



PROGRESSIVE
SURGICAL
Huddle

Keeping you "in the know" in the ASC industry

got compliance?

a pharmacist's insights for success!

Gregory Tertes, R.Ph. ASC Pharmacist Consultants, Inc. 510-710-3640

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Gregory Tertes, R.Ph.





Pharmacist Consultant
ASC Pharmacist Consultants, Inc.

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LEARNING OBJECTIVES

- Understand the many regulators and rules of pharmaceutical waste disposal.
- Know how to comply with the essentials of Drug Enforcement Agency paperwork.
- Understand the changing rules for compounding pharmacies, and how to properly vet one for safety and accuracy.

TOPICS

- Medication Disposal → 
- DEA Paperwork Best Practices → 
- DQSA/Compounding Pharmacies → 
- Consultant Pharmacist - What to expect! → 

MEDICATION DISPOSAL



Hazardous Waste

WASTE

UNUSED

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MEDICATION DISPOSAL

Why do we care about it?

- To comply with Federal, State, and Local Laws and Regulations
- To comply with accrediting agency standards
- To protect patients and staff
- To protect the environment



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MEDICATION DISPOSAL

Federal, State, County, and Local Rules



City/County
Health
Departments



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MEDICATION DISPOSAL



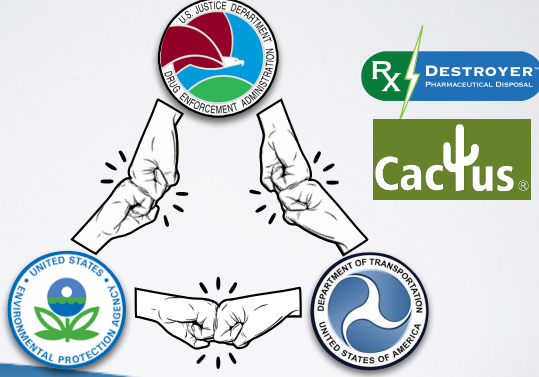
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WASTE

MEDICATION DISPOSAL

DEA Controlled Substances - Waste



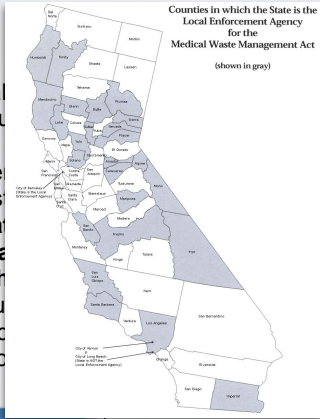
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WASTE

MEDICATION DISPOSAL

- Pharmaceutical substances" must meet requirements.
- "The Department of Health Services requires that controlled substances be disposed of in a secure container that is resistant to tampering and is clearly labeled as containing controlled substances. The container must be sealed and labeled with the name of the controlled substance and the quantity of the substance. The container must be disposed of in a secure container that is resistant to tampering and is clearly labeled as containing controlled substances. The container must be sealed and labeled with the name of the controlled substance and the quantity of the substance.
- "Under no circumstances should controlled substances be flushed down the drain or into the sewer system."



Counties in which the State is the Local Enforcement Agency for the Medical Waste Management Act (shown in gray)

Controlled substances are "controlled substances" as defined by the DEA. The DEA requires that controlled substances be disposed of in a secure container that is resistant to tampering and is clearly labeled as containing controlled substances. The container must be sealed and labeled with the name of the controlled substance and the quantity of the substance. The container must be disposed of in a secure container that is resistant to tampering and is clearly labeled as containing controlled substances. The container must be sealed and labeled with the name of the controlled substance and the quantity of the substance.

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Waste

MEDICATION DISPOSAL

"Pharmaceutical Waste"

Placer County

- Remove ALL medications from vials. (Empty vials)
- Waste is expelled into white pharmaceutical waste bins.
- Including controlled substance waste.
- Solidifier is used to ensure no free liquid liquid
- Incinerate



<https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx>

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Drug Quality and Security Act of 2013



Update: June 15, 2018

- FDA identified multiple substances in Guardian's product, including poloxamer 407 and poloxamer 407 degradants. FDA prepared in-house samples of Guardian's product and found that autoclaving and sonication caused the poloxamer 407 to degrade.
- The amount of poloxamer 407 in Guardian's product (12%) is much greater than the maximum amount of poloxamers in FDA-approved ophthalmic products for topical administration (0.1-0.2%)
- The safety profile of drug products intended for intravitreal injection containing poloxamer 407 is unknown.



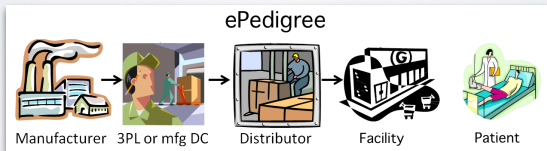
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Drug Quality and Security Act of 2013

DQSA Title II Drug Supply Chain Security Act

- Challenge the influx of counterfeit drugs that may ultimately reach end users or be provided by "dispensers"
- Requires a "pedigree" attestation (Track and Trace)



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CONSULTANT PHARMACIST , WHAT TO EXPECT!



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YOUR PARTNER FOR SAFE MEDICATION SOLUTIONS

SUPPORTING YOU TO BE SAFE EVERY DAY, NOT JUST SURVEY DAY





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THREE FOUNDATION PRINCIPLES

 Patient Safety

 Survey Success

\$ave Money



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SPECIALIST IN ASC

SERVICES

	Pharmacist	ASC Pharmacist Consultants
Check Refrigerator Log	✓	✓
Review Controlled Substance Log	✓	✓
Benchmarking		✓
Assistance with Drug Shortages		✓
Cost Containment Opportunities		✓
Newsletters		✓
Regulatory Guidance		✓
Chart Review		✓
QI Studies		✓
Educational Services		✓
Easy Access		✓
Controlled Drug Management		✓
Policies and Procedures		✓
Quarterly Reports		✓
Quarterly Audit with over 100 items		✓
Knowledge of Accreditation Standards		✓
Medication Safety Focus		✓



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Available on eSupport

eSupport/Operations/Medication Management/Compounding



HOME ESUPPORT • BLOG • FORUM ACCOUNT •

MEDICATION MANAGEMENT: COMPOUNDING

Many ASCs have been cited for drug compounding in their facility. The United States Pharmacopeia sets the medication-compounding standards. Below we have summarized the relevant provisions of the <CPT> guidelines on medication compounding.

[USP <797> Guideline: Pharmaceutical Compounding - Sterile Preparations](#)

If you are using compounded medications in your facility, you must get those medications from a 503B Pharmacy (Registered Outsourcing Facility). [Click here](#) for a table that lists the outsourcing facilities that have submitted registration information that has been determined to be complete. **(NEW)**

[Information Concerning Outsourcing Facility Registration](#)

A contract should be executed between the ASC and the compounding pharmacy. See the Recommended Facility Contract Documentation table on the [Contracts](#) page for the specific supporting documentation that should be obtained. There is also a policy on the [Policy and Procedure Update](#) page.

[CLICK LINKS BELOW TO DOWNLOAD](#)

- [Medication Compounding Clarification](#)
- [PCAB Accreditation Manual](#)
- [Choose an Accredited Pharmacy Fact Sheet](#)

SEARCH

MEDICATION MANAGEMENT

Overview

Compounding

Controlled Substances

Eye Drops

Formulary

Medication Labeling

Medication Safety

Resources

Join the Community!

- For the resources referenced today and SO MUCH MORE...
- Request your free web demo today
- www.progressivesurgicalsolutions.com/esupport
- Email us at info@pss4asc.com
- Or call us! (855) 777-4272



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Mark your Calendars!



\$75

or

FREE

For members

Friday August 24, 2018 11AM PT/ 2PM ET

INFECTION CONTROL RISK ASSESSMENT

Phenelle Segal, RN, CIC
Infection Control Consulting Services

Friday October 26, 2018 11AM PT/ 2PM ET

ASK THE CLINICAL DIRECTOR/ADMINISTRATOR PANEL

Minda Soria, RN
April McElheny, RN
Joan Conine
Jared Abel

Mark your Calendars!



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Friday July 23, 2018 11AM PT/ 2PM ET

QI STUDY REVIEW

Vanessa Sindell, MSN, BSN, RN

Friday September 17, 2018 11AM PT/ 2PM ET

WORKING EFFECTIVELY WITH YOUR MEDICAL STAFF

Alison Galloway, BSN, RN
LaPeer Surgery Center

Get the Full Line Up!

For the full 2018 Webinar Line up visit our website:

<https://progressivesurgicalsolutions.com/progressive-webinars/>



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