

# **The Regulatory Environment The Insurance Landscape**

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# **Regulatory Environment**

***What you need to know!***

- **DEA**
- **PMP**
- **HIPAA**
- **OSHA**
- **IC**
- **EPA—Amalgam Separators**
- **AwDA**
- **Office of Civil Rights 1557**
- **E-Prescribing Mandate**
- **X-Ray**

# **DEA Registration (Controlled Substances)**

**Any dentist who prescribes controlled substances in Schedules II, III, IV, or V must register with the U.S. Drug Enforcement Administration every three years.**

- Including narcotic analgesics, such as hydrocodone and oxycodone.**



# MN Controlled Substances—Limits

Subd. 4. Limit on quantity of opiates prescribed for acute dental and ophthalmic pain. (a) When used for the treatment of acute dental pain or acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 shall not exceed a four-day supply. The quantity prescribed shall be consistent with the dosage listed in the professional labeling for the drug that has been approved by the United States Food and Drug Administration.

(b) For the purposes of this subdivision, "acute pain" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. Acute pain does not include chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.

(c) Notwithstanding paragraph (a), if in the professional clinical judgment of a practitioner more than a four-day supply of a prescription listed in Schedules II through IV of section 152.02 is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat such acute pain.



# Prescription Monitoring Program

- The Minnesota Prescription Monitoring Program (PMP) contains prescription data on all Schedules II, III, IV and V controlled substances, butalbital and gabapentin dispensed in or into Minnesota.
  - Minnesota licensed prescribers and pharmacists, and their delegated staff may be authorized to access information from the PMP database.
- A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.
- Every prescriber licensed and practicing within this state who is authorized to prescribe controlled substances for humans and who holds a current registration issued by the federal Drug Enforcement Administration shall register and maintain a user account with the prescription monitoring program.



# HIPAA

- Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)
- Goal—to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being.
- The Privacy Rule protects all “individually identifiable health information” held or transmitted in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information “protected health information (PHI).”
- A covered entity is permitted to use and disclose protected health information, without an individual’s authorization for.....Treatment, Payment, and Health Care Operations.



# HIPAA

- Dental practices are required to perform a PHI Security Risk Assessment
- Resources on HIPAA
- Samples available
  - Notice of Privacy Practices
  - Business Associate Agreements
  - HIPAA Risk Assessment template
  - ...and more
- <https://www.mndental.org/members/management/regulations/hipaa/>
- MN—Need to have a disclosure form on the release of information.
- MN—Access to Health Records Notice of Rights displayed
- <https://www.health.state.mn.us/facilities/notices/index.html>



# Occupational Safety and Health Administration (OSHA)

- Dental professionals may be at risk for exposure to numerous workplace hazards. These hazards include, but are not limited to, the spectrum of bloodborne pathogens, pharmaceuticals and other chemical agents, human factors, ergonomic hazards, noise, vibration, and workplace violence.
- Federal and State OSHA rules and regulations—PROTECTING EMPLOYEES IN THE WORKPLACE
- MDA partnered with Minnesota OSHA—developed OSHA Training Workbook  
<https://www.mndental.org/members/management/regulations/osha-and-infection-control/>

Minnesota law requires employers to display five state-mandated posters in a location where employees can easily see them. The posters are available at no cost and need to be updated only when Minnesota law changes.

<https://www.dli.mn.gov/about-department/workplace-posters>

1. *Age Discrimination*, 2. *Minimum Wage*, 3. *Safety and health protection on the job*, 4. *Unemployment*, 5. *Workers Compensation*

**NOTE:** *Some U.S. government agencies may have mandatory poster requirements as well.*





# Infection Control Rules and Regulations

- Dental professionals are required to comply with the following rules and regulations in regards to infection control:
  - Minnesota Rule 3100.6300 “Dental health care personnel shall comply with the most current infection control recommendations, guidelines, precautions, procedures, practices, strategies, and techniques specified in the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control publications of the Morbidity and Mortality Weekly Report (MMWR).”
  - 1 Hour of CE required per CE Cycle

## CDC Resource...

### “The Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care”

<https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care2.pdf>

- Checklist available
- Minnesota Rule 6950 is a Health Licensing Board Administrative Rule and goes further in depth regarding some of the elements of infection control requirements in healthcare settings.

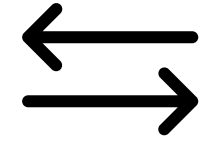


# Hazardous Waste

- In MN, ALL WASTE is considered HAZARDOUS until proven otherwise. Must evaluate or manage as hazardous waste.
- Hazardous waste regulations are administered by the Minnesota Pollution Control Agency (MPCA). MN Administrative Rules, Chapter 7045, Hazardous Waste.
- Metro counties adopt the MN Hazardous Waste Rules but also have their own hazardous waste ordinances which may be more stringent and vary slightly from other counties. Outside the metro area is regulated by the MPCA. Contact the hazardous waste program where your clinic is located.
- Hazardous Waste Manual – Sample:  
<https://www.mndental.org/files/updated-haz-waste-manual-July-2015.pdf>
- MPCA hazardous waste training:  
<https://www.pca.state.mn.us/waste/hazardous-waste-training>



# Amalgam Separators



- State and Federal (EPA)
- Metropolitan Council Environmental Services—Under Section 307, all dental practices connected to public sewers in the seven-county metropolitan area (Anoka, Carver, Dakota, Hennepin, Ramsey, Washington counties) must operate and maintain an amalgam separator from the MPCA approved list.
  - <https://metro council.org/Wastewater-Water/Publications-And-Resources/WasteDischargeRules-pdf.aspx>
- The EPA final rule on amalgam separators is effective as of July 14, 2017, and the date for compliance is July 14, 2020.
- EPA—The EPA requires amalgam separators to achieve at least a 95% removal efficiency.
- One-Time Compliance Report must be submitted to the Control Authority no later than October 12, 2020, or 90 days after a transfer of ownership.  
<https://www.ada.org/en/member-center/oral-health-topics/amalgam-separators>

# AwDA

- The Americans with Disabilities Act is a federal law that prohibits discrimination in access to services and employment against persons who are disabled.
- The Americans with Disabilities Act, Public Law 101-336, was enacted on July 26, 1990.
- Under the Act, your private dental office is considered a place of public accommodation. Therefore, as of January 26, 1992, this law requires that you serve persons with disabilities.
- Applicable to websites!! Accessibility standards set forth by the Web Content Accessibility Guidelines (WCAG) 2.0 AA

**Dental offices need to be aware of the requirements they must follow concerning patients with disabilities. The manner and method of treating those with disabilities, and the physical access to the practice, must be regularly reviewed for compliance with the Americans with Disability Act.**





# 1557 (of the ACA)

- Section 1557 prohibits health programs or facilities that receive federal funds from discriminating on the basis of race, color, national origin, age, disability, or sex.
- Require a covered dental practice to post two kinds of notices: (1) a notice of nondiscrimination, and (2) taglines in the top 15 non-English languages spoken in state indicating that language assistance services, free of charge, are available.
- Both notices must be posted in the dental office and on the dental practice's website, and in significant publications and communications, including communications with individuals.
- In smaller publications and communications, such as postcards and tri-fold brochures, a dental practice may use a shorter form of the nondiscrimination statement and taglines in the top two non-English languages spoken in the state.

# Minnesota's e-Prescribing Requirements

- In 2008, the Minnesota Legislature enacted an e-prescribing mandate. The mandate requires prescribers, pharmacists and pharmacies, and pharmacy benefit managers to be e-prescribing by January 1, 2011.



# Radiation Rules

- All facilities or individuals in possession of x-ray equipment must apply for registration. Registration with payment must be completed by facilities and submitted to MDH. Can be done online. Submission of yearly audits and registration are required.
  - *When buying or selling a practice...notify MDH.*
- A radiation safety officer must be designated and identified within your radiation safety/quality assurance program.

Useful resource!

**MDH maintains a “X-Ray Regulatory Guide for Dental X-Ray Facilities”**

<https://www.health.state.mn.us/communities/environment/radiation/xray/dental.html>

Radiation Safety Manual – Sample:

<https://www.mndental.org/files/radiation-safety-manual.pdf>



# **The Insurance Landscape**



# The Insurance Landscape

- **Dental Benefit Administrators**
  - **Subcontractors of Health Plans (BCBS, Ucare, Medica etc.)**
- **Medicaid—Dental Benefits**
  - **PMAP System**
  - **Reimbursements**
- **MNCare**
- **MNSure**
- **Medicare (Advantage)**

<https://success.ada.org/en/dental-benefits/dental-plan-overview>