FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

# The Evolving Landscape of Controlled Substances: 2026 Regulatory Updates, Technology Innovations, and Stewardship Best Practices

**Matthew J. Seamon, PharmD, Esq**
Associate Professor
Nova Southeastern University Barry and Judy Silverman College of Pharmacy

**Jessica M. Lemoine, PharmD, MS**
Director of Pharmacy
Baptist Health South Florida

1

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Disclosure

The speakers do not have any vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation (within the last 12 months).

2

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Dual Presenters

- **Dr. Matthew Seamon**
  - Pharmacist, Attorney
  - University based academician
  - Will bring a legal-regulatory framework to controlled substances and a perspective on how policy and practice is shifting both state and federally, impacting pharmacists and technician responsibilities
- **Dr. Jessica Lemoine**
  - Pharmacist, Master's Health-System Pharmacy Administration
  - Hospital based clinician
  - Will bring a practical viewpoint on current issues with controlled substance including the evolving role of technology and the central role of pharmacists and technicians

3

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Objectives

**Pharmacist**

1. Discuss federal and Florida laws impacting the prescribing & dispensing controlled substances, including recent regulatory changes impacting patient access including the State's Standing Order Naloxone requirements.
2. Evaluate the appropriate therapeutic legitimacy of controlled substance prescriptions by utilizing E-FORSCE (Florida's Prescription Drug Monitoring Program), opioid stewardship principles, technology and risk mitigation strategies.
3. Analyze controlled substance prescriptions to identify legitimate medical prescriptions & appropriate therapeutic value via drug utilization review, including drug-drug interactions, therapeutic duplication, adverse effects, and high-dose or low-dose prescribing concerns, while applying diversion prevention best practices.
4. Implement best practices and protocols to improve controlled substance stewardship, patient safety, regulatory compliance, and diversion prevention using technology, monitoring, education, and interdisciplinary collaboration.
5. Describe counseling approaches and referral strategies for patients with opioid prescriptions, including education regarding the Statewide Standing Order for Naloxone, proper storage and disposal, and referral to available treatment resources for opioid dependence, addiction, misuse, or abuse.

4

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Objectives

**Pharmacy Technician**

1. Explain technician responsibilities related to controlled substance handling, documentation, inventory reconciliation, security, and recordkeeping, consistent with Federal and Florida laws and updates.
2. Recognize signs of diversion, misuse, or prescriptions lacking a legitimate medical purpose, and describe appropriate reporting procedures and technician responsibilities within the pharmacy workflow.
3. Describe technician support roles in pharmacist-led Prescription Drug Monitoring Program (PDMP) utilization, opioid stewardship, patient education regarding proper storage and disposal of controlled substances, and naloxone education under Florida Law.
4. Discuss workflow processes, including the use of technology that support pharmacist oversight of drug utilization review (DUR) concerns, including identification of potential drug-drug interactions, therapeutic duplication, adverse effects, and dosing guidelines while maintaining controlled substance best practices.
5. Describe team-based strategies that promote controlled substance security, patient safety, diversion prevention, naloxone access, and referral of patients to available treatment resources for opioid dependence, addiction, misuse, or abuse.

5


6

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Warm-Up: Name That Schedule!

- Carisoprodol
- Sodium Oxybate
- Heroin
- FLAKKA
- Codeine
- HGH
- Ayahuasca
- Psilocybin
- Cannabis
- Ketamine
- Buprenorphine

- Butalbital/Aspirin/Caffeine
- Tapentadol
- Phenobarbital/Hyoscyamine /Atropine/Scopolamine
- Codeine + Guaifenesin
- Tramadol
- Hydrocodone/acetaminophen
- Meperidine
- Ketorolac
- Cannabidiol
- Promethazine w/codeine
- Alprazolam

DEA Drug Schedules: dea.gov/drug-information/drug-scheduling

7

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## DEA Regulatory Lightning Updates

**Partial Fills C2 Now Permitted**
DEA permits partial fills of Schedule II prescriptions. Remaining quantity may be filled within 30 days of the original date.

**Two-Step Loss Reporting Update**
Theft/significant-loss reporting: initial notification in writing within 1 business day and a detailed report within 15 days (Form 106).

**Marijuana Rescheduling**
DEA rescheduling hearings for cannabis (Schedule I → III) ongoing. Schedule III status would still be federally regulated marijuana.

**C-II E-Script Transfer allowed prior to initial filling**
DEA amended regulations to allow transfer of electronic C-II prescriptions for initial filling to prevent treatment delays.

**Mail-Back Envelopes Available**
Pharmacies may request pre-paid drug mail-back envelopes from the manufacturers that are part of the OA REMS.

**Suspicious Orders — SORS enhanced oversight and enforcement**
All DEA distributors must report suspicious orders via SORS. FL Statute 499.0121 applies, including the >7,500 units/month max.

DEA: deadiversion.usdoj.gov | thefdalawblog.com (2023-2026) | FL Statute 499.0121

8

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Florida Legislative & Regulatory Updates

**HB 519 — EMS Paramedics Administration of Controlled Substances**
Paramedics may now administer certain CS under supervision. Creates new pharmacy/EMS interfaces and documentation.

**Fentanyl Testing – Gages Law 395.1042**
Hospitals test for fentanyl urine drug screens for possible drug overdose or poisoning. If positive confirmation test required.

**ICD-10 Documentation required for billing**
Opioid diagnoses require ICD-10-CM codes for billing. Most FL pharmacies/systems treat ICD-10 as operationally required.

**SB 136 Cannabis Employment Testing Died in Health Policy**
Public employer cannot act against an employee simply for testing positive for cannabis on a pre-employment drug screen.

**FL CS/SB 844: Sickle Cell Management Continuing Education**
CE Course on Validating CS biennially must contain information on treating sickle cell disease. Approved by Governor 3/27/26.

**Bills to Monitor and be Aware**
Several proposed CS regulatory changes failed this session including delegation of prescribing authority and kratom classifications.

FL Statutes 456.44, 499.0121, HB 519 (2025) | 21 U.S.C. 829a, SUPPORT Reauthorization PL 119-44 (Dec 2025)

9

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## A Peek Into the (Not So Far) Future: AI in Prescribing & Dispensing

**Utah 2026 Pilot Iowa, Idaho**
UT piloting autonomous AI agent authorized (Jan 2026) to provide refills for 192 drugs without direct prescriber involvement; other states exploring similar. Google Doctronic.

**Generative AI drug-seeking bots**
AI systems capable of generating convincing symptom narratives or telehealth chats designed to obtain stimulants, testosterone, benzodiazepines, or pain medications.

**Corporate Analytics Increasingly Required**
Major pharmacy systems deploying algorithmic (overdose) risk scoring to flag/block high-risk prescribers — equity and due-process concerns raised. Can predict overdoses.

**DEA ARCOS and Heightened DEA Analysis**
ARCOS increasingly used in real-time risk management, civil litigation, criminal prosecution, and administrative enforcement actions.

**EHR Dashboards Becoming Universal For Accountability**
Real-time stewardship dashboards: MME trends, PDMP compliance, naloxone rates, benzo co-prescribing

**Hospital Expectations**
DEA assumes predictive analytics: ADC usage patterns, wastage analysis, kit/box returns, prescriber-level outlier detection.

https://www.doctronic.ai/prescription-refill/ — AJHP 2022. 79;16 1345-54.

10

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Telehealth & Controlled Substances: 2026 Status

**7M+**
CS prescriptions issued via telemedicine without a prior in-person visit in 2024 (HHS.gov)

- DEA extended COVID-era telemedicine CS flexibilities again (4th time) through December 31, 2026
- Federally clinicians may prescribe Schedule II–V via audio-video telehealth without prior in-person evaluation [C2 exceptions]
  - Ryan Haight Exemption
  - Florida no CII telehealth prescriptions with limited exceptions
- Audio-only telehealth permitted for Schedule III–V OUD medications (e.g., buprenorphine)
- ~16% of all 44.6 million CS prescriptions in 2024 issued without prior in-person evaluation
- DEA is buying time with extensions — expect tightening once permanent rule is finalized

DEA Telemedicine Extension (2026): dea.gov | HHS Telemedicine Report 2024: hhs.gov | McDermott Will & Emery analysis (2025)

11

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

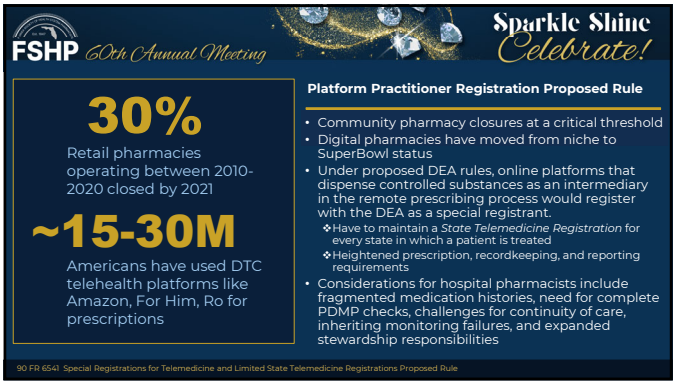
## Florida Telehealth & Controlled Substance Rules (FS 456.47)

- COVID-era federal flexibility continues through 12/31/2026
- **Florida PROHIBITS prescribing Schedule II via telehealth**
  - Exceptions: hospice, LTCF, inpatient hospital, neurologists, and psychiatric patients
- Out-of-state prescribers may register as FL out-of-state telehealth providers; may ONLY use a FL-licensed or nonresident pharmacy to fill
- E-FORCSE (PDMP) check mandatory prior to prescribing/dispensing
- ICD-10 coding and indication documentation for opioids is operationally required for CS dispensing
- Regulatory tension: federal flexibility is loosening while Florida maintains stricter CS prescribing restrictions — pharmacists must know both

FL Statute 456.47 (Telehealth) | FL Health Source: flhealthsource.gov/telehealth/faqs | Ryan Haight Act: 21 U.S.C. 831

12

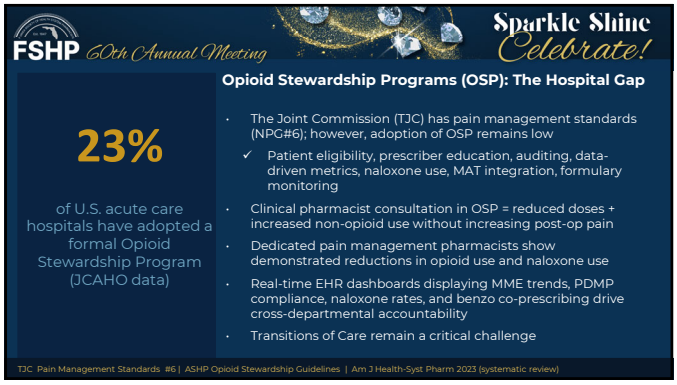

13




14


15


16




17


18

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Florida PDMP: E-FORCSE Requirements (FS 893.055)

- Prescribers AND dispensers MUST consult E-FORCSE for patients ≥16 years for Schedule II–V for new AND refill prescriptions
  - ✓ Reporting exemptions: correctional facilities, admitted hospice, non-opioid CV's, drugs administered (not dispensed), patients under age 16
  - ✓ Willful and knowing failure to consult is a first-degree criminal misdemeanor
  - ✓ Mandatory next-business-day reporting
- If system operationally unavailable may dispense a 3-d supply and document accordingly
- HIPAA and Patient Confidentiality must be protected. NO UNAUTHORIZED ACCESS
- Note: Pharmacy technicians may be delegated access to E-FORCSE

FL Statute 893.055 (E-FORCSE) | FL DOH PDMP: floridahealth.gov | E-FORCSE: e-forcse.com

19

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Patient Counseling Opioid Prescription

- Florida pharmacy law requires ALL outpatient prescriptions [new and refill] OFFER TO COUNSEL and conduct prospective DUR on all prescriptions
  - Pharmacist discretion on what to counsel.
- Important considerations given to MME, indications [acute v chronic pain], reasonable expectations on pain-relief, complementary and alternatives, drug-drug interactions, therapeutic duplication, duration of treatment, adverse effects, proper storage, disposal options, household risk and potential for dependence, addiction, misuse and abuse
- Referral to treatment: If abuse, misuse, dependence, addiction, or opioid use disorder is suspected, use a nonjudgmental approach and refer patients to resources.
  - Remember Rosenhan
- Document counseling provided, naloxone recommendations, referrals, and patient understanding
- Treatment resources include 911, 211, findtreatment.gov, SAMHSA National Helpline, MOUD providers [buprenorphine]

FL Rule 64B16-27.820 Patient Counseling, 64B16-27.810 Prospective Drug Use Review. FL 456.44 Controlled Substance Prescribing

20

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Clinical Benefits of E-FORCSE Consultation in the Hospital

PDMP critical for inpatient concerns and dispensing

*Sure, Red-Flags may trigger possible misuse or diversion, but may also alert to:*

- ✓ Multiple prescribers may alert to care considerations beyond doctor shopping
- ✓ Early fills may show pattern of non-compliance or lack of effectiveness
- ✓ Dangerous combinations may show high risk behavior and need for case management intervention
- ✓ Existing chronic opioid therapy may show tolerance and legitimate pain
- ✓ Look for patterns and evaluate regimens as clinicians, not private investigators
- ✓ Upon discharge counseling can calculate existing home supply
- ✓ Initiate conversations if concerns with addiction for possible long-acting injectable buprenorphine inpatient

21

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## E-FORCSE PDMP: Hospital Pharmacy Workflow Best Practices

**Emergency Department**
Check PDMP for ALL patients with pain complaints, altered mental status, or overdose.

**Admission Med Reconciliation – Beyond Suspicion**
Compare reported home CS medications against PDMP history. Identify discrepancies before admission orders.

**Inpatient Monitoring**
Flag patients with risk and OUD for pharmacist-led clinical review. Consult pain management/addiction medicine as appropriate.

**Discharge Planning and PDMP Considerations**
Ensure CS aligns with documented clinical indication. Verify naloxone has been ordered and counseling documented.

**Pain Agreement Reconciliation**
Identify patients with active pain agreements on admission. Assess with inpatient treatment and discharge planning.

**Documentation should be objective, brief, and non-judgmental**
Avoid labels such as suspicious patient, drug seeking behavior. Caution with clinical notes.

FL Statute 893.055 (E-FORCSE) | E-FORCSE: e-forcse.com | ASHP PDMP Integration Resources

22

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Valid Prescription Requirements & Corresponding Responsibility

- All prescriptions must be issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of professional practice"
  - ✓ Prescriber valid DEA registration, acting within scope of practice, bona fide patient-prescriber relationship, legitimate medical purpose
- Pharmacist has CORRESPONDING RESPONSIBILITY with prescriber — must not fill prescriptions known or suspected to be invalid
- FL Board Rule 64B16-27.831: "every patient's situation is unique" — independent professional judgment required; duty to attempt resolution before refusing
- Duty to report: prescribers involved in diversion must be reported to FL DOH
- FL ID requirement (FS 465.0155, 893.04) for pick up: valid photo ID for patients not personally known; real-time health plan eligibility verification acceptable

21 CFR 1306.04 | FL Statute 465.0155, 893.04 | FL Board of Pharmacy Rule 64B16-27.831 | FL Statute 893.055

23

## Corresponding Responsibility: Fifth Circuit Court Pushback (2025)

**Traditional DEA Doctrine**

- Federal rules places corresponding responsibility on pharmacists — not just prescribers — to ensure every CS prescription serves a legitimate medical purpose.
- DEA has prosecuted pharmacists who filled prescriptions they "should have known" were invalid, even when facially valid.
- FL Board Rule 64B16-27.831 mirrors this: independent judgment required by pharmacists; may not blindly fill.
- Duty to report: prescribers involved in diversion must be reported to FL DOH.

**5th Circuit Rejects DEA's Interpretation 2/13/26**

- Major Legal Decision. Although non-binding and only an isolated circuit [LA, MS, and TX].
- Key holding: Corresponding responsibility is NOT an independent strict-liability duty to investigate every suspicious indicator.
- Pharmacists liable ONLY if: 1) fills 2) an invalid prescription 3) **knowingly**.
- The duty arises only when red flags are "obvious" and cannot reasonably be resolved through standard due diligence.

5th Circuit: ca5.uscourts.gov/opinions/pub/25/25-60068-CV0.pdf | 21 CFR 1306.04 | FL Board Rule 64B16-27.831 | thefdalawblog.com (2025)

24

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Shortages of Controlled Substances (Yes, Still a Critical Matter)

- Drug shortages remain one of the **top hospital pharmacy challenges in 2026**
- Especially:
  - Injectable opioids (e.g., fentanyl, hydromorphone)
- Effects:
  - Forced therapeutic substitutions, Increased error risk, Higher cost alternatives

Pharmacists balancing:

- Pain control vs. availability vs. safety
- Access barriers and legitimate-use "deserts"
  - Corporate safeguards, wholesaler limits, and fear of enforcement can create de facto "opioid deserts" or "stimulant deserts," especially in rural or minoritized communities.
  - Pharmacists are caught between duty to stock/dispense and real fears of audits, contract terminations, or reputational risk.
  - Proactively communicate shortages to prescribers; suggest evidence-based alternatives; document all therapeutic substitutions

FDA Report to Congress CY 2024 @ https://www.fda.gov/media/189325/download

25

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## ASHP Drug Shortage List; only partial

- Amphetamine ER and mixed salts IR
- Clonazepam Oral Tablets
- Dexmethylphenidate ER Capsules
- Dexmedetomidine Inj and premix
- Dextroamphetamine ER Capsules
- Diazepam Oral solution and Injection
- Dronabinol capsules
- Etomidate Inj
- Fentanyl Inj and Transdermal
- Hydrocodone/APAP Tab
- Hydromorphone Inj and IR oral
- Ketamine Inj
- Lisdexamfetamine Caps
- Lorazepam Inj and Tablets
- Meperidine Inj and oral solution
- Methadone Oral Solution
- Methylphenidate ER
- Methylphenidate IR
- Midazolam Inj
- Morphine Inj, oral solution, IR tabs
- Oxycodone and APAP
- Oxycodone IR
- Remifentanyl
- Testosterone Inj and Transdermal

https://www.ashp.org/drug-shortages/current-shortages

26

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Handling Drug Shortages

- Pharmacists must balance clinical impact, safety, cost, future availability and ethical allocation
- MUST proactively monitor and even anticipate shortages
- Need for quick response drug shortage management protocols/process
- Communicate early and across disciplines
- Implement conservation strategies and protect critical-use inventory
- Avoid gray market vendors when possible (remember DSCSA)
- Leverage technology

Understanding and Managing Drug Shortages @ https://www.ashp.org/drug-shortages/current-shortages

27

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Pain Treatment Agreements & Florida Requirements (FS 456.44)

- Opioid Treatment Agreements (OTAs) are risk-management tools — NOT enforceable contracts in the classic legal sense (no true bilateral consideration)
  - ✓ ~27 States required
  - ✓ Florida FS 456.44: chronic non-malignant pain must be prescribed by a single physician or referred elsewhere and must be "seen" at intervals not to exceed 3 months
  - ✓ ANY Signs or symptoms of Substance Abuse, FL requires immediate referral to board-certified pain specialist, addiction medicine, or mental health facility
- Typical elements include single prescriber/pharmacy, urine drug screens, no early refills, risk disclosure, conditions for continuation or discontinuation
- Hospital implications: ask on admission — does the patient have an active pain agreement? Evaluate discharge plan fit; document transition of care

FL Statute 456.44 | Milbank Quarterly OTA Policy Review: onlinelibrary.wiley.com/doi/10.1111/1468-0009.12699 | FSMB Model Policy on CS Prescribing

28

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## NarxCare & Algorithmic Risk Scoring Software: Tools and Tensions

- Transforms PDMP data into automated risk scores — integrated into Florida's E-FORCSE portal and
  - ✓ Should be used as a screening aid not a reason to deny care
  - ✓ Dispensing trend flags: cash payment patterns, controlled/non-controlled drug ratios, geographic clusters, early fill frequencies — analyzed automatically by DEA and corporate systems
- Super-chain pharmacies may use algorithmic data to block prescribers — creating legitimate health equity and patient access concerns
- Hospital System Administrators must be able to defend alert thresholds, analytics outputs, and follow-up documentation if DEA audit arises or legal malpractice claims arise

NarxCare: apprisshealth.com/narxcare | ORT: Webster & Webster 2005 (Pain Med) | DEA ARCOS: deadiversion.usdoj.gov/arcos

29

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## FL Board of Pharmacy Guidance on Filling Controlled Substances

*"The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription."*

*"General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment."*

FL Board of Pharmacy Position Statement | FL Statute 465.0155, 893.04, FL Rule 64B16-27.831

30

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Transition of Care: A Moment of Opioid Risk

**TOC**

Hospital discharge is the most critical failure point for long-term opioid initiation and continuity gaps


- Problems at discharge: overprescribing, poor communication with outpatient providers, duplicate therapies, no taper plan, missing naloxone
- Long-term opioid use can begin from a SINGLE short inpatient exposure — especially post-surgical
- New expectation: pharmacists manage the discharge opioid plan, not just inpatient medication orders
- Collaborative stewardship: deliberate handoff to primary care or community pharmacist at discharge — with shared documentation
- Key question: "Who owns the taper plan and naloxone prescription after hospitalization?" — must be explicitly documented
- Shared protocols, shared data, and sometimes shared liability with external pharmacies is now a reality

Am J Health-Syst Pharm 2024 (Transition of Care OSP) | ASHP Opioid Stewardship Resource Center: ashp.org | CDC Opioid Prescribing Guideline 2022

31

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Naloxone Evolving as Standard of Care

- Available as nasal sprays and injection
- Pharmacists play a central role in identifying patients at increased overdose risk and recommending naloxone when appropriate
- Naloxone co-prescribing is NOW STANDARD OF CARE in many situations
  - ✓ Co-prescribe when: high MME, opioid + benzodiazepine, history of SUD, OUD diagnosis
  - ✓ Florida requires all CII prescriptions for traumatic injury with a severity score of 9 or greater to concurrently prescribe an opioid antagonist
- Embed opioid safety checklists into EHR discharge order sets, workflow medication reconciliation, opioid stewardship initiatives, and transitions of care
- Administration of naloxone is protected under good Samaritan laws

CDC Opioid Prescribing Guideline 2022: cdc.gov/opioids | FL Statute (ISS ≥9 co-prescribing) | ASHP Opioid Stewardship Resource Center: ashp.org

32

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Naloxone Patient Access

- Florida's Surgeon General Statewide Standing Order for Naloxone
  - Allows patients and caregivers to possess, store, and administer naloxone in good faith to a person believed to be experiencing an opioid overdose, even if that person does not have a prescription for naloxone.
  - Emergency responders, law enforcement officers, paramedics, and emergency medical technicians may possess, administer, and store auto-injector 2 mg/0/4mL, 2 mg/2 mL nasal sparay immune from civil and criminal liability
  - Pharmacy must maintain a copy of the standing order
- FDA has approved Naloxone OTC: 4 mg intranasal
  - Most insurance companies /pbms cover naloxone OTC
- Hospitals should have AUTOMATIC naloxone triggers at discharge — not physician-opt-ins
- "Med-to-bed" programs provide and educate bedside naloxone before discharge
- Track metrics: naloxone dispensing rates, opioid prescribing trends, post-discharge follow-up call completion

[FL§ 381.887] Emergency Treatment for Suspected Opioid Overdose https://floridaspharmacy.gov/pdfs/standing-order-naloxone.pdf

33

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Naloxone Patient Access

| | |
|---|---|
| Check PDMP for ALL patients with pain complaints, altered mental status, or overdose | **Admission Med Reconciliation – Beyond Suspicion**<br>Compare reported home CS medications against PDMP history. Identify discrepancies before admission orders. |
| **Inpatient Monitoring**<br>Flag patients with risk and OUD for pharmacist-led clinical review. Consult pain management/addiction medicine as appropriate. | **Discharge Planning and PDMP Considerations**<br>Ensure CS aligns with documented clinical indication. Verify naloxone has been ordered and counseling documented. |
| **Pain Agreement Reconciliation**<br>Identify patients with active pain agreements on admission. Assess with inpatient treatment and discharge planning | **Documentation should be objective, brief, and non-judgmental**<br>Avoid labels such as suspicious patient, drug seeking behavior. Caution with clinical notes |

FL Statute 893.055 (E-FORCSE) | E-FORCSE: e-forcse.com | ASHP PDMP Integration Resources

34

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Naloxone Distribution: Technician Support in Hospital Programs

| | |
|---|---|
| **Support Documentation and Inventory Tracking**<br>Manage tracking for naloxone use, replacement and par levels. Check expiration dates and package integrity. Maintain inventory and stock throughout the hospital. | **In Preparation for Dispensing**<br>Prepare naloxone kits for pharmacist verification. Ensure correct formulation, dose, and quantity per prescriber order. |
| **"Med-to-Bed" Program Support**<br>Coordinate delivery of bedside naloxone before discharge. Confirm pharmacist has completed or scheduled patient/family training. Document delivery in the dispensing system. | **Community Pharmacy Coordination**<br>Technicians can assist in contacting community pharmacies at discharge to confirm naloxone prescription can be filled at the patient's preferred location for continuity of supply. |
| **Disposal & Return Programs**<br>Inform patients about take-back events, mail-back programs', and the ~17,000 authorized receptacles nationwide for unused medications. Check local pharmacies for authorized receptacles | **Metrics Support**<br>Technicians can support tracking of naloxone dispensing rates, patient receipt of education for OSP reporting. Compile reports and serve on committees to improve patient care and safety |

ASHP Naloxone Dispensing Resources | SAMHSA Opioid Overdose Prevention Toolkit | FL Statute (ISS ≥9 co-prescribing) | DEA Take-Back Program

35

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## PDMP Assistance: Technicians Support E-FORCSE Queries

- Pharmacy technicians support PDMP queries under direct supervision
  - ✓ Initiate E-FORCSE query, retrieve and flag concerning findings.
  - ✓ Document reasons for PDMP non-consultation, audit records and perform quality reviews and reports, assist during diversion or compliance investigations
  - ✓ Technicians should NOT interpret PDMP results —reserve clinical judgments for pharmacist
- Can help verify patient identification before querying: must match exactly for reliable results, reconcile aliases and missing inconsistent information
- PDMP training for technicians should be included in annual competency assessments and onboarding
- Technicians could and should serve as delegates for access

FL Statute 893.055 (E-FORCSE) | FL Board of Pharmacy Technician Rules: 64B16 | E-FORCSE: e-forcse.com

36

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Red Flag Analysis for Controlled Substances

- Fills requested on government benefit payment days
- Cash payment — especially with no insurance
- Demanding specific brand, manufacturer, or formulation
- Multiple doctors (doctor shopping) or multiple pharmacies
- Traveling significant distance from home or prescriber
- Appearing agitated, intoxicated, or drug-seeking
- Opioid + benzodiazepine combination — major respiratory risk
- Vague directions ("take as needed") on high-abuse-potential agents
- Full quantities without prior prescription history
- Therapeutic duplications or clinically irrational combinations
- Prescription pattern deviating substantially from that prescriber's normal
- Prescriber outside usual scope of practice or geography
- Early refill requests without documented clinical justification
- Unusual times: early morning, evenings, or holidays

FDA Federal Register 2025-01536 | thefdalawblog.com (2023–2025) | DEA: deadiversion.usdoj.gov

37

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Technician Role in Opioid Safety Counseling Support: Patient Education

*Reminder: All clinical education/counseling MUST be provided by the pharmacist*

- Technicians identify when counseling is needed (new CS prescription, change in dose, first dispensing of naloxone) gather questions and alert the pharmacist of concerns
- Distribute Pharmacy-approved educational materials
  - ✓ CS stored in a secure location inaccessible to others
  - ✓ Disposal 4 patient options — self-discard (flush/mix/trash), DEA take-back events, mail-back programs, collection receptacles
- Assist with logistical and operational procedures
  - ✓ "Med-to-bed" programs: technicians can prepare and deliver bedside naloxone kits before discharge — pharmacist verifies counseling completion
  - ✓ Discharge packet preparation: technicians prepare safe use handouts, naloxone instructions, and disposal information for pharmacist to review with patient
  - ✓ Documentation: technicians help document counseling offer/acceptance/refusal in the medication administration record or dispensing system

FL Statute 465.003 (Pharmacist Counseling) | DEA Take-Back Program | ASHP Naloxone Patient Education Resources | FL Board of Pharmacy 64B16

38

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Are Hospitals the New "Leak Point" for Controlled Substance Risk?

*As retail pharmacy becomes more closely monitored, enforcement pressure may be shifting upstream to hospital settings — which historically have had less rigorous CS oversight.*

**Short Admissions**
Brief stays reduce continuity of CS oversight and longitudinal patient knowledge — pattern detection is harder.

**Multiple Prescribers**
Fragmented prescribing by specialists, residents, and attendings increases ADC discrepancy risk and accountability gaps.

**Less Outpatient Continuity**
Patients may obtain CS inpatient that would trigger red flags at retail pharmacy, bypassing outpatient safeguards.

**Advanced Analytics Required**
DEA now expects ADC usage analysis, wastage pattern review, kit/box return tracking, and prescriber-level outlier monitoring.

**PDMP Underused Inpatient**
Many inpatient settings still do not consistently check PDMP. Best practice: ED → admission med rec → discharge check.

**Audit Trail Imperative**
Documentation is a legal shield. Witnessed wastage must be real-time — never reconstructed after the fact.

thefdalawblog.com: Hospitals Do You Know Where Your CS Are? (2024) | DEA Diversion Control Division | ISMP Medication Diversion Resources

39

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Compelling DEA Hospital Civil Settlements

| Institution | Settlement | Key Violation / Outcome |
|---|---|---|
| McLaren Health Care (MI) | $7.75M | 2021 — Schedule II Rx violations, recordkeeping failures, late theft reporting. 3-yr MOA. |
| Sovah Health (VA) | $4.36M | 2022 — Pharmacy tech: 11,000+ Sched. II doses diverted. Nurse replaced fentanyl with saline. Non-prosecution agreement. |
| Pikeville Medical Ctr (KY) | $4.39M | 2021 — Pharmacy tech diverted 62,780 Sched. II doses. Husband distributed drugs in the community. 3-yr MOA. |
| Univ. of Michigan Health (MI) | $4.30M | 2018 — Nurse fatally overdosed. Anesthesiology resident overdosed. Deficient recordkeeping, 15 unlicensed locations involved. 3-yr MOA. |
| Cheshire Medical Ctr (NH) | $2.00M | 2022 — 657 fentanyl IV bags unaccounted; audit revealed 17,961 additional missing doses. |
| Palomar Health (CA) | $250K | 2024 — Fentanyl diverted from ADCs over 5 months. Entered MOA; increased security & training required. |

40

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## DEA Inspections: What Every Hospital Pharmacist Must Know

**1. Notice of Inspection — Form 82**
DEA may arrive announced or unannounced. COR or authorized agent must review and sign Form 82. Conducted at reasonable times and in a reasonable manner.

**2. Scope of Inspection**
May inspect and copy all records, audit inventory, review storage, ordering, and disposal documentation, in all areas, esp ADC. DEA focuses on systems not missing drugs.

**3. Right to Refuse / Warrant**
Facilities may legally refuse consent. DEA may then seek an administrative inspection warrant. Know your institutional protocol BEFORE DEA arrives.

**4. Inspection Triggers**
Random cyclic (every 3–5 years); anonymous tips; outlier data flagged by ARCOS or SORS; diversion reports. Adverse findings → Letter of Admonition, penalties, or prosecution.

**5. Documentation is your Legal Shield**
Thorough records of legitimate dispensing decisions, red flag resolution, PDMP checks, and clinical justification for high-dose or off-label CS use protect individual pharmacists.

**6. Mock Inspections and Diversion Prevention Practices**
Conduct internal mock DEA-style audits annually. Maintain an inspection-ready binder: DEA registrations, biennial inventory, receipt/dispensing/disposal records, audit logs.

thefdalawblog.com: I Hear You Knockin' Parts 1-3 (2021); Mock Inspections (Sep 2025); Inspection Binder (Aug 2025) | DEA 21 CFR 1316

41

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## DEA Order to Show Cause: What Every Hospital Pharmacist Must Know

- A Show Cause Order initiates proceedings to revoke or suspend a DEA registration
  - ✓ Triggers can include diversion issues, recordkeeping discrepancies, suspicious orders, dispensing or prescribing patterns and security weaknesses / failures (ADC), regulatory non-compliance / non-reporting

Upon receipt:

- ✓ Coordinate with legal IMMEDIATELY…consider personal legal representation
- ✓ Do NOT respond or communicate without attorney guidance EVER
- ✓ Preserve ALL records — Never destroy anything

- Ensure your institution performs mock inspections, has a response team and and a culture of reporting
- Individual pharmacists may receive separate Show Cause Orders and risk losing their ability to handle CS Documentation is your best defense

thefdalawblog.com: DEA Order to Show Cause (Apr 2025) | DEA Form 106: deadiversion.usdoj.gov | 21 CFR 1301.76

42

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Current State of Practice: Corporate Policies vs. Statutory Law

- A critical tension exists between professional practice, corporate policies, and statutory law
  - ❖ Pharmacists and technicians are left balancing license, patient therapy, risk, corporate oversight, sometimes ambiguous law and personal bias
- Pharmacists/Technicians must reconcile employer policy with legal/moral obligations and liabilities
  - ✓ If financial liability is your biggest concern get malpractice insurance and retain a lawyer
  - ✓ If licensure is your biggest concern, then familiarize yourself with the rules, attend Board of Pharmacy Disciplinary Meetings and practice within the four concerns of the law
  - ✓ If job security is your biggest concern, then follow your policy and procedure manual
  - ✓ If clinical impact is your biggest concern, then become BCPMP
- Also remember pain hurts…our professional responsibility is to fill valid prescriptions and support pain relief within the boundaries of the law

thefdalawblog.com: Prescribing/Dispensing Red Flags (2024, 2025) | FL Board of Pharmacy 64B16-27.831 | 21 CFR 1306.04 | ASAM: asam.org (Jul 2024)

43

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

**The Evolving Landscape of Controlled Substances:**
**2026 Regulatory Updates, Technology Innovations, and Stewardship Best Practices**

**Jessica M. Lemoine, PharmD, MS**
Director of Pharmacy
Baptist Health South Florida

44

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## What's Making Headlines

**Miami (2023)** — **Nurse at hospital caught and admitted to stealing fentanyl and midazolam**

- Arrested and charged with grand theft and tampering with a consumer product
- Held in correctional center on $22,000 bond

**New Hampshire (2022)** — **At least 200 bags of fentanyl went missing in a four-month period**

- The nurse allegedly admitted to taking them
- Licenses temporarily revoked
- Nursing license of the hospital CNO temporarily revoked pending hearing
- Pharmacy license of the hospital pharmacy director was suspended temporarily
- Pharmacy board pending decision to suspend or revoke pharmacy permit

Gardner, C. (2023, August 18). *Nurse admits to swapping fentanyl for saline. Miami-Dade police say.* Local 10 News. https://www.local10.com
Rose, M. & Cardinal, E. (2022, June 10). *How did 7 bottles of fentanyl go missing from a hospital? Regulators launch investigation.* Becker's Hospital Review. https://www.beckershospitalreview.com

45

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Corresponding Responsibility

**21 CFR § 1306.04(a)** – *Purpose of Issue of Prescription*

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner…**The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.**"

U.S. Drug Enforcement Administration. (2026). *Purpose of issue of prescription* (21 C.F.R. § 1306.04(a))

46

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## DEA Enforcement Actions

**Corresponding Responsibility** — Elk Pharmacy (2024)

- $500,000 civil penalty
- Federal injunction restricting controlled substance dispensing
  - **Dispensed opioids despite clear "red flags"** indicating potential misuse or diversion
  - Dispensed **high-dose, long-term opioid prescriptions exceeding guideline**
  - Filled prescriptions for patients showing **doctor shopping / pharmacy shopping behavior**
  - Filled prescriptions from a **provider barred from prescribing controlled substances**

**Record Keeping** — Caduceus USA Medical Pharmacy, LLC (2020)

- **$250,000** civil penalty
- Surrendered DEA registration
  - Failed to maintain **accurate records** of controlled substances purchased and dispensed
  - Failed to perform required **biennial inventory count**
  - Did not **maintain controlled substance records separately** from general business records
  - Distributed a controlled substance outside the scope of its DEA registration

U.S. DOJ / DEA. *Court orders NC pharmacy to pay $500K and restrict dispensing.* Dec. 4, 2024
U.S. DOJ. *Pharmacy pays $250K to resolve CSA violations.* Nov. 15, 2020

47

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Preventing Diversion

- Controlled substance (CS) diversion within healthcare systems can create serious risks for patient safety, cause significant harm to the individual diverting the drugs, and expose organizations to substantial legal and regulatory liability.
- Diversion jeopardizes patients both directly and indirectly - through inadequate pain management, inaccurate or incomplete medical documentation, potential exposure to infectious diseases from contaminated drugs or needles, and impaired performance by healthcare workers.
- Beyond patient harm, diversion also places the organization at risk for regulatory violations, fraudulent billing, legal consequences, and erosion of community trust.

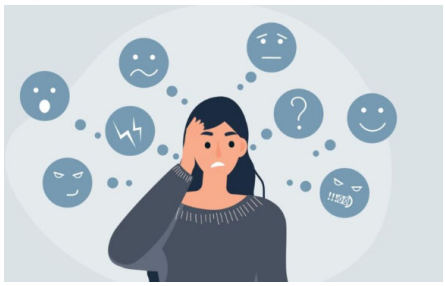
Berge KH, Dillon KR, Sikkink KM, et al. Diversion of drugs within healthcare facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. Mayo Clin Proc. 2012;87(7):674-682
Schaeffer MH, Perz JF. Outbreaks of infections associated with drug diversion by US healthcare personnel. Mayo Clin Proc. 2013;88(8):878-887.

48

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Recognizing Suspect Impairment

- Poor judgment
- Memory lapses
- Drop in attendance and performance at work
- Appears fearful, anxious, or paranoid, with no reason
- Volunteering for shifts or duties outside their norm
- Person may exhibit some physical signs such as tremors, sweating, changes in appetite and sleep patterns



49

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Reporting Guidelines for Suspected Diversion

- Immediate Internal Reporting
- Secure Evidence and Protect Patients
- Conduct a Timely, Documented Investigation
- DEA Reporting Requirements
- State and Local Reporting

50

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Treatment and Recovery Pathways for Impaired Personnel

**State Professional Health Programs (Preferred Pathway)**

- Professional Health Programs (PHPs) are considered the gold standard for impaired healthcare workers.

What they provide:

- Confidential assessment and referral to treatment
- Structured treatment recommendations
- Long-term monitoring (often 3–5 years)
- Mandatory drug testing
- Documentation of fitness for duty

**Employee Assistance Programs (EAP)**

- EAPs are a supportive entry point, but not sufficient alone for confirmed impairment

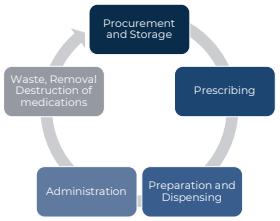
What they provide:

- Initial screening
- Confidential counseling
- Referral coordination
- Support for stress, burnout, or early substance misuse
- EAPs should be used in conjunction with formal treatment and monitoring programs

51

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

Controlled substance diversion can occur at any point in the **Medication Use Process**




John Clark, Toni Fera, Christopher Forster, Kristine Cullickson, Amanda Haye, Lee Murdaugh, Ricky Ogden, Brian O'Neal, Jordan Ruth, Tyler Vest, ASHP Guidelines on Preventing Diversion of Controlled Substances, American Journal of Health-System Pharmacy, Volume 79, Issue 24, 15 December 2022, Pages 2279–2306, https://doi.org/10.1093/ajhp/zxac236

52

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

**Procurement and Storage**

- Purchase order and packing slip removed from records
- Unauthorized individual orders CS on stolen DEA 222 forms
- Product container compromised

**Prescribing**

- Prescription pads are diverted or forged to obtain CS
- Prescriber self-prescribes CS
- Verbal orders for CS created, but not verified by the prescriber
- Written prescriptions altered by patients

## Common Risk Points and Methods of Diversion

**Preparation and Dispensing**

- CS are replaced by product of similar appearance when prepackaging
- Removing volume from pre-mixed solutions
- Multi-dose vial overfill diverted
- Prepared syringe content replaced with saline solution

John Clark, Toni Fera, Christopher Forster, Kristine Cullickson, Amanda Haye, Lee Murdaugh, Ricky Ogden, Brian O'Neal, Jordan Ruth, Tyler Vest, ASHP Guidelines on Preventing Diversion of Controlled Substances, American Journal of Health-System Pharmacy, Volume 79, Issue 24, 15 December 2022, Pages 2279–2306, https://doi.org/10.1093/ajhp/zxac236

53

FSHP 60th Annual Meeting — Sparkle Shine Celebrate!

## Common Risk Points and Methods of Diversion

**Administration**

- CS are withdrawn from ADC on discharged or referred patient
- Medication is documented as given but not administered to the patient
- Waste is not adequately witnessed and subsequently diverted
- Substitute drug is removed and administered while CS are diverted
  Increased use of the automated dispensing cabinet *Override* function
- Inventory function without dispense or refill action
- Frequent transaction cancellations

**Waste, Removal and Destruction**

Offer to administer medications to patients that are not under the person's care

- Wasting medication without a witness
- CS waste is removed from unsecure waste container
- CS waste in syringe replaced with saline
- Expired CS are diverted from holding area

54

**ASHP Controlled Substances Diversion Prevention Program Assessment Tool**

**ORGANIZATIONAL-LEVEL QUESTIONS**

**Organization Oversight and Accountability**

**O.01** **The organization has an established Controlled Substances Diversion Prevention Program (CSDPP) committee that provides leadership and direction for developing policies and procedures for overseeing the CSDPP.**
- ☐ Yes
- ☐ No
- ☐ Not Applicable

**O.01.1** **The CSDPP committee includes representation from (select all that apply):**
- ☐ Administration
- ☐ Anesthesia
- ☐ Communications/Media Relations
- ☐ Compliance
- ☐ Employee Health
- ☐ Human Resources
- ☐ Infection Control
- ☐ Information Technology
- ☐ Legal
- ☐ Medical Staff
- ☐ Nursing

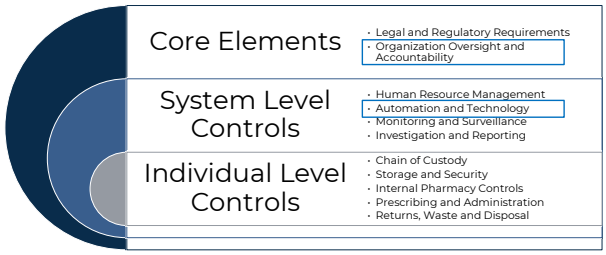
American Society of Health-System Pharmacists. (n.d.). Controlled substance diversion prevention. https://www.ashp.org/diversion-prevention

- Practical resource to help organizations determine how their site aligns with the best practice recommendations provided in the ***ASHP Guidelines on Preventing Diversion of Controlled Substances (2022).***
- Following completion of the gap assessment, the results reveal opportunities for enhancement and support the creation of a targeted action plan for the organization.

55



## Controlled Substance Diversion Prevention Program




John Clark, Toni Fera, Christopher Fortier, Kristina Gustickson, Amanda Hays, Lee Mundaugh, Ricky Ogden, Brian O'Neal, Jordan Rush, Tyler Vest, ASHP Guidelines on Preventing Diversion of Controlled Substances, American Journal of Health-System Pharmacy, Volume 79, Issue 24, 15 December 2022, Pages 2279–2294, https://doi.org/10.1093/ajhp/zxac260

56



## Organization and Oversight Accountability

- **Promote a Team-Based Approach**
  - Encourage open communication, shared responsibility, and non-punitive reporting so staff feel safe raising concerns.
- **Controlled Substance Diversion Prevention Committee**
  - Committee representatives should include but not limited to medical staff, nursing, security, human resources, compliance, risk management, administration, legal, communications, information technology and employee health.
  - Provide leadership and direction for developing policies and procedures for overseeing the controlled substance diversion prevention program.
  - Monitor surveillance data, review cases, and close process gaps.
- **Provide Ongoing Staff Training**
  - Educate teams on diversion risks, red flags, and proper documentation practices to maintain vigilance.

57



## Effective Controls

**21 CFR §1301.71-Security Requirement**

All registrants must provide **"effective controls and procedures to guard against theft and diversion of controlled substances."**

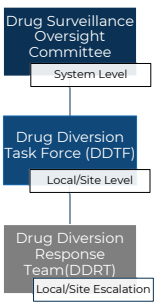
- Well educated and vigilant staff is a powerful resource in the fight against drug diversion
- Training can be an effective control
  - Training should be:
    - Standardized-employee onboarding, annually
    - Measurable-knowledge check/quizzes
    - Documented

U.S. Drug Enforcement Administration. (2024). Security requirements generally (21 C.F.R. § 1301.71)

58



## Controlled Substance Surveillance Program




59



## Drug Surveillance Oversight Committee

System Level

- **Membership:** Executive Sponsor, Medical Director, Anesthesia, Nursing, Pharmacy, Risk Management, Employee Health, and Legal
  - Review the compliance of the drug diversion program
  - Conducts yearly audits of Drug Diversion Task Force Program compliance
  - Ensure compliance with regulatory requirements e.g., Drug Enforcement Administration (DEA), regulatory boards, survey agencies, accreditation standards, law enforcement, system policies
  - Evaluate and review new emerging solutions
  - Develop new policies and procedure for controlled substances

60

## Drug Diversion Task Force (DDTF)

Local/Site Level

- **Membership:** Hospital Leadership (COO), Chief Nursing Officer (CNO), Chief of Anesthesia, Directors of Nursing(DON), Director of Pharmacy (DOP), Director of Security, Director of Human Resources, Director of Risk, Director of Quality, and Employee Health
  - Review and trend *monthly* key performance indicators, auditing data and compliance metrics for Pharmacy, Anesthesia and Nursing Departments
  - Review user and area access
  - Assess data for opportunities for improvement and develop action plans

61



## Drug Diversion Response Team(DDRT)

Local/Site Escalation

- **Membership:** Hospital Leadership (COO), Chief Nursing Officer (CNO), Chief of Anesthesia (as needed), Directors of Nursing (DON), Director of Pharmacy (DOP)- CHAIR, Director of Security, Director of Human Resources, Director of Risk and Employee Health
  - Responsible for leading and directing the investigation and manages the investigation of all reports suspected drug diversion
  - 24-hour escalation time frame
  - Develop recommendations and next steps with input from all disciplines
  - Incident Reporting

62



## Integrating Technology

Key Capabilities:

- **Continuous Data Collection and Analysis**
  - Integrate data from multiple sources—such as automated dispensing cabinets (ADC) electronic health records (EHRs), RFID tracking, and AI-driven analytics—to provide continuous visibility into medication handling and usage.
- **Early Warning and Rapid Detection**
  - Gather and analyze data from EHRs, dispensing systems, and other clinical sources to detect unusual patterns or discrepancies as they emerge. This proactive approach improves early detection of adverse events and diversion risks.
  - Advanced monitoring platforms use AI and machine learning to identify emerging safety concerns, abnormal access behaviors, or inventory irregularities, enabling faster intervention.
- **Automated Reporting & Prioritization**
  - Automation reduces reliance on manual reporting, improves accuracy, and prioritizes high-risk signals for investigation, streamlining hospital oversight workflows.

63



## Evaluating Drug Diversion Technologies

| | Option 1 | Option 2 |
|---|---|---|
| **Primary focus** | Medication reconciliation & discrepancy tracking | AI-powered diversion detection & clinical surveillance |
| **Approach** | Transaction-level matching | Behavioral + multi-source analytics |
| **AI sophistication** | Moderate (rules + automation) | Advanced (ML risk models, >60 risk factors) |
| **Data sources** | Primarily pharmacy + ADC + inventory | 7+ systems (EHR, ADCs, wholesaler, HR, etc.) |
| **Detection style** | Flags mismatches ("something doesn't add up") | Predicts suspicious behavior patterns |
| **Workflow support** | Strong (task queues, investigation tools) | Strong + integrated analytics dashboards |
| **Scope** | Pharmacy-focused | Enterprise-wide (pharmacy, nursing, anesthesia, etc.) |
| **Resources** | ++++ | ++ |
| **Financial Impact** | $$ | $$$$ |

Wolters Kluwer, Sentri7 Drug Diversion solution overview https://www.wolterskluwer.com/en/solutions/sentri7/sentri7-clinical-surveillance/drug-diversion
Blueslight, ControlCheck Drug Diversion Monitoring https://blueslight.com/drug-diversion-monitoring

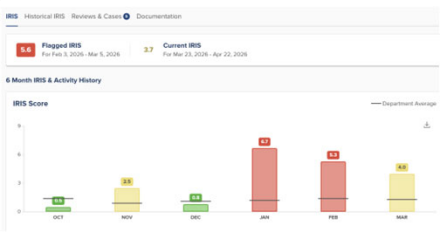
64



## Predictive Analytics

**Individual Risk Identification Score (IRIS)**
- Machine learning driven metric that identifies provides who's behavior suggests risk for controlled substance diversion

**Core Factors that contribute to IRIS Score:**
1) Action Times
2) Waste Networks
3) Dispense Trends
4) Variance Trends
5) Shift Analysis
6) Peer Benchmarking
7) Anomalous Behavior Detection




65



## AI Integrated Waste System

Enhances diversion prevention through high-definition, 360-degree video monitoring that documents every disposal event in real time, improving transparency, auditability, and accountability.


Powering Your Hospital and Pharmacy Operations | Blueslight

66

## Challenges of Managing Diversion Monitoring Platforms

- **High Data Volume and Alert Fatigue**
  - Effective monitoring requires dedicated pharmacy, nursing, compliance and IT support.
- **Resource and Staffing Burden**
  - Teams can become overwhelmed, delaying investigation of true diversion risks.
  - Smaller hospital may struggle to maintain the personnel for timely review.
- **User Adoption and Engagement**
  - Staff may resist new monitoring process and perceive them as punitive resulting in poor engagement.

67

## Strengthening Diversion Prevention in Pharmacy Practice

- Pharmacy Technicians play an important role in diversion prevention
- Pharmacy Technicians are the first to detect abnormalities within pharmacy internal controls
- Responsibilities generally fall into three tightly connected areas: **handling, documentation, and reconciliation**

68

## Medication Handling

- **Technician responsibilities:**
  - Automated dispensing cabinets- restocking and delivery
  - Internal return bin
  - CII Safe/secure vaults
  - Unit dose packaging and IV preparation
  - Witness and documentation of waste often with a Nurse/Pharmacist
  - Damaged product

69

## Medication Documentation

- **Technician responsibilities:**
  - Tracks dispensing, administration, waste and returns
  - Detailed audit trails for each transaction and users
  - Reconciling invoices with purchased stock
  - Reverse distributor-witness and double check

70

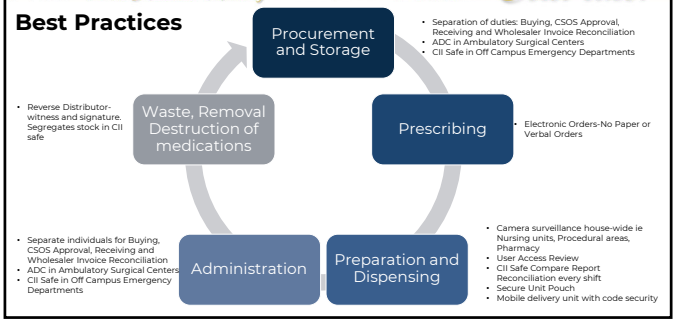
## Medication Reconciliation

**Technician responsibilities:**

- Anesthesia machine weekly counts
- Assist Pharmacist with CII safe Monthly count
- CII Safe Compare reports
- Resolve discrepancies at ADC
- Assist with biennial inventory

71

## Best Practices




72

FSHP 60th Annual Meeting Sparkle Shine Celebrate!

## Summary

- Implement a comprehensive, multidisciplinary approach to ensure shared accountability and oversight
- Deploy technology solutions that enable real-time visibility and predictive analytics to support timely decision-making
- Sustain organizational vigilance through continuous monitoring, routine audits, and staff education and engagement

73

FSHP 60th Annual Meeting Sparkle Shine Celebrate!

Questions?

74

FSHP 60th Annual Meeting Sparkle Shine Celebrate!

**The Evolving Landscape of Controlled Substances: 2026 Regulatory Updates, Technology Innovations, and Stewardship Best Practices**

**Matthew J. Seamon, PharmD, Esq**
Associate Professor
Nova Southeastern University Barry and Judy Silverman College of Pharmacy

**Jessica M. Lemoine, PharmD, MS**
Director of Pharmacy
Baptist Health South Florida

75