a 3 day supply of controlled substance to the patient.
- First offense will be a citation, following second offense disciplinary action will be taken.

New requirements for PDMP

- Exemptions for “health care practitioner administering a controlled substance directly [...] to treat the patient during that particular treatment session” and “pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply” have been eliminated.
- Pharmacists would need to report to the PDMP in these circumstances.
New requirements for PDMP

- When a controlled substance is dispensed, the following must be reported to PDMP as soon as possible, but no later than the close of the next business day:
  - Name of prescriber, DEA #, NPI #, and date of prescription
  - Date prescription was filled and method of payment
  - Name, address, telephone, and DOB of the person for whom the prescription was written
  - Name, NDC, quantity, and strength of substance dispensed
  - Name, DEA #, permit #, and address of dispensing pharmacy
  - Whether the prescription is new or a refill, and # of refills ordered
  - Name of individual picking up prescription and type of identification

- A prescriber or dispensing provider who willfully and knowingly fails to record the dispensing of controlled substances commits a misdemeanor of the first degree.

Prescribing Limit on Schedule II acute pain prescriptions

- This law defines acute pain as “the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.”

- Does not include pain related to cancer, terminal illness, palliative care, and traumatic injury with severity score of 9 or greater.

- For acute pain, Schedule II prescriptions for opioid drugs will be limited to a 3 day supply, but a 7 day supply may be prescribed if the following conditions are met:
  - The prescriber believes, in their professional judgment, that more than a 3 day supply is “medically necessary” to treat the acute pain
  - The prescriber must then indicate “ACUTE PAIN EXCEPTION” on the prescription
  - The prescriber must document in the patient’s medical records the acute medical condition and lack of alternative treatment options

- For treatment of pain other than acute pain, the prescriber must indicate “NONACUTE PAIN” on the prescription for Schedule II opioid drugs.

- Dispensing of Schedule II and Schedule III medications related to the performance of a surgical procedure are exempt from these limits.

- For the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, a prescriber who prescribes a Schedule II controlled substance listed must concurrently prescribe an emergency opioid antagonist.
Background: acute pain prescribing limits

- Massachusetts first imposed a 7-day limit on new opioid prescriptions in 2016
- 28 states have passed similar laws as of Nov 2017
- A study published by the CDC in 2017 found that the chances of chronic use begin to increase after the third day and rise rapidly thereafter
- Concluded "prescribing <7 days (ideally ≤3 days) of medication when initiating opioids could mitigate the chances of unintentional chronic use"

HB21 Summary

- PDMP must be consulted prior to dispensing a controlled substance
- Dispensing information must be reported to the PDMP by no later than the close of the following business day
- Schedule V prescriptions must also be reported
- Schedule II opioid prescriptions for acute pain will be limited to 3 days, or up to 7 days if an acute pain exception is indicated
- The prescriber must indicate "NONACUTE pain" on Schedule II opioids prescribed for pain other than acute pain

Any Questions?
References:


