Opioids: The Patient, The Process, The Big Picture

Disclosures

Stacey Swartz declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Ronna Hauser declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Jaclyn Shine is an employee of Cardinal Health. The conflict of interest was resolved by peer review of the slide content.

Learning Objectives

- Discuss new counseling guidelines for patients with prescription opioids.
- Outline a process for handling prescriptions to ensure that they are legal and a process to address pharmacy shopping by patients.
- Discuss federal regulations and developments on the state level to address prescription drug monitoring.

Opioids: The Patient, The Process, The Big Picture

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Co-Owner and Pharmacist in Charge
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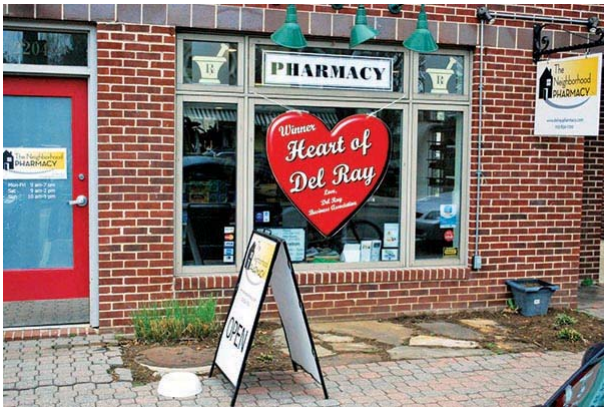
About Us

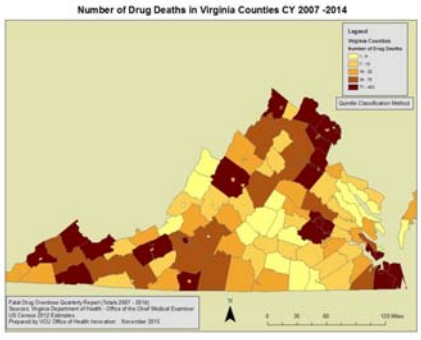
- Located in Alexandria, Virginia – located within short driving distance of several states and DC
- Start up pharmacy in 2009 – now in our 10th year



Our Location

At the Intersection of Several States

Virginia Opioid Deaths



Evolution of our Opioid Procedures

In 2009

- Narcotics in a small safe
- Confirmed all opioid prescriptions with the MD
- Accepted all out of state prescriptions
- Stocked all opioids

In 2018

- Narcotics in a locking cabinet
- Check all opioid prescriptions to the PMP
- Only accept written prescriptions from VA/DC/MD
- We do not stock certain opioids, some are hospice only

Participation in National Drug Take Back Day

- We have partnered with local law enforcement for DEA Take Back Days
- Held our own Alexandria take back days when DEA stopped holding the national take back days
- We now have events 4 times a year

SUBSTANCE ABUSE PREVENTION COALITION OF ALEXANDRIA

SHERIFF ALEXANDRIA VIRGINIA

The Neighborhood PHARMACY

703-836-1700
www.delraypharmacy.com

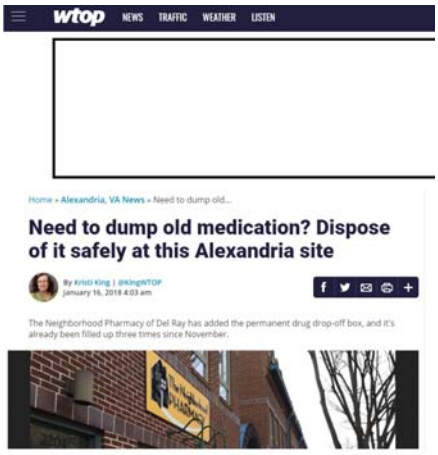
DEA Approved Collection Site

- In late 2017, we became an approved DEA collection site
  - With start up funding from the Substance Abuse Prevention Coalition of Alexandria and continuing support of the Alexandria Sheriff's Department
  - Involved modification to existing DEA license, purchasing a DEA compliant take back collection receptacle and creating policies and procedures for collection and removal
  - We are listed on the DEA website and VA Board of Pharmacy websites as collection location

ROI

Lots of Good PR

- Earned media
- Public goodwill
- City connections



Looking Toward the Future

- Virginia has declared a public health emergency
  - Change in prescribing requirements for opioids
- Policies for veterinary opioids
- Integration of PMP into dispensing system

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June 29, 2018

The Opioid Epidemic

- 91 Americans die each day from an opioid overdose
- Deaths from prescription opioids have more than quadrupled since 1999
- Most common drugs involved in opioid overdose deaths:
  - Oxycodone (OxyContin)
  - Hydrocodone (Vicodin)
  - Methadone

Why involve pharmacists?

- Essential part of the healthcare team
- On the front lines of dispensing opioid medications
- Can provide medication related services
- Access to prescription drug monitoring programs
- Almost all states allow pharmacists the ability to dispense naloxone under a standing order

Proper Storage

- Out of plain sight
  - *"Make sure you store your medication out of plain sight."*
- Out of reach of children and pets
  - *"Keep your medication out of the reach of children and pets as opioids can be especially dangerous for them."*
- Consider a lock box
  - *"Placing your medication in a locked box can help keep the medication from being stolen or misplaced."*

Proper Disposal

- Do not keep extra or unneeded opioid medication in home medicine cabinet
- Dispose of unused medication appropriately
  - Bring to a local police station or medication disposal site
    - https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s5
    - https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

"Dispose of your medications when you no longer need them, rather than storing them in the medicine cabinet."

Counsel on Adverse Events

- Sedation drowsiness, dizziness
  - *"For example, you may experience drowsiness and dizziness – so you need to make sure to avoid things that can increase these effects like alcohol or Benadryl. You also need to make sure to avoid driving or operating machinery."*
- Constipation
  - Recommend over-the-counter therapy if appropriate
- Respiratory depression
  - Especially if used in combination with benzodiazepines and/or alcohol
  - Educate on signs and symptoms and what to do

Counsel on Adverse Events

- Nausea
- Potential for physical dependence and/or addiction with chronic use
  - *"Since these medications are very strong and good at blocking pain, you can become dependent on them. Only use it when you need it, and then only the smallest amount necessary."*
  - *"There are other things you can try as well to reduce your pain, like…."*

Counsel on Adverse Events (Extended Use)

- Increased sensitivity to pain
- Depression
- Tolerance
  - *"When you use an opioid regularly, the body becomes accustomed to the drug and eventually needs larger or more frequent doses to get the same effect."*
- Physical dependence leading to withdrawal when the medication is stopped
  - Nausea, vomiting, cramps, sweating, chills, diarrhea
  - *"When you stop this medication, you may have withdrawal symptoms. Some people describe it as a bad case of the flu with things like strong cramping, nausea, sweating, chills, diarrhea, anxiety or muscle aches."*

Naloxone Therapy

- The CDC recommends consideration of naloxone therapy for at risk patients:
  - Those having a history of overdose or a substance use disorder,
  - Higher opioid dosages (greater than or equal to 50 MME/day), or
  - concomitant benzodiazepine use

- Counseling:
  - How to use naloxone therapy & recognize when they need it
  - Signs of opioid overdose: struggling to breathe, pinpoint pupils, clammy skin

Naloxone Counseling

- Using Naloxone in an Overdose:
  1. Call 911, report if the individual is unresponsive
  2. Administer naloxone intranasally or intramuscularly
  3. Begin rescue breathing
  4. If the individual is still unresponsive, administer the second dose 2-3 minutes after the first dose
  5. Remain with the individual until help arrives

- Naloxone shelf-life is 12-18 months
- Duration of action is 30-90 minutes, so patients can slip back into overdose if long-acting opioids were taken

Counseling Best Practices

- Use active listening
- Be empathetic
- Avoid stigmas (e.g. addiction)
- Make yourself available
- Ask open-ended questions

Conversation Starters

- *"It looks like you recently took a short term course of pain medication. Are you aware of the best ways to get rid of any mediation you have left over?"*
- *"How well is your medicine controlling your pain?"*
- *"What other medicine have you used to control your pain?"*
- *"Besides medicine, what other ways do you manage your pain?"*
- *"What side effects are you aware of with opioid therapy?"*

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National Community Pharmacists Association

Opioid Abuse

NCPA Recommended Solutions

- Expand Consumer Access to Naloxone with pharmacists participating in wider distribution of naloxone, including allowing pharmacists to directly prescribe
- Establish Limits on Maximum Day Supply for Certain Controlled Substances
- Expand Electronic Prescribing of Controlled Substances (EPCS)
- Encourage Pain Relief Alternatives for Pain Management
- Prohibit Certain Controlled Substances from Being Delivered to Patients via Physician Offices or via Mail
- Utilize Appropriately Structured Lock-In Program in Part D
- Enhance Prescription Drug Monitoring Programs:
- Increase Health Care Provider Education
- Increase Use and Access to Medication Assisted Treatment
- Expand the Ability of Pharmacies to Identify Individuals with Substance Use Disorders
- Expand Access to Controlled Substance Take-Back Programs

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LEGISLATION

Key legislation relating to the opioid crisis

The Opioid Crisis Response Act of 2018 (S. 2680)
- Sen. Lamar Alexander (R-TN), 17 cosponsors (8 GOP, 9 Dem)
- Reallocates federal funds and increases flexibility for opioid related programs in the FDA, NIH, SAMHSA, CDC and other agencies
- Expands a CARA grant program to train first responders to safely respond to fentanyl cases

Passed the Senate HELP Committee on April 24, 2018

The Comprehensive Opioid Recovery Centers Act of 2018 (H.R. 5327)
- Rep. Brett Guthrie (R-KY-2), 4 cosponsors (1 GOP, 3 Dem)
- Funds grants under the Public Health Service Act to create comprehensive opioid recovery centers and outreach programs

H.R. 5327 passed through the House Energy & Commerce Committee, Health Subcommittee's markup on April 25, 2018

Jessie's Law (S. 581, H.R. 5009)
- Sens. Manchin (D-WV), 6 cosponsors (2 GOP, 3 Dem, 1 Ind.)
- Reps. Tim Walberg (R-MI), 15 cosponsors (8 GOP, 7 Dem)
- Requires HHS to develop standards for hospitals for physicians to readily access consenting patients' histories with opioid addiction

House bill passed subcommittee and is waiting for a full Energy & Commerce Committee vote
Though Jessie's law has not passed the House, language from the bill was included in the omnibus bill signed into law in March 2018

CARA 2.0 Act of 2018 (S. 2456, H.R. 5311)
- Sen. Rob Portman (R-OH), 10 cosponsors (3 GOP, 7 Dem)
- Rep. Marsha Blackburn (R-TN), 5 cosponsors (2 GOP, 3 Dem)
- Reauthorizes and expands many CARA programs and limits initial pain prescriptions to three days

Sources: Congress.gov, 2018; GovTrack.us, 2018.

Additional Key Opioid Legislation

- H.R. 3528, the *Every Prescription Conveyed Securely Act*
  - maintained provisions sought by NCPA to exempt long-term care patients and to ensure that patients' choice of pharmacy is respected
- H.R. 4275, the *Empowering Pharmacists in the Fight Against Opioid Abuse Act*
- H.R. 4841, the *Standardizing Electronic Prior Authorization for Safe Prescribing Act*
- H.R. 5684, the *Protecting Seniors from Opioid Abuse Act*
  - adds beneficiaries at risk for prescription drug abuse to list of targeted individuals eligible for MTM
- H.R. 5675 Requires drug management programs for at risk beneficiaries
- H.R. 5676 authorizes the suspension of payments pending investigations of credible allegations of fraud by pharmacies
- S. 2645 the *Access to Increased Drug Disposal Act*, Senator Joni Ernst (R-IA) creates a DEA demonstration that provides grants to states to encourage greater participation in prescription drug take-back programs

Additional Key Opioid Legislation

- H.R. 5808, the *Medicaid Pharmaceutical Home Act of 2018*
  - would have required states to institute lock-in programs for patients at-risk of opioid abuse but would not have taken into account beneficiaries' choice of pharmacy
- H.R. 5801, the *Medicaid PARTNERSHIP Act*
  - would have placed duplicative requirements on pharmacists to check PDMPs, in addition to prescribers.
- Due to NCPA's advocacy efforts, both bills were changed to ensure that beneficiary choice of pharmacy is taken into account and that pharmacists would not be mandated by the federal government to check PDMPs.

2019 Medicare Part D Final Rule

- Implementing lock-in provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA). Hospice, cancer, and LTC patients are EXEMPT.
  - The Final Rule finalizes the definition of frequently abused drug to include opioids and benzodiazepines for drug management programs under CARA
  - Drug management programs may include allowing plans to lock patients into one or more prescriber(s) and one or more pharmacy(ies) to receive their frequently abused drugs.
  - Assisted living facility patients ARE NOT EXEMPT UNLESS THE ALF is serviced under a single contract with a pharmacy.
  - The Secretary must approve beneficiary notices for lock-ins
  - Beneficiary preference must prevail for in-network pharmacies
  - Chain pharmacies are considered one pharmacy for lock-in purposes

TABLE 1: 2019 CLINICAL GUIDELINES/OMS CRITERIA* FOR IDENTIFYING POTENTIAL AT-RISK BENEFICIARIES

Minimum Criteria Applied (Sponsors with Drug Management Programs Must Review)	Impact to Part D Program
≥ 90 MME and either: 3+ opioid prescribers **AND** 3+ opioid dispensing pharmacies **OR** 5+ opioid prescribers (regardless of the number of opioid dispensing pharmacies) Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber. Pharmacies with multiple locations that share real-time data are counted as one pharmacy.	44,332 beneficiaries in 2017 (69.9% were LIS) Represents 0.10% of 45,218,211 Part D beneficiaries in 2017 LTC beneficiaries included in estimate but are exempt. Estimate does not include pharmacies grouped as one pharmacy; CMS does not have system capability.
Supplemental Criteria Applied (Sponsors with Drug Management Programs May Review as Many as Manageable)	**Impact to Part D Program**
Any Level MME and: 7+ opioid prescribers **OR** 7+ opioid dispensing pharmacies Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber. Pharmacies with multiple locations that share real-time data are counted as one pharmacy.	22,841** beneficiaries in 2017 (77.8% were LIS) Represents 0.05% of 45,218,211 Part D beneficiaries in 2017 LTC beneficiaries included in estimate but are exempt. Estimate does not include pharmacies grouped as one pharmacy; CMS does not have system capability.

*Benzodiazepines are a frequently abused drug for purposes of Part D drug management programs but are not a factor in the these clinical guidelines/MS criteria. Buprenorphine products are not used to determine the beneficiary's average daily MME. However, prescription opioids including all formulations of buprenorphine for pain and MAT, are used to determine opioid prescribers and opioid dispensing pharmacies under the minimum criteria. Similarly, sponsors must include all prescription opioids, including all buprenorphine products, to determine opioid prescribers and opioid dispensing pharmacies under the supplemental criteria.
**Note: A total of 25,480 beneficiaries met the supplemental criteria alone. The estimate is 22,841 beneficiaries after removing duplicate beneficiaries already identified by the minimum criteria.

2019 Medicare Part D Final Call Letter

- **CMS is improving drug utilization review controls in Medicare Part D for the 2019 contract year. The following are important changes for pharmacies:**
  - **There is a new hard safety edit for opioids.** All Part D sponsors must implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply.
  - **All Part D sponsors must implement a real-time safety edit at 90 MME (morphine milligram equivalent) per day at the time of dispensing.** This formulary-level safety edit would trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME.
- "Sponsors should exclude beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer related pain."

NCPA & NACDS 90 MME Concerns & Ask to CMS

- CMS Requirements of Concern:
- "…sponsors should instruct the pharmacist (e.g., through messaging to the pharmacist through the claim billing transaction communications) to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted. These extra care coordination steps are what distinguish the new care coordination edit from a traditional soft edit."
- "Pharmacies should be provided the override code without needing to contact the plan sponsor, or sponsors should allow the pharmacist to call the plan's help desk for the plan to put in an override in real time if the plan sponsor does not have the capability to utilize automated codes. Plan sponsors should make it clear to pharmacies to only use the override code upon completion and documentation of the care coordination activities, and plan sponsors may consider auditing pharmacies' documentation."

NCPA & NACDS 90 MME Concerns & Ask to CMS

Primary concerns:

- Lack of System Capabilities and Operational Challenges
- Attempts to Promulgate New Rules without Proper Notice and Comment Rulemaking

Our ask to CMS:

- CMS should reconsider this requirement and look at other solutions
- use the traditional coverage determination process for conditions considered to be a CMS hard edit
- eliminate prescriber attestation documentation requirement
- Alternatively, CMS should seek to implement through proper notice and comment rulemaking

Questions?

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