

Avoiding Risk and Achieving Compliance

Health Care Laws and
Regulations You Need To Know

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The logo for Dinsmore, featuring the word "Dinsmore" in a serif font. The "Din" is in a dark brown color, and "smore" is in a blue color. The letter "o" in "more" has a small blue triangle above it, resembling an accent mark.

Dinsmôre

State Laws & Regulations

Health care regulation comes from both state and federal laws and regulations. Both provide sources of risk and exposure to individual providers and health care institutions.

For individual health care providers, the initial and primary source of regulation is from the rules and regulations of the state in which you practice.

Sources of State Regulations

Some examples for Ohio physicians are as follows:

State Medical Board of Ohio. What does it do:

- ▶ Establishes standards and parameters for physician and licensee practice and conduct through:
 - 1) rules of practices; and
 - 2) enforcement by investigation and discipline
- ▶ All Board activities and legal authority begin with a complaint.
- ▶ Complaints and complainants are confidential.

Complaint Process:

Initial review (close or continue?) 38%

Investigation (close or continue?) 54%

Discipline 8%

Investigative Techniques and Tools

- ▶ Interview – usually unannounced
- ▶ OARRS
- ▶ Subpoena medical records and documents
- ▶ Subpoena for deposition
- ▶ Submit to interrogatories
- ▶ Failure to cooperate is disciplinary offense RC § 4731.22(B)(34)
- ▶ Confidential process RC § 4731.22(F)(5)
- ▶ No access to peer review RC § 4731.22(F)(4) and R.C. § 2305.252

Top Reasons for Disciplinary Action:

2014

Impairment – 31%

Prescribing – 21%

Criminal Acts – 18%

Other Board Actions – 6%

2013

Impairment – 40%

Prescribing – 26%

Other Board Actions – 11%

Criminal Acts – 8%

- ▶ Ohio's Board is consistently ranked #1 or near the top of all US medical boards for disciplinary actions according to Public Citizen

Practice Areas that lead to Board scrutiny:

- ▶ Prescribing (to patients, co-workers, friends, and family)
- ▶ Medical Record Documentation
- ▶ Personal Relationships – Professional Boundaries
- ▶ Professional Behavior
- ▶ Impairment

Use OARRS as a practice aid – it will soon be the law

- ▶ Practice Insight Reports are helpful for compliance.
- ▶ Know that effective April 1 new Ohio law makes obtaining OARRS report mandatory before prescribing or dispensing either an opioid analgesic or a benzodiazepine.
- ▶ Know the “red flag” rules for OARRS - OAC Section 4731-11-11 – which make an OARRS check mandatory in signs of abuse or diversion.

Avoid Risk by Knowing the Board's Rules

- ▶ Office Based Surgery Rules
- ▶ Controlled Substance Rules
- ▶ Intractable Pain
- ▶ Pain Management Clinics
- ▶ Delegation of Medical Tasks
- ▶ Laser Rules
- ▶ Termination of Patient
- ▶ Sexual Misconduct and Impropriety

Recent Board Initiated Actions

| Cites | Nov | Dec | Jan |
|-------------------------|-----|-----|-----|
| Other Board Actions/Dea | | 4 | 4 |
| Impairment | 4 | 3 | 2 |
| Rx | | | |
| Rules - Laser/ Sx | | | 2 |
| Minimal Std | | | |
| Convictions | 1 | 1 | 4 |
| Sexual Boundary | | 1 | 1 |
| Application/Fraud | | | |
| Scope of Practice | | | 1 |

Recent Final Orders/Consents

| Orders/Consents | Nov | Dec | Jan |
|-------------------------|-----|-----|-----|
| Other Board Actions/DEA | 2 | 1 | |
| Impairment | 6 | 4 | 9 |
| Rx | 1 | | 2 |
| Rules - Laser/ Sx | | | |
| Minimal Std | | | |
| Convictions | 1 | 1 | |
| Sexual Boundary | | | 1 |
| Application/Fraud | 1 | | |
| Scope of Practice | | | 1 |

Suggestions to Achieve Compliance & Avoid Board Action:

- ▶ Know the Rules of Practice
- ▶ Use OARRS (or it will be used against you)
- ▶ Watch for boundary issues – friends, family, co-workers
- ▶ Document, document, document
- ▶ Use internal peer review, compliance programs, and EMR technology all to your advantage

Other Sources of State Regulations

Ohio Department of Health – Facility Regulation:

Required licensure and standards for the following ambulatory facilities in Ohio:

- 1) ambulatory surgical facilities and
- 2) freestanding inpatient rehabilitation facilities, radiation therapy centers, diagnostic imaging centers, birthing centers, dialysis centers, and mobile diagnostic imaging center

The rules create various standards, requirements, and civil penalties for instances of non-compliance.

Other Sources of State Regulations

Ohio Pharmacy Board:

State Agency that has administrative and law enforcement authority.

Nearly any entity or location that stores and/or dispenses dangerous drugs will be subject to Pharmacy Board regulation.

Terminal Distributors, Wholesale Distributors

State Laws & Regulations

Ohio Pharmacy Board:

Every authorized prescriber will be subject to Pharmacy Board regulation. This includes: physicians, podiatrists, dentists, advance practice nurses and physician assistants who hold certificates to prescribe, and optometrists holding therapeutic pharmaceutical agents certificates

They operate OARRS!

Federal Regulations and Statutes

- ▶ The federal government has taken a much more active role as a source of regulation in health care in the past quarter century.
- ▶ The following is a summary of some of those areas of risk which require compliance for health care providers and institutions.

Federal Regulations and Statutes

Anti-kickback Statute / Stark Law

- ▶ These laws regulate referrals by or to physicians and the monetary benefits associated with such referrals.
- ▶ The Stark Law is a “self-referral law.” It has civil financial and administrative penalties.
- ▶ The Anti-kickback Statute prohibits receiving/giving a thing of value in exchange, or to induce, a referral. It is a criminal statute and penalties can be criminal and financial.

Federal Regulations and Statutes

▶ Anti-kickback Statute / Stark Law

- ▶ Compliance with both is done through Safe Harbors for the Anti-kickback Statute and with various Exceptions for the Stark Law.
- ▶ Complicated area of law with VERY HIGH RISKS!
- ▶ Guiding principal – if you have a business, financial, or family relationship with a referral source or where you refer, compliance guidance is needed.
- ▶ To learn more go to: <http://oig.hhs.gov/> and www.cms.hhs.gov/PhysicianSelfReferral/

Federal Regulations and Statutes

What is it: The Federal False Claims Act imposes significant civil liability on any person who submits a claim to the federal government that he or she knows (or should know) is false.

- ▶ Civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages.
- ▶ False claim for failure to refund? Yes, if 60 day overpayment rule is violated.

Federal Regulations and Statutes

HIPAA

- ▶ The Privacy Regulations are well known and include a relatively comprehensive set of rules governing the use and disclosure of protected health information by covered entities (which includes health care providers). Penalties are both civil and criminal. HIPAA is governed and enforced by the US Dept. of Health and Human Services, Office of Civil Rights.
- ▶ To learn more go to: www.hhs.gov/ocr/hipaa/

Federal Regulations and Statutes

The Data Bank (fka National Practitioner Data Bank-NPDB)

- ▶ The Data Bank defines itself as:
- ▶ *An alert or flagging system intended to facilitate a comprehensive review of the professional credentials of health care practitioners, health care entities, providers, and suppliers; the information from the Data Bank should be used in conjunction with, not in replacement of, information from other sources.*
- ▶ To learn more go to : www.npdb.hrsa.gov/
- ▶ Only certain sources report and can access reports.
- ▶ Only certain events are reportable (malpractice, licensure, hospital adverse actions, health care related-civil and criminal judgments).

Federal Regulations and Statutes

Medicare / Medicaid Exclusion

- ▶ Exclusion from the federal payors can be devastating on a physician's career. Chemical dependency cases that are handled satisfactorily on the state level can be redefined on the federal level to essentially end a career as it unleashes a chain of events which prevent or vastly limit your employability.
- ▶ To learn more go to: <http://oig.hhs.gov/>

Federal Regulations and Statutes

DEA

- ▶ The DEA has become the most recent federal agency to take on a more active role in physician and facility regulation.
- ▶ General Rule: If you are subject to Ohio Pharmacy Board authority, you will be subject to DEA authority.
- ▶ Scope – generally controlled substances, not all dangerous drugs.
- ▶ Registration requirements can be tricky – location matters.

Suggestions to Achieve Compliance

- ▶ Adopt, implement, and continue to use a comprehensive corporate compliance plan. These programs are designed to educate providers and employees regarding regulatory requirements particularly regarding coding and health care fraud and abuse.
- ▶ HHS/OIG have guidance materials available to help with such plans and to provide compliance information and support.
- ▶ Learn more at <http://oig.hhs.gov/compliance/101/index.asp>

Questions?

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