VIRGINIA BOARD OF DENTISTRY

Regulatory Advisory Panel Discussion on the prescribing of opioids in the practice of dentistry

AGENDA

January 23, 2017

Department of Health Professions

Perimeter Center – 9960 Mayland Drive, 2nd Floor Conference Center

Henrico, Virginia 23233

TIME

9:00 a.m. **Call to Order – John M. Alexander, D.D.S., Chair**

Evacuation Announcement – Ms. Palmatier

PURPOSE: **The Regulatory Advisory Panel is asked to address the prescribing of opioids for acute and chronic dental related pain and develop a guidance document and points to be addressed in regulations.**

To facilitate discussion, panelists are encouraged to bring copies of any documents related to prescribing opioids in dental treatment.

12:00 p.m. **Adjourn**

Statement on the Use of Opioids in the Treatment of Dental Pain

This guideline is being updated. A revised version is due for release in early 2017.

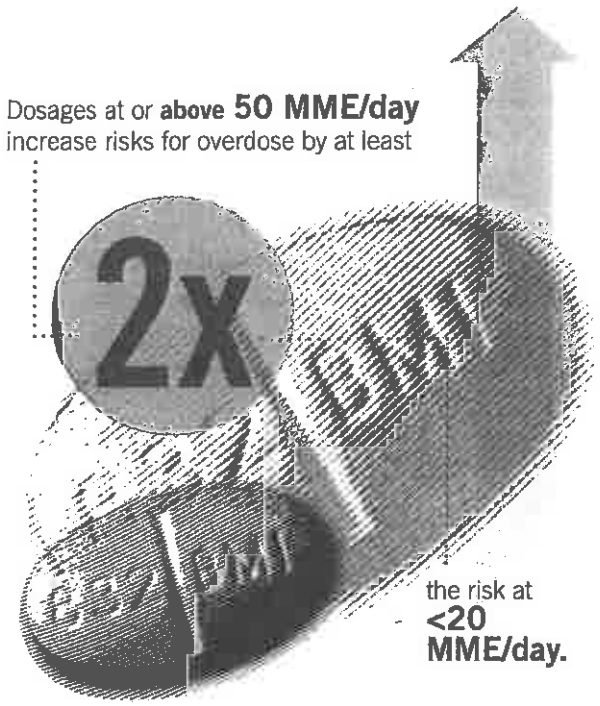
1. The ADA encourages continuing education about the appropriate use of opioid pain medications in order to promote both responsible prescribing practices and limit instances of abuse and diversion.
2. Dentists who prescribe opioids for treatment of dental pain are encouraged to be mindful of and have respect for their inherent abuse potential.
3. Dentists who prescribe opioids for treatment of dental pain are also encouraged to periodically review their compliance with Drug Enforcement Administration recommendations and regulations.
4. Dentists are encouraged to recognize their responsibility for ensuring that prescription pain medications are available to the patients who need them, for preventing these drugs from becoming a source of harm or abuse and for understanding the special issues in pain management for patients already opiate dependent.
5. Dentists who are practicing in good faith and who use professional judgment regarding the prescription of opioids for the treatment of pain should not be held responsible for the willful and deceptive behavior of patients who successfully obtain opioids for non-dental purposes.
6. Appropriate education in addictive disease and pain management should be provided as part of the core curriculum at all dental schools.

Adopted October 2005

CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE

Higher Dosage, Higher Risk.

Higher dosages of opioids are associated with higher risk of overdose and death—even relatively low dosages (20-50 morphine milligram equivalents (MME) per day) increase risk. Higher dosages haven't been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME).



WHY IS IT IMPORTANT TO CALCULATE THE TOTAL DAILY DOSAGE OF OPIOIDS?

Patients prescribed higher opioid dosages are at higher risk of overdose death.

In a national sample of Veterans Health Administration (VHA) patients with chronic pain receiving opioids from 2004–2009, **patients who died** of opioid overdose were prescribed an average of **98 MME/day**, while **other patients** were prescribed an average of **48 MME/day**.

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.

HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

50 MME/day:

- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (<3 tablets of methadone 5 mg)

90 MME/day:

- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained-release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)

CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

« All Events (http://pcss-o.org/calendar-of-events/)

Providing Safe and Effective Pain Management while Preventing Diversion and Misuse of Opioids

April 19, 2017 @ 3:00 pm - 4:00 pm ET

Presenter(s): Michael E. Schatman, PhD, CPE, Director of Research, U.S. Pain Foundation

More information coming soon!

Date:
APRIL 19, 2017

Time:
3:00 PM - 4:00 PM

Event Category:
Webinars (http://pcss-o.org/calendar-of-events/category/webinars/)

Sponsor
American Dental Association (http://pcss-o.org/organizer/american-dental-association/)

Website:
(http://www.ada.org/en/) (http://www.ada.org/en/)

« Previous (http://pcss-o.org/event/2002-to-2016-the-evolution-of-buprenorphine-practice/)

Next » (http://pcss-o.org/event/peer-assistance-for-the-dental-team-member-with-opioid-

dependency/)

VaAware (http://vaaware.com/)

My Rf

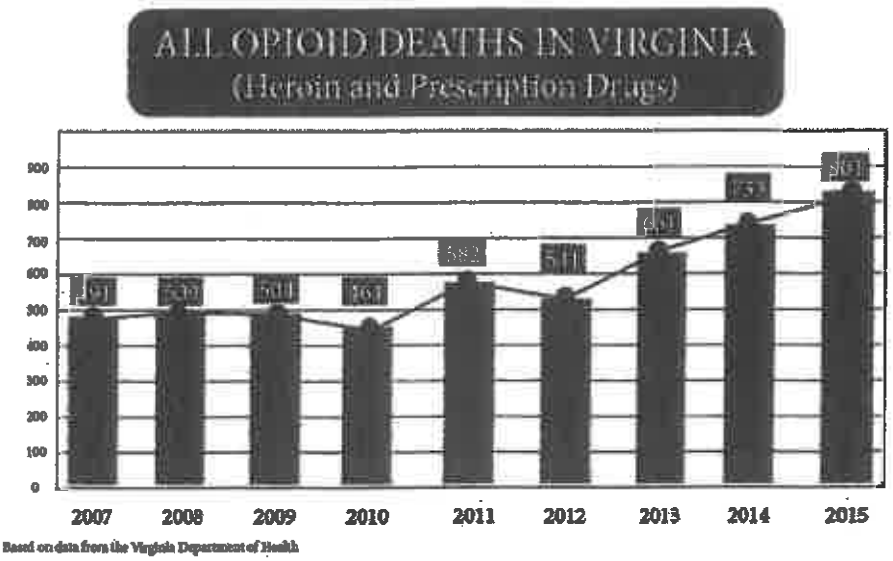
Addiction, prevention & recovery resources

* PMP request if opioid More than 14 day

MENU

A Crisis of Addiction

In 2014 Virginia Governor Terry McAuliffe convened a Task Force on Prescription Drug and Heroin Abuse (http://www.dhp.virginia.gov/taskforce/default.htm) to address the crisis in opioid addiction and overdose that the Commonwealth – and indeed, our entire country – is facing. More Virginians now die every year from an overdose than in automobile accidents, and nationally there is an overdose death every 20 minutes.



Based on data from the Virginia Department of Health

VaAware is a collaboration among four Virginia agencies, the Department of Health (http://www.vdh.virginia.gov/), Department of Behavioral Health and Developmental Services (http://www.dbhds.virginia.gov/), Department of Criminal Justice Services (http://www.dcjs.virginia.gov/), and Department of Health Professions (http://www.dhp.virginia.gov/).

Here you will find information of where to find treatment if you or a loved one is struggling with addiction, access to resources in your part of Virginia, and the latest research and data on this crisis.

Information for Practitioners (http://vaaware.com/learn/information-for-practitioners/), which includes information on prescribing, pain

management, addiction and continuing education opportunities.

There is also a section For Law Enforcement (http://vaaware.com/learn/information-for-law-enforcement/), recognizing the key roles our law enforcement agencies play in this crisis, such as being first responders to an overdose, and their ability to offer convenient disposal options for Virginians.

Thank you for taking the time to visit VaAware. Working together we will find ways to end the tragedy of opioid overdose deaths.

(http://www.mass.gov/eohhs/gov/departments/dph/stop-addiction/state-without-stigma/)

Find a treatment facility near you.

(http://drugfreeva.org/grab-a-lifering/)
Click on the link & scroll down the page

GetTested

(http://vaaware.com/)

Find Free, Fast, and Confidential HIV, STD, and Hepatitis Testing Near You

Enter ZIP Code

SHARE INFO

Virginia's Opioid Addiction Crisis: A Public Health Emergency

On Monday, November 21, 2016, in collaboration and consultation with the Virginia Board of Pharmacy, Department of Health Professions and Department of Behavioral Health and Developmental Services, State Health Commissioner Dr. Marissa J. Levine declared the Virginia opioid addiction crisis a public health emergency (https://governor.virginia.gov/newsroom/newsarticle?articleId=18348). The declaration came in response to the growing number of overdoses attributed to opioid use, and evidence that Carfentanil, a highly dangerous synthetic opioid used to sedate large animals such as elephants, has made its way into Virginia. In response to the Public Health Emergency, Dr. Levine has issued a standing order (http://www.vdh.virginia.gov/content/uploads/sites/4/2016/11/Standing-Order-w-o-DEA-FINAL.pdf) that allows all Virginians to obtain the drug Naloxone that is used to treat narcotic overdoses in emergency situations. The standing order serves as a prescription written for the general public, and removes a potential barrier to access to naloxone.

- Opioid Addiction Crisis Declared a Public Health Emergency in Virginia (https://governor.virginia.gov/newsroom/newsarticle?articleId=18348) – Governor's Press Release
- State Health Commissioner Comments on Opioid Addiction Declaration (http://www.vdh.virginia.gov/blog/2016/11/21/state-health-commissioner-comments-on-opioid-addiction-declaration/)
- Fentanyl for First Responders, Safety and Handling (https://www.fentanylsafety.com/)
- November 21, 2016 Telebriefing -- Read the transcript (http://www.vdh.virginia.gov/commissioner/telebriefing-transcript/)
- Standing Order (http://www.vdh.virginia.gov/content/uploads/sites/4/2016/11/Standing-Order-w-o-DEA-FINAL.pdf)
- Protocol for Prescribing and Dispensing of Naloxone (http://www.vdh.virginia.gov/content/uploads/sites/4/2016/11/NaloxoneProtocolForPharmacists-11-10-16-CURRENT-version.pdf)
- If you have unused, expired or unwanted medications and need a way to safely dispose of them, you can now get a drug disposal bag from your Local Health Department (http://www.vdh.virginia.gov/local-health-districts/). Learn more about how to safely dispose of medications. (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.)
- REVIVE! How to Recognize and Respond to an Opioid Overdose Emergency with Naloxone (http://www.vdh.virginia.gov/content/uploads/sites/4/2016/11/osps-revive-pharmacy-dispensing-brochure-copy.pdf)
- The Surgeon General's Report on Alcohol, Drugs and Health (https://addiction.surgeongeneral.gov/)

Useful Links

- Where to Find Treatment (http://drugfreeva.org/grab-a-lifering/)
- National Institute on Drug Abuse (https://www.drugabuse.gov/)

- Centers for Disease Control & Prevention (http://www.cdc.gov/drugoverdose/index.html)
- Substance Abuse and Mental Health Services Administration (http://www.samhsa.gov/)

Regional Organizations

- Road to Recovery – Northern Shenandoah Valley (http://roadtorecovery.info/)
- One Care of Southwest Virginia (http://onecareva.org/)
- Sink or Swim – Northern Neck (http://drugfreeva.org/)

Resources

- Facts & Figures (http://vaaware.com/home/facts-figures/)
- VDH Opioid Overdose Data Quarterly Report – Q3 2016 (http://www.vdh.virginia.gov/content/uploads/sites/13/2016/09/Opioid-Overdose-Data-Quarterly-Report-Q3-2016_111516.pdf)

VaAware | Addiction, prevention & recovery resources

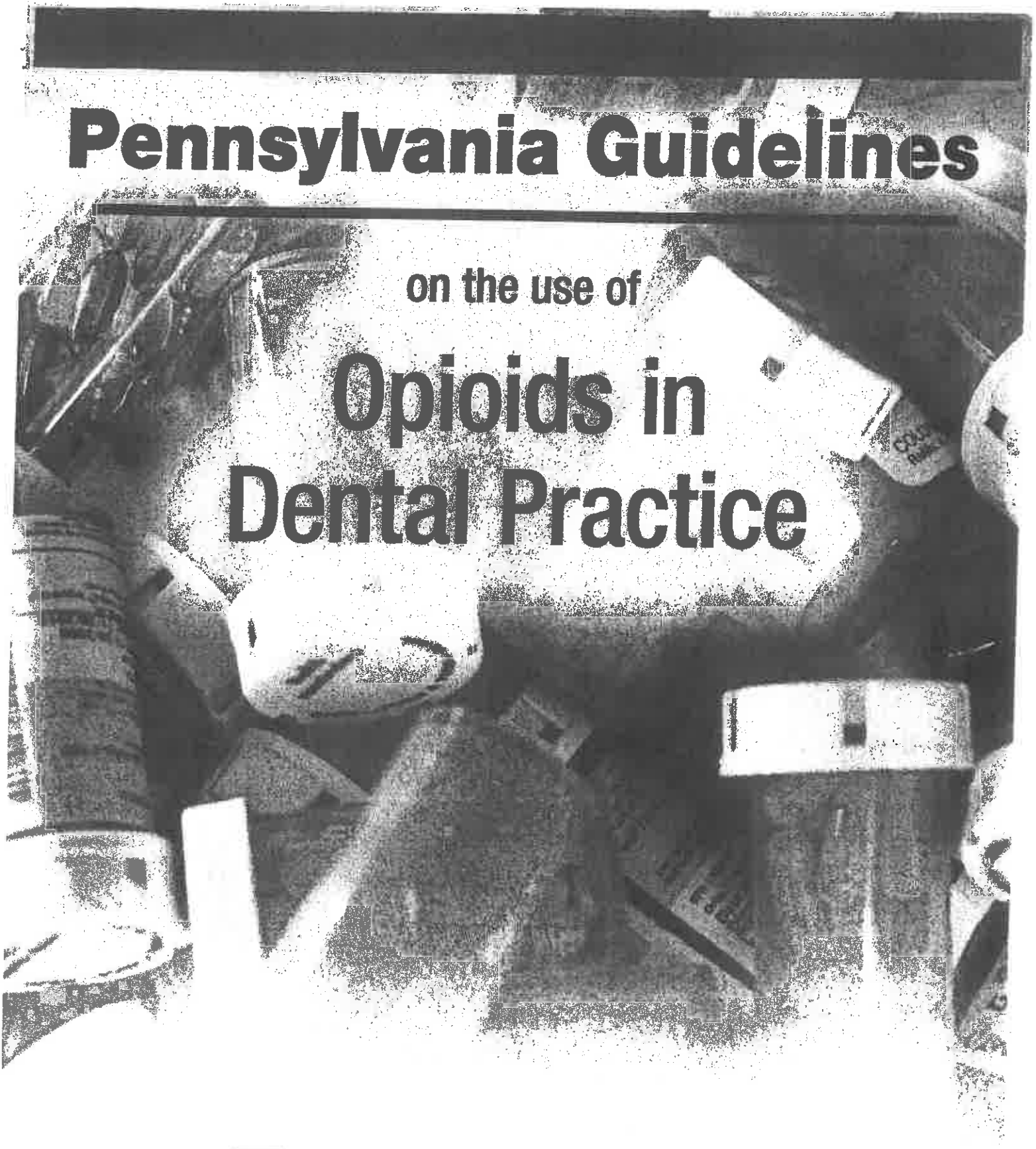
(http://vaaware.com)

Email us at info@vaaware.com (mailto:matt.treacy@dhp.virginia.gov)

Pennsylvania Guidelines

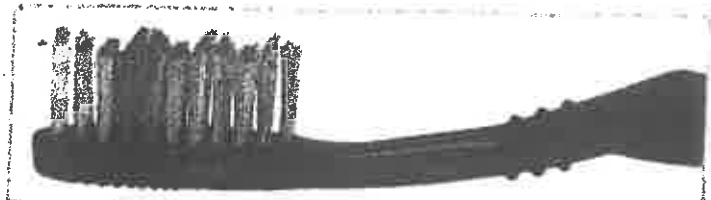
on the use of

Opioids in Dental Practice



pennsylvania

Pennsylvania Dental Association



Pennsylvania Guidelines on the Use of Opioids in Dental Practice

Dentists provide acute pain treatment as part of routine dental care and management of dental emergencies. In addition, dentists may be involved in the management of chronic oral-facial pain. Acute and chronic pain therapy may involve the administration of potent opioids. However, the prescribing of potent opioids is associated with significant risk of harm, including sedation, altered mental status, and respiratory depression and arrest, as well as the risk for misuse, diversion and substance use disorders.

These guidelines address the use of opioids for the treatment of acute dental pain. Guidelines are available to provide information regarding the use of opioids for the treatment of chronic non-cancer pain, including chronic head and face pain. These guidelines are intended to help health care providers improve patient outcomes when providing this treatment, including avoiding potential adverse outcomes associated with the use of opioids to treat pain. These guidelines are intended to supplement and not replace the individual prescriber's clinical judgment.

Opioid analgesics may be necessary for the relief of pain, but improper use of opioids poses a threat to the individual and to society. Providers have a responsibility to diagnose and treat pain using sound clinical judgment, and such treatment may include the prescribing of opioids. Providers also have a responsibility to minimize the potential for serious adverse effects, including the abuse and diversion of opioids. Therefore, providers should use proper safeguards to minimize the potential for abuse and diversion of opioids.

Dental care providers should incorporate the following key practices into their care of the patient receiving opioids for the treatment of acute dental pain:

1. Before initiating pain therapy, clinicians should conduct and document a medical and dental history, including documentation and verification of current medications, and a physical examination. Appropriate diagnostic imaging and testing, if indicated, should be completed before starting therapy. If opioids are to be prescribed, the initial evaluation should include documentation of the patient's psychiatric status and substance use history.

2. Clinicians should administer non-steroidal anti-inflammatory drugs (NSAIDs), as first-line analgesic therapy, unless contraindicated. NSAIDs have been demonstrated to be very effective for the treatment of dental pain, and indeed are often more effective than opioids. Consideration should be given to initiating NSAID therapy immediately before the procedure, then continuing dosing on a scheduled basis immediately following the procedure.

   A. Clinicians may wish to consider the administration of a selective NSAID, such as celecoxib, to avoid an increased risk of bleeding.

   B. Extreme caution should be used in patients taking any other anticoagulant, as the risk for bleeding is significantly increased when NSAIDs are used in combination with other anticoagulants, including aspirin.

C. Caution should be used in patients with a history of hepatic or renal impairment, or who report a previous adverse reaction to acetaminophen and/or NSAIDs.

3. Acetaminophen has been shown to be synergistic with NSAIDS with the efficacy of low dose opioids. When clinicians administer acetaminophen, it should be on a scheduled basis unless contraindicated

4. Clinicians should consider the use of local anesthetic techniques, including local infiltration of dental local anesthetics and regional nerve blocks whenever possible to assist in pain management and reduce the requirement for opioid analgesia.

5. If an opioid is to be administered, the dose and duration of therapy should be for a short period of time, and for conditions that typically are expected to be associated with more severe pain. Do not prescribe doses or amounts that are in excess to the expected opioid requirements.

A. When opioids are indicated, the provider should choose the lowest potency opioid necessary to relieve the patient's pain.

B. Long-acting opioids or extended-release preparations are contraindicated for the treatment of acute procedural pain.

C. Providers should be aware of concurrent medications and the potential for drug interactions. Interactions with other medications the patient is taking can either increase or decrease the potency of certain analgesics. The provider should assess the risk for drug-drug interactions before prescribing analgesics.

i. Some concurrent medications, such as antidepressants, can interfere with the metabolism of some prescribed opioids and can increase the risk of adverse events.

ii. Opioids should not be administered in combination with benzodiazepines or other centrally acting sedating medications, due to the increased risk of serious adverse effects, including death, when these medications are used together.

D. Care should be used when prescribing opioid combination product medications, to ensure that the total dose of acetaminophen does not exceed 3,000 mg / day in adults.

E. Care should be used when administering opioids to individuals with obstructive sleep apnea, as these patients are at increased risk for opioid-induced adverse events.

F. Upon development of a controlled substances database by the Commonwealth of Pennsylvania, providers should access the database as indicated.

6. Unless the clinician has training and experience in the use of opioids for the treatment of non-cancer pain or chronic facial pain, long acting or extended-release opioids should not be prescribed.

A. Patients reporting unexpectedly prolonged pain, especially those patients who do not have clear evidence of ongoing pathology, should not be prescribed opioids. The clinician should consider patient referral to appropriate dental or chronic pain specialists in patients who request continuation of opioids beyond the normal, expected recovery period.

B. A patient whose behavior raises the provider's concern for the presence of a substance use disorder should be encouraged to seek evaluation and possible treatment for this condition through his or hers "primary medical care provider," local substance treatment programs, or other appropriate referral sources.

7. The clinician should coordinate pain therapy with other clinicians before the procedure whenever possible in patients who are receiving chronic opioids, who have a history of a substance use disorder, or who are at high risk for aberrant drug-related behavior. It is not appropriate to refer patients receiving chronic opioid therapy to the emergency department to obtain prescriptions for opioids.

8. Extreme caution should be exercised when responding to requests for opioid analgesics, especially from patients who are new to the practice or who have not been recently seen and evaluated. In general, it is not proper to prescribe opioids absent a face-to-face patient evaluation.

9. Providers should provide patients with instructions on safe disposal of unused medications, including opioids, to ensure these medications are not available for possible diversion or misuse.

10. Clinicians should be aware of and understand current federal and state laws, regulatory guidelines, and policy statements that govern the prescribing of controlled substances.

References

[1] American Society of Anesthesiologists Task Force on Acute Pain M. Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology 2012; 116:248-73.

[2] Becker DE. Pain management: Part 1: Managing acute and postoperative dental pain. Anesthesia progress 2010; 57:67-78; quiz 9-80.

[3] Becker DE. Drug therapy in dental practice: general principles. Part 2 - pharmacodynamic considerations. Anesthesia progress 2007;54:19-23; quiz 4-5.

[4] Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantine JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C, American Pain Society-American Academy of Pain Medicine Opioids Guidelines P. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. The journal of pain : official journal of the American Pain Society 2009;10:113-30.

White Paper

American Association of Oral and Maxillofacial Surgeons

Prescription Drug Abuse and Prevention

America is in the midst of a prescription opioid epidemic. It is estimated that 6.5 million Americans and 2.5% of the population age 12 years and older are current nonmedical users of psychotherapeutic drugs. Of these, 4.3 million, or 66.2%, reported the use of pain relievers for nonmedical purposes.[1]

As oral and maxillofacial surgeons (OMSs) and lawful prescription drug prescribers, we know that when used as prescribed, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from invasive procedures. We also recognize, however, that acute pain medication prescribed following oral and maxillofacial surgery may frequently be the first exposure many American adolescents have to opioid prescriptions, and that roughly 12% of all immediate release opioid prescriptions in the US are related to dental procedures.[2] Dentists, including OMSs who primarily manage acute pain, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

Over the past decade, a number of approaches have been proposed to address this issue. The AAOMS provides the following positions in response to several of these proposals.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs), if properly funded, implemented and updated by dispensers, are valuable tools for detecting a practice known as "doctor-shopping" and preventing the diversion of prescription opioids. AAOMS believes that federal and state efforts to develop these programs should be supported and properly funded. AAOMS further believes that in order to prove useful in preventing abuse and diversion, dispensers should enter data into a PDMP in real time. In addition, if the prescription is for a period of less than 7-days, it should not be mandatory to check a PDMP for acute pain patients who receive an opioid following an invasive surgical procedure, as the risk of abuse and diversion is low in these instances. Furthermore, because checking the PDMP is an administrative task, the AAOMS believes that approved auxiliary personnel should be authorized to access the system on the doctor's behalf.

Continuing Education

The training received during their residencies implicitly qualifies OMSs to manage their patients' pain and in particular acute pain following invasive procedures. Nevertheless, AAOMS encourages our members to be aware of public health trends that may impact patient care and supports voluntary provider participation in continuing education (CE) programs that focus on drug abuse and responsible prescribing practice. AAOMS is working with the National Institute on Drug Abuse (NIDA) to develop an education course to help prescribers, including oral and maxillofacial surgeons, talk to adolescents about substance use and abuse. We also helped develop and encouraged our members to participate in the Substance Abuse and Mental Health Services Administration's (SAMHSA) online training on "Safe Opioid Prescribing for Acute Dental Pain." Prescribing, while important, is but a small part of the overall care that is provided to each patient. A significant increase in CE requirements in this one topic would be overly burdensome and could possibly prevent a practitioner from obtaining needed CE in other critical areas of patient care. AAOMS believes that to be most effective, CE should be managed at the state level and be customized so that it is relevant to each type of prescribing situation. AAOMS further believes that provider specialty organizations, such as the AAOMS, should be included as accepted practitioner training organizations for CE requirements. Finally, there remains a need beyond prescriber CE to educate patients and the public at large about opioid abuse and diversion. AAOMS supports such collaborative education efforts that include governmental agencies, non-profit organizations and prescriber organizations.

Prescribing Guidelines

The AAOMS appreciates the development of prescribing guidelines, which may be helpful to some practitioners

as they determine the proper course of post-operative treatment for their patients. AAOMS recognizes and encourages our members who provide chronic pain management to consider the *CDC Guideline for Prescribing Opioids for Chronic Pain.*[3] AAOMS also supports efforts currently underway by several OMS residency training programs to develop and utilize acute prescribing guidelines. If government entities seek to develop prescribing guidelines, we encourage them to recognize the unique care provided by OMSs by involving them in the development process, and to avoid a one-size-fits-all approach as patient pain management needs vary from patient to patient. AAOMS encourages provider and/or patient discretion by allowing them to partially fill a prescription with the option to acquire the remaining amount only when necessary. Implementation of such a practice will not only reduce the risk of a patient's overdose or addiction, but also significantly lessen the risk of diversion of unused medications. AAOMS also supports additional pain management strategies, such as the use of long-acting local anesthetics during surgery of the dentoalveolar complex and nonsteroidal anti-inflammatory drugs (NSAIDS) either preoperatively and/or postoperatively for acute pain control in conjunction with the judicious use of opioids or as a substitute.

Supporting Practitioner Judgement

Only the treating practitioner, not subjective policy, can determine a patient's medical needs. It is the position of the AAOMS that the patient-practitioner relationship must be upheld, allowing the practitioner to have the final say regarding the management of a patient's pain including drug types, dosage and treatment duration. Practitioners should be informed of the latest public health trends, including possible alternatives to opioid pain treatment; but in the end, practitioners should be trusted to treat their patients according to their best professional judgement. As with any issue, should a practitioner be shown to be practicing contrary to the standard of care, the practitioner should be referred first for peer review, followed by prescription writing counseling/continuing education and then, if necessary, punitive remediation.

References:

1 *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration. September 2015.*

2 *JADA. July 2011; 142(7): 800–810.*

3 *CDC Guideline for Prescription Opioids for Chronic Pain. Recommendations and Reports. 65(1); 1-49. March 2016.*

June 2016, AAOMS Committee on Government Affairs

New hospital guidelines advise caution with ER opioid prescriptions

By Elizabeth Simpson
The Virginian-Pilot
Apr 12, 2016

RICHMOND

A state hospital association released guidelines Tuesday to tackle opioid abuse, taking particular aim at prescriptions given in emergency rooms.

The Virginia Hospital & Healthcare Association has been working since January crafting the guidelines, which advise scrutiny of prescriptions for people in chronic pain.

That includes better communication between health providers in emergency rooms and the patients' primary care doctors, and using a state database of prescriptions that can flag people who are doctor-shopping for drugs.

During the past nine years, there have been more than 4,000 deaths related to prescription opioid overdoses in Virginia, according to the association. More than 1,300 babies were born between 2011 and 2014 with a condition called "neonatal abstinence syndrome" due to their mothers' drug use.

Nationally, 61 percent of drug overdose deaths involved some type of opioids.

Anna Kostric, a clinical pharmacy specialist with Sentara Medical Group, worked on the committee. She said the group wanted to create clear lines in prescription writing but also emphasize the importance of providers' clinical judgment in a particular situation.

"We're hoping this will help establish consistency by giving guidance that is straightforward and also give them backing when they're faced with different situations," Kostric said.

The committee included representatives from the state's hospitals and the Virginia College of Emergency Physicians. The panel made 14 recommendations, including:

- Prescriptions for opioids from the emergency department should be written for the shortest possible duration. In situations that involve chronic pain or diagnostic uncertainty, this generally should be for no more than three days.
- Hospitals should screen for substance abuse and have some interventions in place, including referrals to treatment programs.
- Emergency room providers should not provide prescriptions for drugs that were lost, destroyed, stolen or finished too early, and should also require a photo identification.
- Providers should check the statewide database, the Prescription Monitoring Program, to see whether a patient has a history of shopping around for doctors to fill prescriptions.

- Emergency department health providers should avoid prescribing long-acting or controlled-release opioids such as oxycodone, fentanyl patches or methadone unless there's a clinically based reason to do so.
- Emergency personnel should communicate with and coordinate care of a patient with a chronic pain condition with the patient's primary care doctor.

COLORADO
Department of
Regulatory Agencies

Policy for Prescribing and Dispensing Opioids

Colorado Dental Board, Colorado Medical Board, State Board of Nursing, and State Board of Pharmacy

In collaboration with the Nurse-Physician Advisory Task Force for Colorado Healthcare

PREAMBLE

Prescribing and dispensing medication for the appropriate treatment of pain is a priority for Colorado healthcare providers. However, in 2013 the misuse and abuse of prescription opioids became a public health epidemic in the United States in general, and Colorado in particular, leading to drug addiction, death from overdose, and increased costs to society.

In order to address this crisis, the Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Pharmacy, and the Nurse-Physician Advisory Task Force for Colorado Healthcare collaborated to identify opportunities and provide meaningful guidance to prescribers and dispensers in Colorado.

The Boards recognize that reversing the trend of opioid misuse and abuse requires coordinated efforts to increase public awareness, take-back events for safe disposal, addiction treatment and recovery options, and enforcement, among others. The Boards and the practitioners they license are one part of a multi-pronged solution.

The Boards recognize the complexities faced by prescribers in the appropriate management of pain.[1] The demands on practitioners considering opioid prescribing differ depending on patient diagnosis, practice settings, and/or conditions. Importantly, long-term therapies addressing cancer-related treatment, palliative and/or hospice care involve different considerations from short-term therapies appropriate for acute or chronic non-cancer pain.

Pain and addiction specialists play an important role in healthcare and the communities they serve to compassionately and safely care for patients. Many of the tools and practices referenced in this policy were developed by such specialists. The need for therapeutic care of pain in Colorado patients exceeds the supply of specialists in the state. However, other types of providers can successfully treat many painful conditions and achieve the function and relief the patient seeks. Accordingly, this policy is intended to educate prescribers and dispensers broadly by providing useful tools that may be utilized at the point-of-care to support clinical decision making.

The Boards further recognize that decreasing opioid misuse and abuse in Colorado should be addressed by collaborative and constructive policies aimed at improving prescriber education and practice, decreasing diversion, and establishing the same guidelines for all opioid prescribers and dispensers. This includes opioid therapies for both acute and chronic non-cancer pain,[2] because the Boards find that treatment for pain often does not fall clearly into one category or another.

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[1] "Boards" as used in this policy means the Boards overseeing prescribing and dispensing of opioids and involved in the drafting of this policy: the Colorado Medical Board, State Board of Nursing, Colorado Dental Board, and the State Board of Pharmacy.

[2] Pain is categorized by a number of descriptors ranging from duration, impact, or physiological response, among others. For the purpose of this policy, the term "chronic, non-cancer pain" is utilized to refer to pain that lasts longer than 90 days and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, or rheumatoid arthritis.

Diversion and "doctor shopping" accounts for 40% of drug overdose deaths.[3] To address the dual issues of access to appropriate pain management and opioid-related adverse outcomes, prescribers have dual obligations: to manage pain and improve function while reducing problems resulting from misuse and abuse of prescription opioids in the patient and community. Pharmacists share a corresponding responsibility with the prescriber to assure that a prescription order is valid in all respects and is appropriate for the patient and condition being treated.

Therefore, the Boards have agreed to the following guidelines regarding opioid prescriptions in Colorado. Providers prescribing and/or dispensing opioids should:

- Follow the same guidelines
- Use the Colorado Prescription Drug Monitoring Program (PDMP)
- Be informed about evidence-based practices for opioid use in healthcare and risk mitigation
- Educate patients on appropriate use, storage and disposal of opioids, risks and the potential for diversion
- Collaborate within the integrated healthcare team to decrease over-prescribing, misuse and abuse of opioids.

Opioid prescribers and dispensers must conform to the regulations set forth by the respective licensing board and other laws.

To this end, we, the Boards regulating the prescribers and dispensers in Colorado, have developed this joint policy incorporating the guidelines above.

This policy provides guidelines, and does not set a standard of care for prescribers and dispensers. This policy represents the Boards' current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Boards or the public. Prescribers may use an alternative approach if the approach satisfies the requirements of the applicable statutes, regulations, and standard of care. The Boards will refer to current clinical practice guidelines and expert review in approaching cases involving the management of pain. [4]

[3] Paulozzi, L., Baldwin, G., Franklin, G., Ghiya, N., & Popovic, T. (2012). CDC Grand Rounds: Prescription drug overdoses — a U.S. epidemic. *Center for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), 61*(01), 10-13. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm

[4] A "policy" is adopted by a board to provide guidance to licensees regarding the board's position on various subjects. Policies are unlike statutes or rules in that they are not law. Conversely, "board rules" have the force of law and set forth requirements to which licensees must adhere.

Table of Contents

BEFORE PRESCRIBING OR DISPENSING

Develop and maintain competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. In some clinical situations consultation with a specialist is appropriate. Pharmacists must maintain competence in the appropriateness of therapy. See the Appendix for a list of resources and tools for developing and maintaining competence.

Utilize safeguards for the initiation of pain management

The decision to prescribe or dispense opioid medication for outpatient use may be made only after a proper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end-of-life care.

Not all pain requires opioid treatment. Prescribers should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids for outpatient use and again before increasing dosage or duration. Risk assessment is defined as identification of factors that may lead to adverse outcomes and may include:

- Patient and family history of substance use (drugs including alcohol and marijuana)
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants or to determine other drug-drug interactions)
- Mental health/psychological conditions and history
- Abuse history including physical, emotional or sexual
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep apnea, elderly, or history of renal or hepatic dysfunction)
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately when aberrant drug-related behavior is presented. See the Appendix for a description of such behaviors.

See the Appendix for additional resources related to assessment, including resources for alcohol and substance use screening and guidelines for treating patients with risk factors.

If the assessment identifies risk factors, prescribers should exercise greater caution before prescribing opioids as detailed in subsequent sections, consider conducting a drug test or consulting a specialist and put in place additional safeguards as part of the treatment plan.

3. Assess Pain

An appropriate pain assessment should include an evaluation of the patient's pain for the:

- Nature and intensity
- Type
- Pattern/frequency
- Duration
- Past and current treatments
- Underlying or co-morbid disorders or conditions
- Impact on physical and psychological functioning

4. Review PDMP

Prescribers and dispensers should utilize the Prescription Drug Monitoring Program (PDMP) prior to prescribing or dispensing opioids.

Collaborate with the healthcare team

Prescribers and dispensers should collaborate within the healthcare team to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

When Prescribing or Dispensing

Verify a provider-patient relationship

A bona fide provider-patient relationship must exist. The prescriber or dispenser should verify the patient's identification prior to prescribing or dispensing opioids to a new or unknown patient.

For pharmacists, this includes exercising judgment and conducting research if appropriate (such as use of the PDMP or communication with the prescriber or relevant pharmacies) when the prescription order is:

- For a new or unknown patient

- For a weekend or late day prescription
- Issued far from the location of the pharmacy or patient's residential address
- Denied by another pharmacist.

Additional Safeguards

Ensure the dose, quantity, and refills for prescription opioids are appropriate to improve the function and condition of the patient, at the lowest effective dose and quantity, in order to avoid over-prescribing opioids.

Factors that have been associated with adverse outcomes include: 1) opioid doses greater than 120 mg morphine equivalents per day 2) certain formulations and 3) treatment exceeding 90 days. Additional safeguards have been found to reduce these risks.

Dosage

Opioid doses >120 mg morphine equivalents per day is a dosage that the Boards agree is more likely dangerous for the average adult (chances for unintended death are higher) over which prescribers should use clinical judgment, put in place additional safeguards for the treatment plan (such as utilizing a treatment agreement), consult a specialist or refer the patient; and dispensers should be more cautious.[5] Benzodiazepines are known to potentiate the effects of opioids and may increase the risk of adverse outcomes. See the Appendix for additional resources on dose calculators

Formulation

In addition to noting and responding to this dosage marker, prescribers and dispensers must use clinical judgment regardless of dose, especially when:

- The prescription is considered an outlier to what is normally prescribed, or
- Transdermal, extended relief or long-acting preparation is prescribed.

Duration

Treatment **exceeding 90 days** should be re-evaluated as opioids may no longer be as effective.

One way to distinguish pain is as either acute (that lasting less than 90 days) or chronic (that lasting 90 days or greater). Management of each presents its own unique challenges. The overwhelming majority of prescribers treat patients with acute pain; in fact the pain for these patients lasts considerably less than 90 days.

[5] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med 2010;152(2):85-92.

If a prescriber extends short-term treatment, and results in exceeding 90 days, prescribers should re-conduct the risk and pain assessments, review the PDMP and undertake the additional safeguards.

PRESCRIBING AND DISPENSING FOR ADVANCED DOSAGE, FORMULATION OR DURATION

Tools and Trials

Prior to issuing prescriptions that are outliers to the dosage, formulation and duration guidelines described above (for chronic, non-cancer pain), prescribers should determine whether the patient improves functionally on opioids, which could include an opioid trial, and whether the pain relief improves his/her ability to comply with the overall pain management program.

Monitoring

The prescribing and dispensing of opioids for chronic pain must be monitored on an ongoing basis, such as:

- assessing for improved function
- rechecking the PDMP, and
- random drug screening according to the prescriber's clinical assessment.

These monitoring tools and others should be documented in a treatment agreement signed by the patient, described more below. Prescribers should not increase an initial opioid dosage without rechecking the PDMP.

Treatment Agreements

Prescribers should utilize treatment agreements (also commonly referred to as a plan or contract) and should ensure the patient understands the terms of the agreement. This may be accomplished by having the patient review and sign the treatment agreement.

A treatment agreement often includes information about proper:

- Goals of treatment
- Patient education (proper use, risks of addiction, alternatives)
- Controls (single prescriber, single pharmacy for refills)
- Random drug testing and restrictions on alcohol use
- Storage, disposal, and diversion precautions (including detailed precautions related to adolescents and/or children and visitors to the home).
- Process and reasons for changing/discontinuing the treatment plan; communicating reduction or increase of symptoms; and referring to a specialist.

See the Appendix for resources on sample agreements.

Patient Education

Prescribers should educate patients regardless of the dosage, formulation and duration of opioid therapy on proper use, risks of addiction, alternatives, storage, and disposal of opioids and the potential for diversion (see the Appendix for resources on disposal). Risks may include but are not limited to: overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death.

Pharmacists should offer to review information with the patient about risks, disposal, and other applicable topics.

Providers should educate patients about the risks and benefits of medications that exceed the dosage, formulation and duration guidelines indicated above which may place them at increased risk for long-term dependence and unintended adverse drug effects. Patients who have a previous history of substance use disorder (including alcohol) are at elevated risk.

When alerted to these risk factors, patients can make more informed decisions about their healthcare treatment. For example, some patients have reduced or forgone opioids when alerted to the risk factors. If a decision is made to continue with opioid therapy, a satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function and/or improved quality of life. The use of an interdisciplinary team and family members may be considered as a part of the treatment plan and ongoing monitoring.

Discontinuing Opioid Therapy

The prescriber should consider discontinuing opioid therapy when:

- The underlying painful condition is resolved;
- Intolerable side effects emerge;
- The analgesic effect is inadequate;
- The patient's quality of life fails to improve;
- Functioning deteriorates; or
- There is aberrant medication use.

The prescriber discontinuing opioid therapy should employ a safe, structured tapering regimen through the prescriber or an addiction or pain specialist. There is a risk of patients turning to street drugs or alcohol abuse if tapering is not done with appropriate supports. Prescribers of opioids should be familiar with treatment options for opioid addiction. See the Appendix for tips on tapering.

APPENDIX

PDMP

Colorado Prescription Drug Monitoring Program (PDMP):
http://www.hidinc.com/copdmp

Preventing diversion through appropriate disposal

In order to prevent diversion, providers should provide information regarding appropriate disposal, including the following:

- Secure unused prescription opioids until such time they can be safely disposed. Specifically, ensure that prescription opioids are not readily accessible to other family members (including adolescents and/or children) or visitors to the home.
- **Take-back events are preferable to flushing prescriptions down the toilet or throwing them in the trash.** Only some medications may be flushed down the toilet. See the FDA's guidelines for a list of medications that may be flushed: www.fda.gov
- **Utilize take-back events and permanent drop box locations**
- Utilize DEA disposal guidelines if take-back or drop boxes are unavailable. Those guidelines include:
    - **Take the drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter; then put them in a sealable bag, empty can, or other container to prevent the medication from leaking out of a garbage bag;**
    - Before throwing out a medicine container, tell the patient to scratch out all identifying information on the prescription label to protect their identity and personal health information; and
    - Educate patients that prescriptions are patient specific. Patients may not share prescription opioids with friends, family or others and may pose serious health risks, including death.
- Use activated charcoal absorption technologies to inactivate unused medications or used fentanyl patches.

Record keeping

Prescribers who treat patients with opioids should maintain accurate and complete medical records according to the requirements set forth by their licensing board.

Discontinuing/tapering opioid therapy

Weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account several factors related to risk, symptom, and alternatives.

Opioid Taper Plan and Calculator:
"Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of

Washington Agency Medical Directors Group. 2010 Online: www.agencymeddirectors.wa.gov

Withdrawal Symptoms Assessment:
"Clinical Opiate Withdrawal Scale" The National Alliance for Advocates for Buprenorphine Treatment. Online at: www.naabt.org

Aberrant drug-related behavior

Prescribers and dispensers should use clinical judgment when aberrant drug-related behaviors are observed. Such behavior should be reported to the proper authorities and/or healthcare team as appropriate.

Aberrant drug-related behaviors broadly range from mildly problematic (such as hoarding medications to have an extra dose during times of more severe pain) to felonious acts (such as selling medication). These are any medication-related behaviors that depart from strict adherence to a prescribed therapeutic plan of care.

Prescribers and dispensers should observe, monitor and take precautionary measures when a patient presents aberrant drug-related behaviors such as:

- Requesting early and/or repeated refills
- Presents at or from an emergency department seeking high quantities of a prescription
- Denied by other prescribers or dispensers
- Presents what is suspected to be a forged, altered or counterfeit prescription.
- Forging prescriptions
- Stealing or borrowing drugs
- Frequently losing prescriptions
- Aggressive demand for opioids
- Injecting oral/topical opioids
- Unsanctioned use of opioids
- Unsanctioned dose escalation
- Concurrent use of illicit drugs
- Failing a drug screen
- Getting opioids from multiple prescribers
- Recurring emergency department visits for chronic pain management*

Prescribers and dispensers should be alert for subjective behaviors such as being nervous, overly talkative, agitated, emotionally volatile, and evasive, as these may be signs of a psychological condition that may be considered in a treatment plan or could suggest drug misuse.**

**"Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of Washington Agency Medical Directors Group. 2010 Online: http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf*

***Webster LR, Dove B. Avoiding Opioid Abuse While Managing Pain. Sunrise River Press, North Branch, MN 2007.*

Practitioner Considerations

Healthcare team:
Consider that the patient may be receiving opioids from another prescriber. Contact the patient's healthcare team when appropriate which may include the following:

- Physician
- Specialist (pain, addiction, etc.)
- Dentist
- Advanced Practice Nurse (APN)
- Physician assistant
- Pharmacists
- Area emergency rooms
- Surrounding (within 5 miles) or historical pharmacies

Authorities:

- If the prescriber or dispenser suspects illegal activity, the matter should be referred to the Drug Enforcement Agency (DEA) and local law enforcement.
- If a prescriber or dispenser suspect illegal activity on behalf of another prescriber or dispenser, at a minimum, the matter should be reported to the appropriate licensing board.

Prescribers and dispensers should be aware that:

- There is no legal obligation to prescribe or dispense a prescription; and,
- Colorado law strongly encourages prescribers and dispensers of opiate antagonists "to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including but not limited to instructions concerning risk factors for overdose, recognition of overdose, calling emergency medical services, rescue breathing and administration of an opiate antagonist." (Section 18-1-712(3)(b), C.R.S.)

Additional Resources and Tools

Establishing and maintaining competence:
Tenney, Lili and Lee Newman. "The Opioid Crisis: Guidelines and Tools for Improving Pain Management" Center for Worker Health and Environment, Colorado School of Public Health.

Functional and pain assessment:
"Functional Assessment" Colorado Division of Workers Compensation

Patient agreements:
"Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP - R)" PainEDU.org Online at: www.painedu.org

Pain tool kit:
Various resources for assessing and managing pain including risk assessments, patient

agreements, dose and conversion calculators among others.

Center for Worker Health and Environment, Colorado School of Public Health. Online at:
http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Pages/Pain-Management-CME.aspx

Substance use screening and brief counseling:
SBIRT Colorado
www.ImprovingHealthColorado.org

Drug abuse resources:
Substance Abuse and Mental Health Services Administration: www.samhsa.gov

NIH National Institute on Drug Abuse: www.drugabuse.gov or www.nida.nih.gov

abc NEWS WRIC.COM NEWS WHERE YOU LIVE

Heroin now kills more Americans than gun crime

By Associated Press (http://wric.com/author/associated-press/)
Published: December 9, 2016, 8:33 pm

FILE - This Tuesday, May 19, 2015 file photo shows a firearm and 154 pounds of heroin worth at least $50 million displayed during a Drug Enforcement Administration news conference in New York. According to government data released Thursday, Dec. 8, 2016, drug overdose deaths in the U.S. surpassed 50,000 in 2015, the highest mark in at least 15 years. (AP Photo/Mark Lennihan)

NEW YORK (AP) – More than 50,000 Americans died from drug overdoses last year, the most ever.

The disastrous tally has been pushed to new heights by soaring abuse of heroin and prescription painkillers, a class of drugs known as opioids.

Heroin deaths rose 23 percent in one year, to 12,989, slightly higher than the number of gun homicides, according to government data released Thursday.

Deaths from synthetic opioids, including illicit fentanyl, rose 73 percent to 9,580. And prescription painkillers took the highest toll, but posted the smallest increase. Abuse of drugs like Oxycontin and Vicodin killed 17,536, an increase of 4 percent.

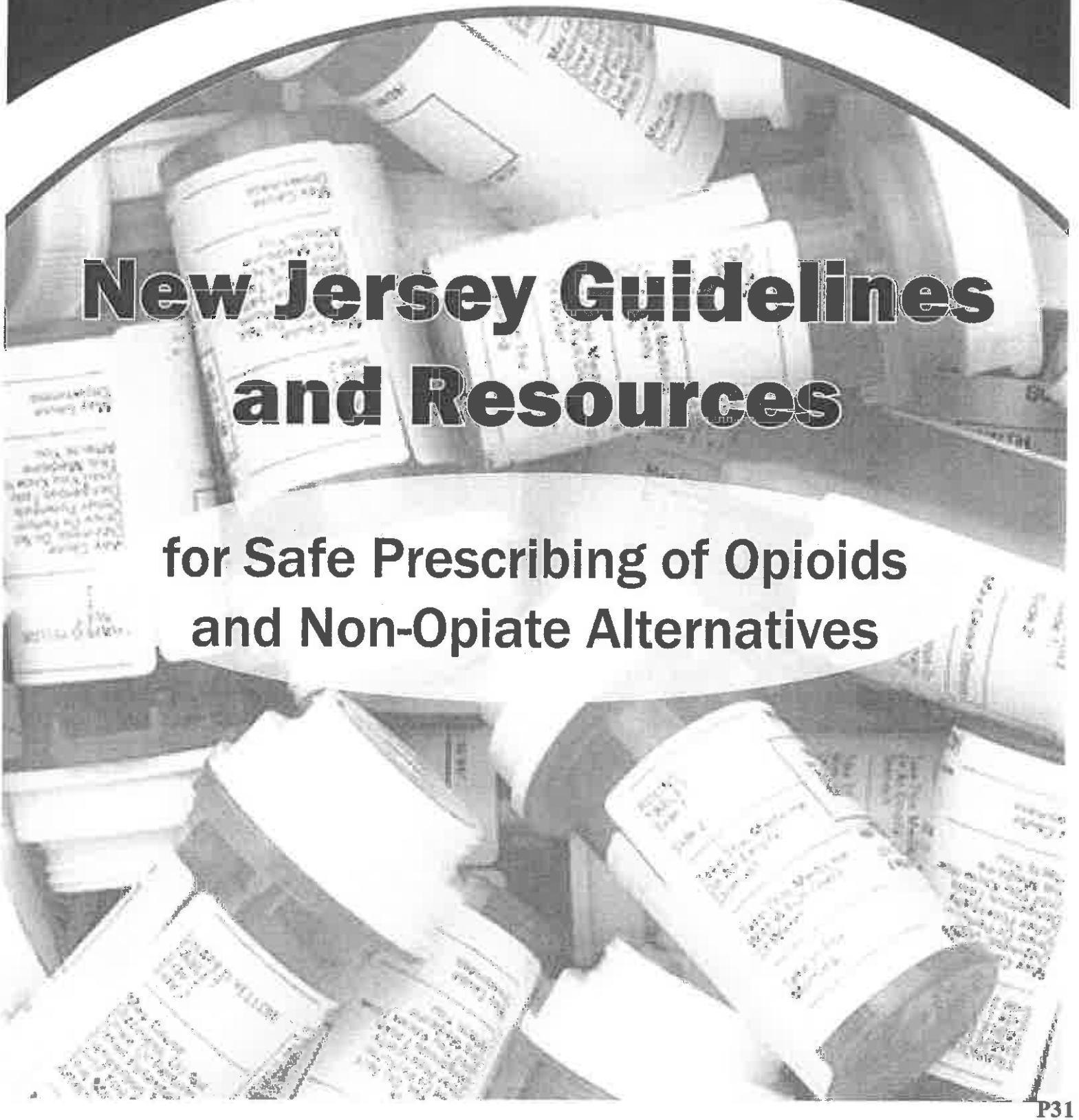
"I don't think we've ever seen anything like this. Certainly not in modern times," said Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention.

The new numbers were part of the agency's annual tally of deaths and death rates in 2015.

Overall, overdose deaths rose 11 percent last year, to 52,404. By comparison, the number of people who died in car crashes was 37,757, an increase of 12 percent. Gun deaths, including homicides and suicides, totaled 36,252, up 7 percent.

As part of its annual report the CDC also found that rates for 8 of the 10 leading causes of death rose last year, causing the nation's life expectancy to go down for the first time in more than 20 years. Drug overdoses were a significant factor, but an unexpected increase in the death rate from heart disease, the nation's No. 1 killer, was another major reason.

New Jersey Dental Association



New Jersey Guidelines and Resources

for Safe Prescribing of Opioids and Non-Opiate Alternatives

Contents

NJDA New Jersey Dental Association

A Message to our Members about New Jersey's Opioid Crisis

As the opioid public health crisis in New Jersey continues, we have the opportunity to serve a key role in educating our communities and our patients about the devastation of opioids, both by reducing the number of prescriptions written and by offering non-opiate alternatives for acute dental pain.

As ethical providers of healthcare, we have an obligation to educate ourselves about safe prescribing, about how to have a frank discussion with patients and, in the case of minors, their parents or caregivers, as well as how to identify possible abuse and recommend help.

While these guidelines address alleviation of acute dental pain, they are not intended to supersede an individual practitioner's assessment of their patient's condition or level of pain. The treating of chronic pain is briefly discussed on page 8.

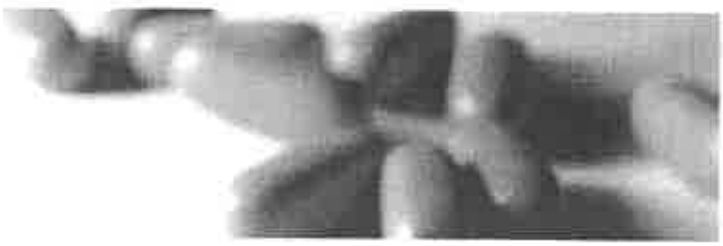
Please use this resource and share the information with your staff and patients.

Sincerely,

Elisa Velazquez, DMD
Chair, NJDA Council on Governmental and Public Affairs

NJDA Opioid Guideline Subcommittee
Mark A. Vitale, DMD
Gregory LaMorte, DDS
Mitchell Weiner, DMD
Kevin Corry, DDS

New Jersey Dental Association



Overview

There is a documented epidemic of opioid and heroin abuse in New Jersey. The NJDA has joined with the ***Partnership for a Drug Free NJ*** to advocate for the responsible use and disposal of prescription opiates. The NJDA is committed to informing our members of the latest research. We want to keep you abreast of the latest findings on the efficacy of analgesics and responsible dosing. We share a special rapport with our patients. We are in an excellent position to educate them about the addictive potential of prescribed opiates.

According to the ***Centers for Disease Control & Prevention*** (CDC), *"More people died from drug overdoses in 2014 than in any year on record. The majority of drug overdose deaths (more than six out of ten) involve an opioid. And since 1999, the number of overdose deaths involving opioids (including prescription opioid pain relievers and heroin) nearly quadrupled. From 2000 to 2014 nearly half a million people died from drug overdoses. 78 Americans die every day from an opioid overdose."*

In New Jersey, the numbers are as sobering. While many dentists may believe their patients are not likely to be abusers, the fact is that drug abuse and overdose are on the rise across all demographic groups, regardless of income, ethnicity and age. Abuse among 18 to 25 year olds in the US has jumped dramatically – by 109% -- in the past ten years. Among new heroin users, approximately three out of four report abusing prescription opioids prior to using heroin.[1]

In the following section, efficacy of opioids and non-opiate alternatives in the treatment of acute pain will be discussed. We respect our members' judgment when prescribing and making health decisions with their patients and offer this information only as guidance. It is with this in mind that NJDA urges its membership to review the data.

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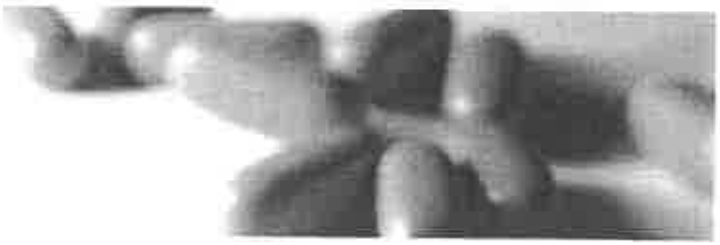

Efficacy of Opioids and Non-Opiates in Acute Pain

Dentists have the choice of three different classes of medications when treating pain. We decide based on the perceived effectiveness of each medicine, its side effects, and the physical status of the patient. Acetaminophen can exacerbate pre-existing liver disease. NSAIDs are contraindicated with a history of kidney disease or stomach ulcers. Opioids pose a potential risk to anyone with a personal or family history of addiction.

Many have long believed that opioids are the strongest pain medications and should be used for more severe pain. Scientific literature does not support that belief. Studies have shown NSAIDs are just as efficacious as opioids.

Postoperative pain is most often studied. It is acute pain due to tissue trauma. It also occurs in a controlled environment (hospital or medical office) where rigorous study protocols can be followed.

The Number Needed to Treat (NNT) offers a measurement of the impact of a medicine or therapy by estimating the number of patients that need to be treated in order to have an impact on one person. The concept is statistical, but intuitive, for we know that not everyone is helped by a medicine or intervention — some benefit, some are harmed, and some are unaffected. The NNT tells us how many of each. The data below tell us about the NNT as it relates to the number of patients that are helped. A lower number means a more effective treatment.

- Oxycodone 15 mg: NNT is 4.6. Since it is hard to conceptualize 4.6 people, consider that you would have to treat 46 people for 10 to get 50 percent relief of their pain. Thirty-six of those 46 people would not get adequate pain relief. (Gaskell, Derry, Moore, & McQuay, 2009)

- Oxycodone 10 mg + acetaminophen 650 mg: NNT for this combination treatment (Equivalent to two 5 mg Percocet pills) is 2.7. Clearly this is better than oxycodone alone. Acetaminophen adds a significant benefit. (Gaskell et al., 2009)

- Naproxen 500 mg (or naproxen sodium 550 mg): NNT for this is also 2.7. Naproxen is an NSAID. Naproxen sodium is known to many by the brand name Aleve®. (C Derry & Derry, 2009)

- Ibuprofen 200 mg + acetaminophen 500 mg: The combination of these two OTC medicines provided the best pain relief of all, with an NNT of 1.6. (CJ Derry, Derry, & Moore, 2013)

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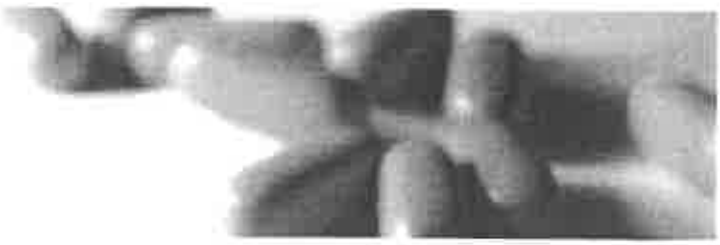

A review article in the 2013 Journal of the American Dental Association addressed the treatment of dental pain following wisdom tooth extraction. It concluded that 325 mg of acetaminophen (APAP) taken with 200 mg of ibuprofen provides better pain relief than oral opioids. Moore et al. concluded: "The results of the quantitative systematic reviews indicated that the ibuprofen-APAP combination may be a more effective analgesic, with fewer untoward effects, than are many of the currently available opioid-containing formulations.[2]"

In summary, regarding acute pain, many state that NSAIDs and acetaminophen should be used for mild to moderate pain, and opioids should be used for severe pain. There is, however, no scientific evidence to support this recommendation. In fact, the evidence indicates that NSAIDs are more effective for severe pain. The combination of acetaminophen and an NSAID may be the strongest option available for oral treatment of acute pain.

In some situations, limited use of opioids is appropriate. But for many situations in which opioid painkillers are used today, current literature tells us that there are more appropriate alternatives. When there is a treatment that is proven to be both more effective and safer, it is the treatment of choice.

Note: This scientific content has been edited down from a National Safety Council position paper: ***http://www.nsc.org/RxDrugOverdoseDocuments/Evidence-Efficacy-Pain-Medications.pdf***.[3]

New Jersey Dental Association

Dispensing Opioids in the Dental Practice

Prior to prescribing, the dentist should observe the following protocols:

- Conduct a thorough medical and dental history, including documentation of current medications taken.
- Consideration should be given to local anesthetics to assist in pain management.
- Use of NSAIDs as a first-line therapy, unless contraindicated.
  - ◊ Additionally, NSAIDs should be given immediately prior to treatment, with continued dosing as needed following the procedure.
  - ◊ Exercise caution when using NSAIDs in patients taking anti-coagulants as the combination poses a significant increased risk in bleeding.
  - ◊ Adverse reactions to NSAIDs in patients with a history of renal (kidney) disease.
  - ◊ Refer to the previous section of this guide for scheduled dosing of acetaminophen with NSAIDs.

If opioids are to be prescribed:

- Pain therapy should be coordinated with the patient's other medical providers when possible, especially in cases where there is a history of substance abuse.
- The ***NJ Prescription Monitoring Program*** database must be accessed prior to writing a new Schedule II prescription for a patient of record or a new patient. NOTE: NJPMP will migrate to AWARxE in November, 2016.
- The dose and duration should be for as short a time period as possible.
- Opioid combination medications including acetaminophen should not exceed 3,000 mg/day of acetaminophen for adults.
- In general, it is not appropriate to prescribe via phone request or to patients who are new to the practice without a thorough evaluation.
- Mandated by NJ law, ***safe disposal instructions***, must be given to patients, to ensure unused medications are not misused or improperly disposed of.
- The NJDA Opioid Guideline Subcommittee recommend that dentists include in the patient record the signed ***informed consent***, developed by the NJDA, outlining the possible deleterious effects of opiods.

NJDA New Jersey Dental Association

Patient Communication & Informed Consent

Having a open discussion with your patient and parent or guardian is vital to safe prescribing. **When the decision to prescribe an opiate-based medication is determined, dentists should:**

1) Discuss the possible side effects, including addiction and misuse, with the patient and parent or guardian. The NJDA has developed an ***informed consent*** that can be used or adapted for use by the clinician.

2) Explain to the patient the dosage and scheduling of the medication.

3) Further explain how you will dispense refills if needed. Refill by phone absent a follow-up examination is discouraged.

4) Refer to the NJ Prescription Monitoring Program before prescribing and if/when a refill is requested or needed. Explain the NJPMP to your patient.

5) Provide information on safe disposal of unused medications (see below).

6) If you suspect a patient is misusing prescription medications, the ***American College of Preventive Medicine*** offers tips on how to talk to your patients about misuse of prescriptions.

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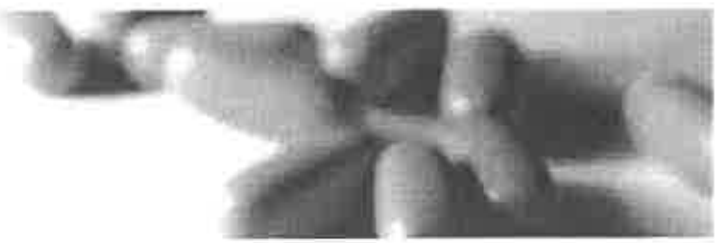


Safe Disposal of Unused Medications

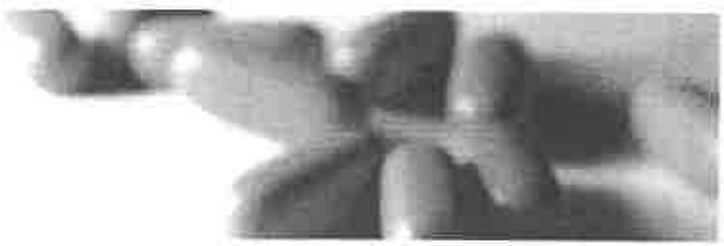
NJ law requires prescribers to provide a notice about ***drug take back programs*** upon dispensing to each patient a controlled dangerous substance (CDS) prescription medication. Specifically, the new law requires prescribers to furnish to each patient, with any CDS prescription drug or medicine dispensed for that patient a notice prepared by the Division of Consumer Affairs .

The NJ Division of Consumer Affairs has devised a notice in ***English*** and ***Spanish*** for you to give your patients.

Prescribing for Chronic Pain

Dentists who need to prescribe for chronic conditions are urged to become familiar with the ***CDC Guidelines for Prescribing Opioids for Chronic Pain.***

NJDA
New Jersey Dental Association



The NJ Prescription Monitoring Program (NJPMP/AWARxE)

The ***NJPMP*** is a statewide database that collects prescription data on Controlled Dangerous Substances (CDS) dispensed in outpatient settings. The purpose of NJPMP is to help stem the tide of the dangerous practice of "doctor shopping" and the equally dangerous prevalence of "pill mills." Beginning November 16, 2016, the NJPMP software will be upgraded to a new platform, AWARxE. NJPMP also offers a free app for Android and iPhones.

Doctor shopping is the practice of individuals visiting multiple medical and dental practitioners to obtain prescriptions for the same medication. The prescriptions, filled at different pharmacies, are either used by the individual or sold as street drugs.

Pill mills are clinical practices that dispense CDS drugs outside the legitimate scope of practice and in violation of NJ law.

As of November 1, 2015 all prescribers holding CDS registrations need to register to access the NJPMP. Additionally, any practitioner who dispenses or prescribes Schedule II medications must refer to the database for new prescriptions for a patient of record or a new patient.

The database is updated daily. NJPMP is able to generate reports on unusual prescribing patterns related to specific patients. These reports are intended to help practitioners and pharmacists discuss drug misuse and abuse with the patient and refer the individual for help.

Safeguarding Prescription Pads

All licensees are required to notify the ***Office of Drug Control*** in the New Jersey Division of Consumer Affairs within seventy-two (72) hours of being made aware that any New Jersey Prescription Blank has been stolen or forged. A New Jersey Prescription Blank Incident Report Form must also be completed and filed within seven (7) days after notification.

NJDA New Jersey Dental Association

References

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2. Moore PA, Hersh, EV; Combining Ibuprofen and Acetaminophen for Acute Pain Management after third-molar extractions JADA. ***http://jada.ada.org/article/S0002-8177%2814%2960509-2/pdf***. Published August 2013. Accessed October 2016.

3. Teater, D; Evidence for the efficacy of pain medications. ***http://www.nsc.org/RxDrugOverdoseDocuments/Evidence-Efficacy-Pain-Medications.pdf***. Published October 2014. Accessed October 2016.

Resources

Centers for Disease Control and Prevention:
https://www.cdc.gov
http://www.cdc.gov/drugoverdose/index.html
New Jersey Prescription Monitoring Program (NJPMP):
http://www.nj.gov/lps/ca2/pmp/
NJ Division of Consumer Affairs Drug Take Back Program:
http://www.njconsumeraffairs.gov/meddrop
NJ Office of Drug Control (Reporting stolen or forged prescription blanks):
http://www.njconsumeraffairs.gov/dcu/Pages/default.aspx
The American Medicine Chest Challenge (Disposing of unused medications):
http://www.americanmedicinechest.com/
American Dental Association:
https://www.ada.org/en/advocacy/advocacy-issues/prescription-drug-abuse
Partnership for a Drug Free NJ:
http://drugfreenj.org/
American College of Preventive Medicine. Doctor/Patient Conversations (#10):
http://www.acpm.org/?page=useabuserxclinref&terms=%22drug+and+abuse%22

New Jersey Dental Association

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food,

Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of

natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not,

otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-

certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning -- may be habit-forming, " or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist, " "pharmacy, " and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

Code 1950, §§ 54-399, 54-487; 1952, c. 451; 1958, c. 551, § 54-524.2; 1966, c. 193; 1968, c. 582; 1970, c. 650; 1971, Ex. Sess., c. 94; 1972, c. 798; 1975, c. 425; 1976, c. 14; 1977, c. 193; 1978, c. 833; 1979, c. 435; 1980, c. 150; 1988, c. 765; 1991, cc. 519, 524; 1992, cc. 737, 793; 1996, cc. 37, 152, 158, 407, 408; 1997, cc. 20, 677, 806; 1998, c. 470; 1999, cc. 661, 750; 2000, cc. 861, 878, 935; 2003, cc. 509, 639, 995; 2005, cc. 475, 839; 2006, c. 346; 2012, c. 213; 2013, cc. 412, 504, 544, 765; 2014, cc. 674, 719; 2015, cc. 158, 180, 300; 2016, cc. 221, 495.

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in

clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability.

D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

1983, c. 528, § 54-524.50:1; 1985, c. 336; 1988, c. 765; 1991, cc. 519, 524; 1992, c. 793; 1996, cc. 152, 158, 408; 1997, c. 806; 1998, c. 101; 1999, c. 745; 2000, cc. 882, 924; 2001, c. 465; 2003, c. 639; 2004, c. 744; 2006, c. 432; 2010, c. 74; 2015, cc. 32, 115; 2016, c. 86.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use in emergency situations; and epinephrine for use in emergency cases of anaphylactic shock.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the immediate and direct supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified

protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, as well as any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency or the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis

treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal and a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. Law-enforcement officers as defined in § 9.1-101 and firefighters who have completed a training program may also possess and administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Code 1950, § 54-497; 1956, c. 225; 1970, c. 650, § 54-524.65; 1973, c. 468; 1976, cc. 358, 614; 1977, c. 302; 1978, c. 224; 1980, cc. 270, 287; 1983, cc. 456, 528; 1984, cc. 141, 555; 1986, c.

81; 1987, c. 226; 1988, c. 765; 1990, c. 309; 1991, cc. 141, 519, 524, 532; 1992, cc. 610, 760, 793; 1993, cc. 15, 810, 957, 993; 1994, c. 53; 1995, cc. 88, 529; 1996, cc. 152, 158, 183, 406, 408, 490; 1997, cc. 272, 566, 806, 906; 1998, c. 112; 1999, c. 570; 2000, cc. 135, 498, 861, 881, 935; 2003, cc. 465, 497, 515, 794, 995, 1020; 2005, cc. 113, 610, 924; 2006, cc. 75, 432, 686, 858; 2007, cc. 17, 699, 702, 783; 2008, cc. 85, 694; 2009, cc. 48, 110, 506, 813, 840; 2010, cc. 179, 245, 252; 2011, c. 292; 2012, cc. 787, 803, 833, 835; 2013, cc. 114, 132, 183, 191, 252, 267, 328, 336, 359, 617; 2014, cc. 88, 491; 2015, cc. 302, 387, 502, 503, 514, 725, 732, 752; 2016, c. 144.