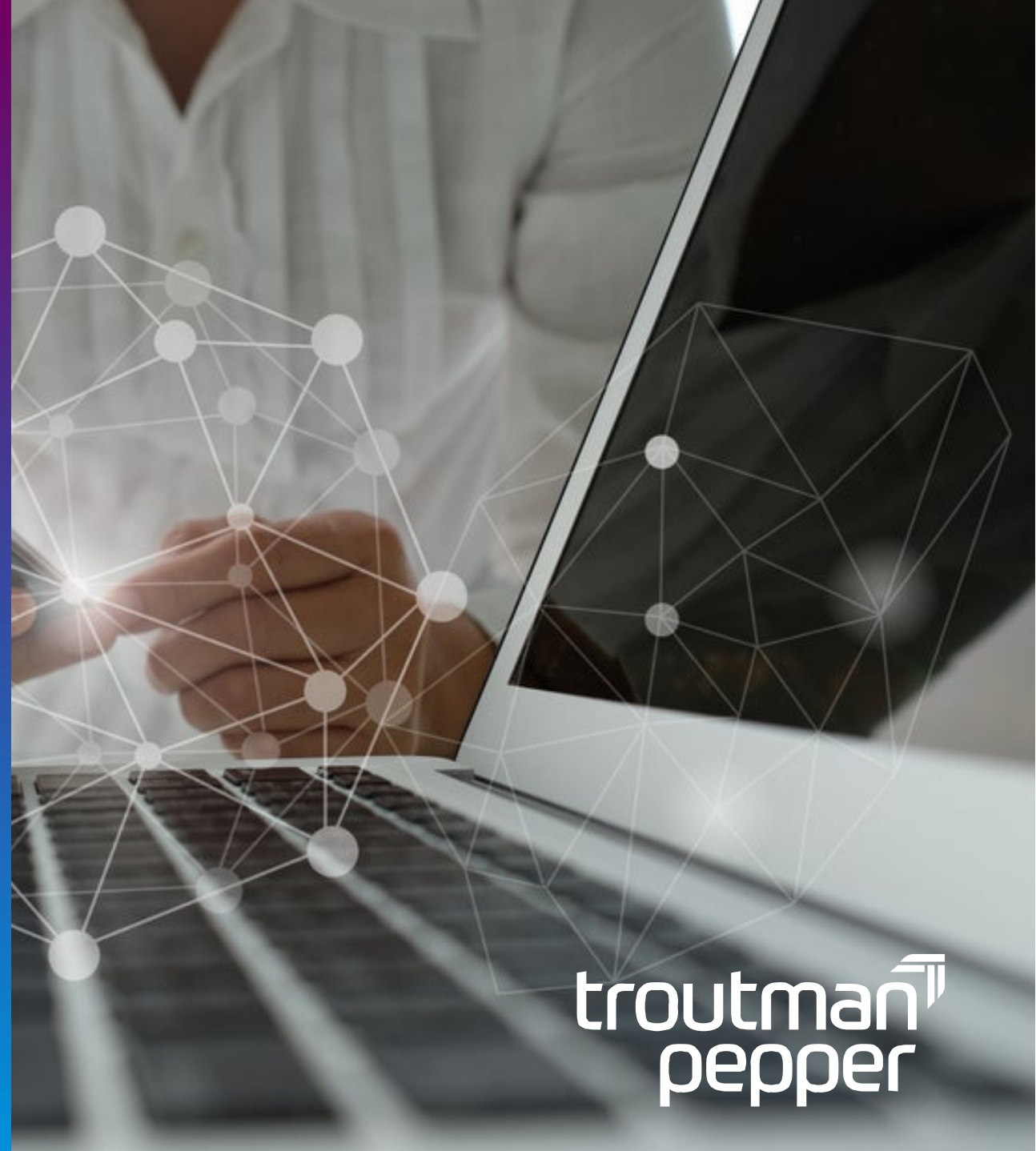


Multistate Pharmacy Compliance 101: Navigating Pharmacy Disciplinary Procedures

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troutman
pepper

Panelists



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Abbey provides strategic counsel to pharmaceutical, health care, technology, energy, and retail companies responding to internal and government inquiries alleging individual or corporate misconduct, including violations of the False Claims Act (FCA), the Anti-Kickback Statute (AKS), and the Foreign Corrupt Practices Act (FCPA). Abbey takes a thoughtful and deliberate approach to investigating allegations of fraud, conflicts of interest, bribery, or other misconduct, helping each client make informed and practical decisions.



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Emma represents a wide range of health care providers, including physicians, management service organizations, dental service organizations, hospitals, clinical laboratories, skilled nursing facilities, ambulatory surgical centers, DMEPOS suppliers, and behavioral health providers.

Firm Overview

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We provide sophisticated legal solutions to clients' most pressing business challenges, across several primary client industries, including:



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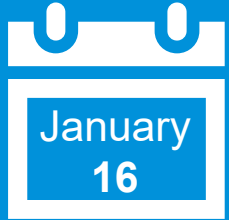


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Multistate Pharmacy Compliance 101 Series



Navigating Pharmacy Disciplinary Procedures

Tuesday, January 16, 12:00 p.m. – 1:00 p.m. ET



Navigating Pharmacy Transactions

Thursday, February 22, 12:00 p.m. – 1:00 p.m. ET



Legal Landmines for Multistate Pharmacies

Tuesday, March 19, 2024 – 12:00 p.m. – 1:00 p.m. ET

Pharmacy Overview

Prescription
and OTC

Changing
consumer
trends

Impact of
COVID-19

Pharmacy Overview

A multistate pharmacy is a pharmacy that operates in more than one state. This means that the pharmacy is licensed and complies with the pharmacy laws and regulations of each state in which it operates. There are several types of pharmacies that can operate as multistate pharmacies:

**Chain
Pharmacies**

**Mail-Order
Pharmacies**

**Specialty
Pharmacies**

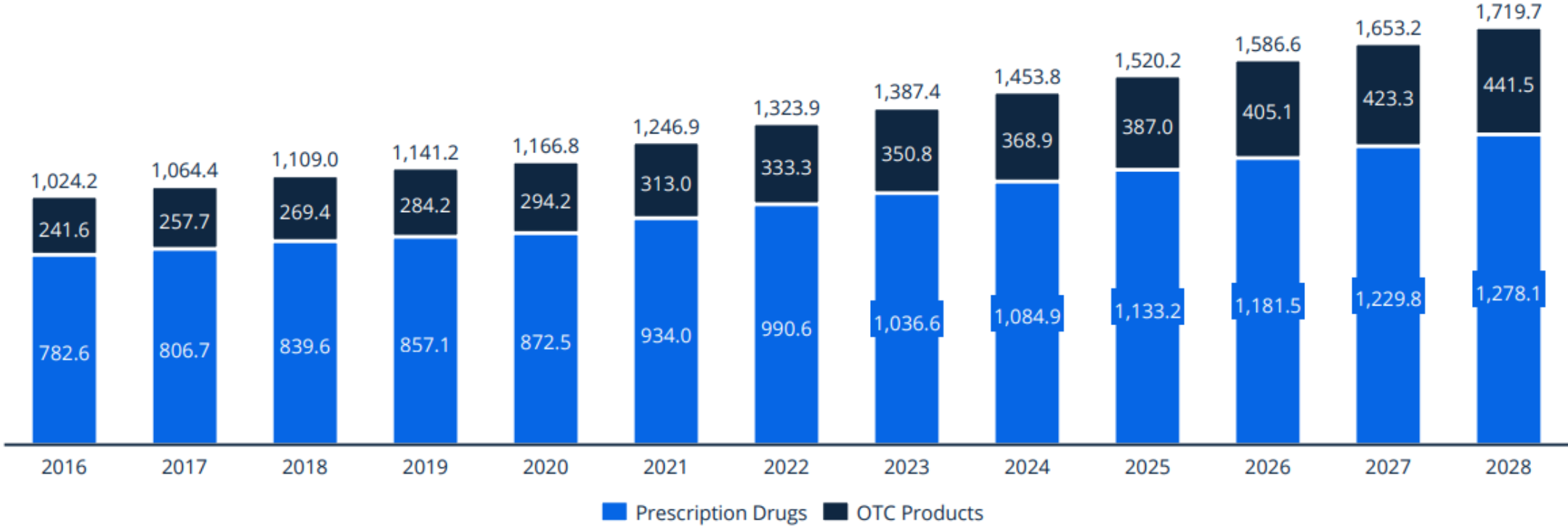
**Compounding
Pharmacies**

**Online
Pharmacies**

**Facility
Pharmacies**

Pharmacy Overview

Worldwide Pharmacies market revenue in billion US\$



Pharmacy Overview

Private equity (PE) firms have shown increasing interest in the pharmacy space for several reasons:

Consolidation Opportunities

The pharmacy industry is highly fragmented, especially among independent pharmacies. This provides opportunities for PE firms to acquire, consolidate, and streamline operations for increased efficiency and profitability.

Growth Potential

The aging population and increasing prevalence of chronic diseases are driving demand for prescription medications, presenting growth opportunities.

Regulatory Changes

Changes in healthcare regulations can create opportunities for PE firms. For example, changes allowing pharmacists to provide more clinical services can create new revenue streams.

Technological Advancements

The rise of telemedicine and online pharmacies presents opportunities for PE firms to invest in innovative companies and technologies.

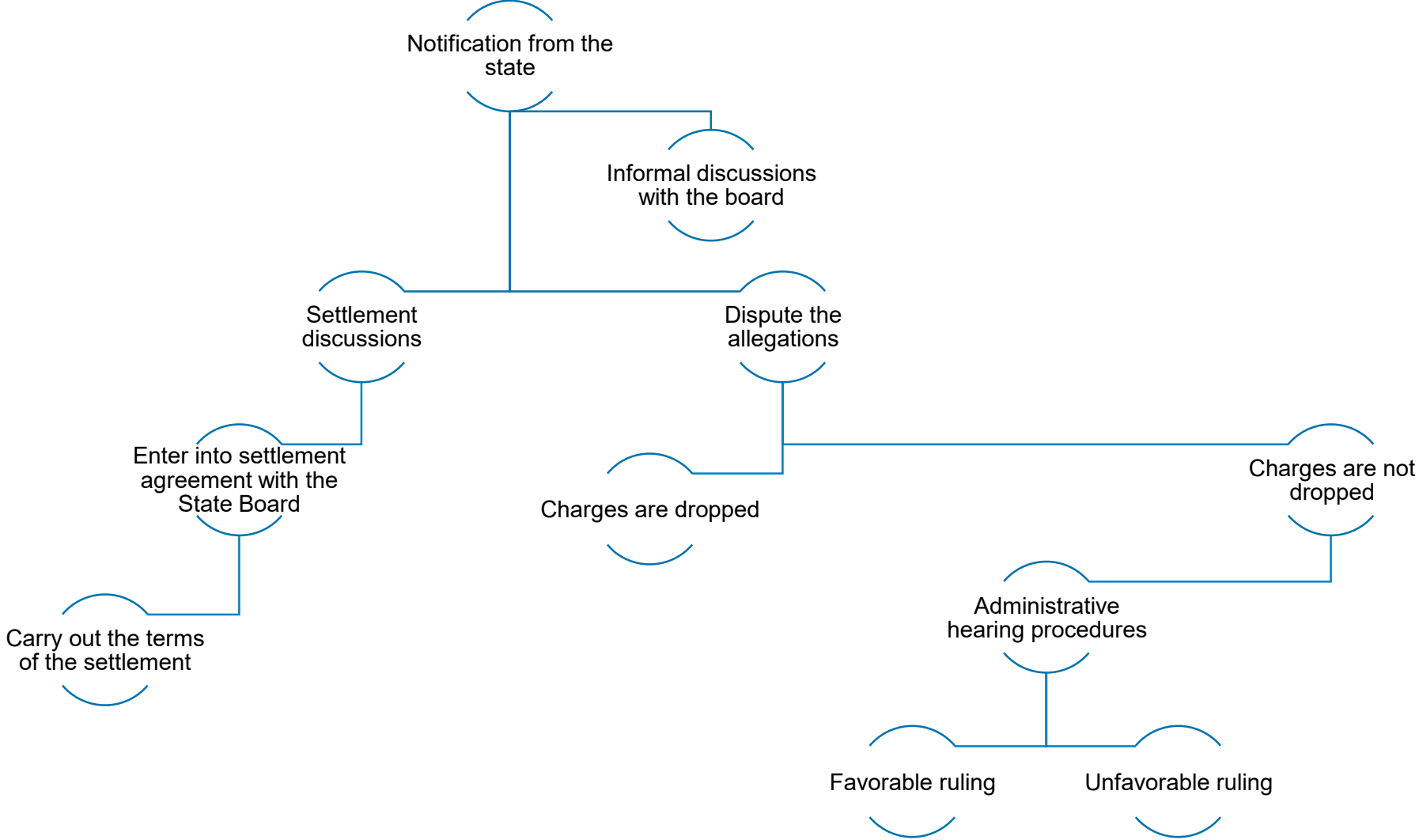
CLE Code #1 Pharmacy

Pharmacy Registrations

Proper pharmacy registrations are difficult to fully understand—in addition to federal registration, some states require different licenses/registrations than others. For instance, depending on the state of the pharmacy, they may need to apply for:

1. Drug Enforcement Administration (“DEA”) license
2. State pharmacy license
3. State business license
4. Registered agent registration

Disciplinary Action Process



Disciplinary Actions

The following are common disciplinary action triggers:

- Insufficient or lapsed licenses
- Dispensing medications without a valid prescription
 - Heightened scrutiny when controlled substances are involved
- Safety / medication handling violations
- Record-keeping violations
- Errors in pill counts
- Discipline in other states

Disciplinary Actions

Reprimand

Fine

Limitation

Suspension

Revocation

Disciplinary Actions

Non-Resident Pharmacy

Texas

California

Iowa

Conduct

Failed to renew Missouri license

Committed safety violations in California

Failed to obtain license in Kansas before shipping prescriptions to Kansas

Result

License revoked and pharmacy barred from reapplying for seven years

Surrendered licenses in California and Wisconsin

Required to pay a fine to the Kansas Board of Pharmacy

After Discipline

Abide by the terms of the settlement/final order

Disclose the discipline

- What needs to be disclosed?
 - The states have different disclosure requirements depending on the discipline
- How does the discipline need to be disclosed?
 - Some states require disclosure affirmatively within a pre-determined time-period
 - Some states require disclosure upon a licensure renewal application

After Discipline

In general, pharmacies operating in multiple states must apply for “non-resident pharmacy” licenses/registrations (or the state’s equivalent to a non-resident pharmacy) in each state it seeks to operate in

- Except Massachusetts
- States have different rules for when a license is required (ex: isolated transactions vs regular business)

The application process usually involves:

- Initial applications
- Renewal applications
 - Some states require renewals annually, every two years, etc.

On initial and renewal applications, questions about disciplinary actions are often asked

After Discipline

5. Has any owner, partner, officer or the pharmacist-in-charge ever been, or is now, addicted to any drugs, controlled substances or alcoholic beverages?
6. Has any owner, partner, officer or the pharmacist-in-charge ever had an application for a pharmacy technician, pharmacist, pharmacy intern, pharmacy, drug distributor or any other healthcare registration, license, permit, or certificate denied, disciplined or refused in this state, or any other state or country? *(If yes, copies of any denial/refusal/disciplinary documents must be provided)*
7. Has any owner, partner, officer or the pharmacist-in-charge ever had any controlled substance registration, license, permit, or certificate denied, disciplined or refused in this state, or any other state or country? *(If yes, copies of any denial/refusal/disciplinary documents must be provided)*
8. Has any owner, partner, officer or the pharmacist-in-charge ever been adjudged insane or incompetent by or in any state, country or court?

After Discipline

ANSWER THE FOLLOWING QUESTIONS: (attach additional sheet(s) if necessary)

1. Has any licensing or other credentialing agency ever taken any disciplinary action against you, including but not limited to any warning, reprimand, suspension, probation, limitation, or revocation? **If yes, attach a sheet providing details about the action, including the name of the credentialing agency and date of action.**
2. Is disciplinary action pending against you in any jurisdiction? **If yes, attach a sheet providing details about pending action, including the name of the agency and status of action.**

Potential Collateral Consequences

Settlement-
mandated
monitoring

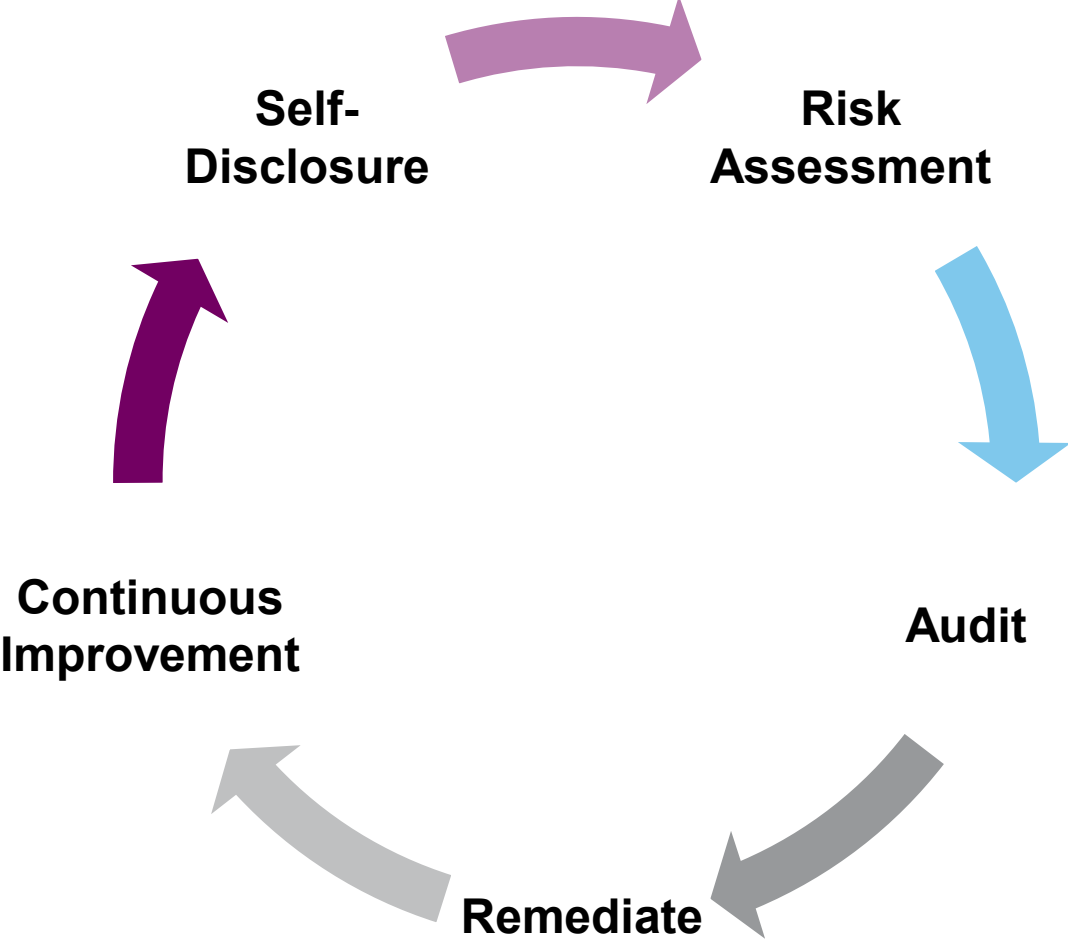
Federal or
state law
enforcement

Federal or
State anti-
fraud and
abuse laws

Reciprocal
discipline

CLE Code #2 Regulations

Compliance Best Practices

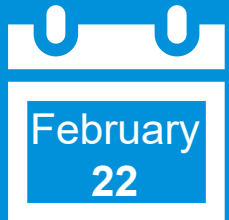


Questions & Answers

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