

Oral Chemotherapy and In-House Dispensing, and Other Pharmacy Challenges

DGH Consulting

Dawn Holcombe, MBA, FACMPE, ACHE

Agenda

- ▶ The roles and challenges of specialty pharmacy, pharmacy benefits managers, and in-house physician dispensing for oral oncology drugs
- ▶ Changes affecting pharmacy regulations for oncology centers
- ▶ What are USP <797> and <800> and why do we care?
- ▶ The impact for medical practices

Oral Drugs A Rising Component of Care

- ▶ Estimated to account for 25% to 33% of all anti-cancer agents in the pipeline
- ▶ In 2015, FDA approved 18 cancer drugs, 9 were orals
- ▶ Higher Cost
- ▶ Not usually stocked in retail pharmacies
- ▶ Often in combination with intravenous treatments
- ▶ Require patient monitoring and oversight
- ▶ Similar side effect profiles to injections/infusions
- ▶ Notably lower patient compliance and adherence, for many reasons
 - ▶ Financial
 - ▶ Patient decisions

Oral Drug Coverage

- ▶ Commercial - billed under pharmacy benefits, not medical benefits
- ▶ Limited under Medicare Part B
- ▶ Medicare Part D
- ▶ As part of drug plans for Medicare Advantage contractors (Part C)
- ▶ Patient Obligations
 - ▶ Pharmacy drug tiers with co-pays and co-insurance
 - ▶ Benefit Design Co-pays and Co-insurance
 - ▶ On formulary positioning
 - ▶ Medicare - Part D donut hole, out of pocket expenses (no supplemental insurance or co-pay coupons allowed)

In-Office Dispensing

- ▶ Almost half of US community oncology practices
- ▶ Competition: retail pharmacy, pharmacy benefit managers, specialty pharmacies
- ▶ State Laws: Vary related to physician license and pharmacy regulations. (Not allowed in MA, MT, TX and UT) Usually address:
 - ▶ Providing prescriptions
 - ▶ Disclosures to patient of rights for other dispensing options
 - ▶ Additional permits and licenses that may be needed
 - ▶ Requirements for proper medication labeling, dispensing and direct physician supervision of dispensing
 - ▶ Drug and inventory storage requirements
 - ▶ Limitations of controlled substance dispensing
 - ▶ Pharmaceutical recordkeeping requirements
 - ▶ Limitations on employment of pharmacists or staff with “pharmacy” in title

In Office Dispensing Benefits

- ▶ Close to patient
- ▶ Coordination of coverage and dispensing while patient in office and with other treatments
- ▶ Short fill options aligned with care to monitor effectiveness, tolerance and symptoms
- ▶ Rapid physician management of adverse events and needed modifications

In-Office Dispensing: Challenges

- ▶ Cost of Drug acquisition and inventory
- ▶ Limitations on Permitted Dispensing Providers (state, regulatory and payer restrictions)
 - ▶ Network limitations
 - ▶ First fill limitations
- ▶ Competition
- ▶ Dispensing Network Control and Restrictions (CVS/Caremark)
- ▶ Pharmacy Management and Reporting Needs
- ▶ Patient Compliance and Adherence Expectations and Responsibility
- ▶ Technology needs for reporting and analytics for patient compliance, adherence, outcomes and appropriate utilization oversight

Dispensing Network Challenges

- ▶ Community Oncology Alliance - White Paper *Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care* accessible at: http://www.communityoncology.org/wp-content/uploads/2016/08/PBMs_Physician_Dispensing-WhitePaper_COA_FL.pdf
- ▶ 5 PBMs control network access for <80% of US covered lives
- ▶ CVS/Caremark - redefined Medicare definition of pharmacy networks allowed to dispense Part D drugs
- ▶ CVS Caremark eliminating physician in office dispensing in 2017 for covered Part D patients
- ▶ PBM Dispensing fees for white-bagged drugs

In-Office Dispensing: Strategies for Success

- ▶ Learn the regulations and laws governing in office dispensing in state
- ▶ Investigate development resources and in-office dispensing support resources, learn from best practices and experienced cancer groups
- ▶ Evaluate volumes and patient mix for potential inventory and insurance requirements
- ▶ Engage local and federal agencies regarding the value of physician in-office dispensing for oral agents
- ▶ Review facilities, projected volume, margins and competition in local market for in-office dispensing
- ▶ Review patient needs and resources in local market, identify values and care enhancements possible from in-office dispensing
- ▶ Educate: practice team, payers, employers, regulators, legislators, patients about the issues and advantages of in-office dispensing
- ▶ Integrate the in-office dispensing and support into the practices care management and quality enhancement initiatives, track for improved patient outcomes and quality measures

In-Office Dispensing and Payers

- ▶ Coverage beyond the first fill (contracts with NCODA practices)
 - ▶ Excellus Blue Cross Blue Shield
 - ▶ Univera Healthcare
 - ▶ CDPHP
 - ▶ MVP Healthcare
 - ▶ Regence BlueCross BlueShield
- ▶ Limitations to First Fill
- ▶ Limited Participation in Dispensing Networks
- ▶ No limitations at this time
- ▶ Don't forget Employers!

CT Regulations

- ▶ Chapter 370 - Medicine and Surgery https://www.cga.ct.gov/current/pub/chap_370.htm#sec_20-14c
- ▶ Dispensing and labeling of drugs by prescribing practitioner
- ▶ **Sec. 20-14e. Dispensing of drugs. Prescribing and dispensing of oral antibiotic drugs for chlamydia or gonorrhea. Dispensing of contact lenses containing a drug or ocular agents-T.** (a) A drug dispensed by a prescribing practitioner shall be personally dispensed by the prescribing practitioner and the dispensing of such drug shall not be delegated except that, in emergency departments of acute care hospitals licensed under chapter 368v, the tasks related to dispensing such drug may be carried out by a nurse licensed pursuant to chapter 378 under the supervision of the prescribing practitioner.
- ▶ (b) A patient's medical record shall include a complete record of any drug dispensed by the prescribing practitioner.
- ▶ (c) A prescribing practitioner dispensing a drug shall package the drug in containers approved by the federal Consumer Product Safety Commission, unless requested otherwise by the patient, and shall label the container with the following information: (1) The full name of the patient; (2) the prescribing practitioner's full name and address; (3) the date of dispensing; (4) instructions for use; and (5) any cautionary statements as may be required by law.
- ▶ **Sec. 20-14f. Report to commissioner of intent to continue to dispense drugs other than professional samples.** A prescribing practitioner who, as part of his practice, dispenses any drug other than professional samples shall notify the Commissioner of Consumer Protection that he is engaged in the dispensing of drugs and shall, biennially, upon the date of renewal of the controlled substance registration required by section 21a-317, inform the commissioner of his intent to continue to dispense drugs to his patients.

CT Physicians and Pharmacies

- ▶ Chapter 400j - Pharmacy
https://www.cga.ct.gov/current/pub/chap_400j.htm#sec_20-596
- ▶ **Sec. 20-596. (Formerly Sec. 20-168b). Ownership of pharmacies by prescribing practitioners.** (a) No prescribing practitioner, spouse of a prescribing practitioner, except a spouse who is a pharmacist, or dependent child of a prescribing practitioner shall have an ownership or investment interest in a pharmacy.
- ▶ **Sec. 20-597. (Formerly Sec. 20-169). Pharmacy to be supervised and managed by pharmacist. Regulations re prescription department. Change in management, ownership or name of pharmacy.** (a) No place of business may be operated as a pharmacy unless a pharmacy license has been issued for the place of business and unless it is under the direct supervision of a pharmacist on the premises
- ▶ (b) In addition to the on-premises supervision of a pharmacy required in subsection (a) of this section, a pharmacy shall be managed by a pharmacist practicing at the pharmacy on a full-time basis who is listed as manager in the application for a pharmacy license made under section 20-594 or enrolled with the commission under subsection (c) of this section. The managing pharmacist may also act as the supervising pharmacist. No pharmacist may manage more than one pharmacy at the same time.

Pharmacy Technician Duties

Job Title: Pharmacy Technician / Trainee	Department: Pharmacy
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Job Summary:

Reports directly to the Pharmacy Supervisor and responsible for the preparation of the prescription by retrieving, counting, pouring, weighing, measuring, and sometimes mixing the medication. Prepares the prescription labels, selects the type of prescription container, and affixes the prescription and auxiliary labels to the container. Computes and determines price and files the prescription, which must be checked by a Registered Pharmacist before it is given to the patient.

Duties and Responsibilities:

1. Greets and receives customers and provides assistance by explaining and clarifying prescriptions, answering simple queries, providing assistance in locating pharmacy items and etc.
2. Assists the Registered Pharmacist in providing and dispensing medication and other health care products to patients.
3. Receives written prescriptions or requests for prescription refills from patients and prescriptions sent electronically from the doctor's office.
4. Performs routine tasks to help prepare prescribed medication for patients, such as counting tablets and labeling bottles.
5. Consults the Pharmacy Supervisor and/or Registered Pharmacist and refers any questions regarding prescriptions, drug information, or health matters to a pharmacist.
6. Verifies whether the information on the prescription is complete and accurate.
7. Prepares the prescription by retrieving, counting, pouring, weighing, measuring, and sometimes mixing the medication.

In-Office Dispensing: Resources

- ▶ ACCC Publication: Dispensing Pharmacy: A Value Proposition for Oncology Practices <https://www.accc-cancer.org/resources/pdf/Dispensing-Pharmacy-A-Value-Proposition-for-Oncology-Practices.pdf>
- ▶ Community Oncology Pharmacy Alliance (COPA) <http://www.coapharmacy.com/>
- ▶ McKesson Specialty Health <https://oncology.mckessonspecialtyhealth.com/clinical-tools/in-office-dispensing>
- ▶ National Community Oncology Dispensing Association, Inc. <http://www.ncoda.org/>
- ▶ Oncology Supply (ION) Specialty Oncology Network <https://www.oncologysupply.com/Solutions/Dispensing>

Why Are Pharmacy Regulations Affecting Medical Practices and Hospitals?

Organizations ranging from the federal Food and Drug Administration, state and federal Occupational Safety Administrations, state boards of pharmacy and legislatures, and clinical research and healthcare networks are selectively regulating and enforcing compliance with USP Chapters in the oncology pharmacy space, including in oncology cancer centers and practices.

Prudent clinical practice requires that oncology cancer centers and practices review their own processes and facilities for compliance, as well as develop an ongoing continuous quality improvement process for future applications and requirements.

Pharmacy Regulatory Process

- ▶ FDA
 - ▶ US Pharmacopeia
 - ▶ State Boards of Pharmacy
 - ▶ State Legislatures
-
- ▶ Licensed pharmacy - falls under these processes

Who makes the rules for doctors?

- ▶ Medical Board
- ▶ Licensing
- ▶ Hospitals

- ▶ Federal Agencies - OSHA, FDA, NIOSH, JCHO
- ▶ Professional Societies - ASCO, ONS
- ▶ State Agencies - Insurance Commission, Board of Pharmacy
- ▶ Other Agencies - FDIC, IRS, GAO
- ▶ Other Entities - NCQA, USP

- ▶ Public Opinion and Pressure

What is USP?

- ▶ A scientific nonprofit organization
 - ▶ Sets standards for identity, strength, quality and purity of medicines worldwide
- ▶ USP drug standards are enforceable in the United States
- ▶ USP does not do its own enforcement - left to FDA, Joint Commission and individual state boards of pharmacy
- ▶ Boards of pharmacy enforcement are limited to licensed pharmacies, historically.
- ▶ Local State legislatures starting to consider legislation based upon USP standards - Maryland
- ▶ JCAHO wrote in 2006 they were not (at that time) surveying for compliance with the details of USP 797.

What are <797> and <800>

- ▶ USP General Chapter <797> of the United States Pharmacopeia is an enforceable set of standards describing procedures and requirements for the compounding of all sterile products.
- ▶ USP Chapter <797> has been adopted and/or enforced by the Food and Drug Administration (FDA), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and now, all State Boards of Pharmacy.
- ▶ The purpose of USP <797> is to prevent harm and fatality to patients due to the improper preparation of compounded sterile products.
- ▶ The purpose of USP <800> is to extend this same protection to the people who prepare and handle of hazardous drugs.

The Objective of USP <797>

- ▶ The objective of USP Chapter <797> is to prevent harm to patients, including death, which could result from the following with respect to Compounded Sterile Preparations (CSPs)
 - ▶ •Microbial contamination
 - ▶ •Excessive bacterial endotoxins
 - ▶ •Variability in the intended strength of correct ingredients
 - ▶ •Unintended chemical and physical contaminants
 - ▶ •Ingredients of inappropriate quality.

Why Do We Care About <797>?

- ▶ It claims to be the national standard, and is often taken as such until challenged
- ▶ Seismic complications in pharmacy compounding have widened the spotlight of change to include practices and hospitals
- ▶ It is on the books and enforceable by anyone in authority who chooses to point their finger at the chapter.
- ▶ We are vulnerable in the court of public opinion even if not technically addressed by the chapter

Why new USP regulation spotlight?

- ▶ preventable patient morbidity and mortality related to poor pharmacy sterile compounding practices
- ▶ 1998 - Congress exempted compounding pharmacies from oversight of FDA - theory- mixing drugs one prescription at a time didn't warrant federal inspection
- ▶ New England Compounding Center - 2012
 - ▶ 17,000 vials of a steroid contaminated with a fungus shipped to clinics and hospitals in 23 states
 - ▶ More than 50 patients died, around 700 injured
- ▶ New Public and regulatory scrutiny

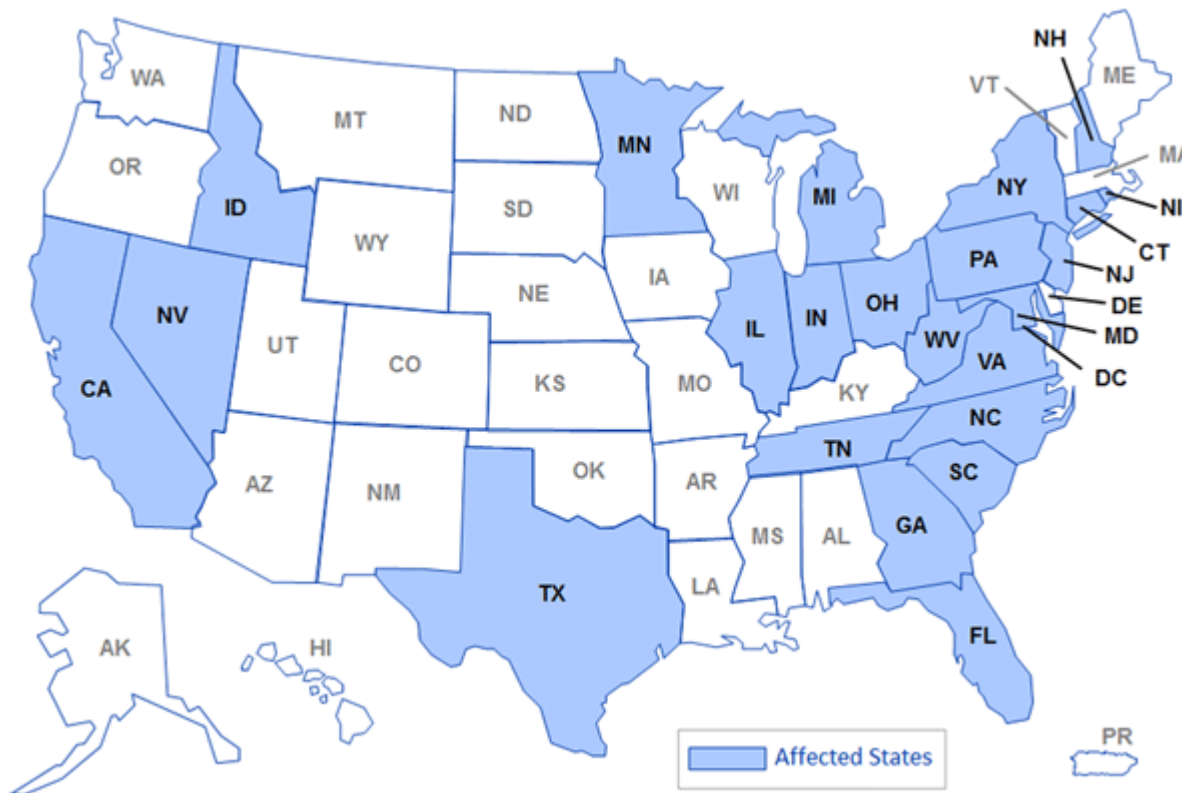
Fungal Meningitis Outbreak of 2012

- ▶ New England Compounding Center (NECC)
 - ▶ Licensed as a pharmacy
 - ▶ *BUT ACTED* like a manufacturer
 - ▶ Took advantage of gaps in the regulatory system
 - ▶ Massive Regulatory failure
- ▶ Distributed thousands of injectable dosage forms into interstate commerce that were contaminated with microbes
 - ▶ 17,000 multiple dose vials were recalled
 - ▶ 751 patients infected in 20 states
 - ▶ 64 died
 - ▶ Most survivors must continue to take a noxious mix of antifungal drugs
- ▶ <797> never failed pharmacy - a few pharmacies failed <797>

Fungal Meningitis Aftermath

- ▶ Media Attention - Public Outrage - Congressional Hearings
- ▶ “There OUGHT to be a LAW!” (there already was a law)
- ▶ Federal - Drug Quality and Security Act of 2013
- ▶ States - Many, many revisions of state administrative regulations (pharmacy, medicine, nursing) - some in place, more on the way
- ▶ Enforcement Paradigm Shifted:
 - ▶ Huge increase in numbers of inspectors
 - ▶ Giant leaps in training, competency, and acumen of inspectors
 - ▶ Sea Changes in methodologies of enforcement (NABP’s VPP, etc.)

Map of Healthcare Facilities that Received Three Recalled Lots of Methyprednisolone Acetate (MPA) from NECC associated with the Multistate Outbreak of Fungal Meningitis and other Infections
OCTOBER 23, 2013 FURTHER UPDATES TO THE CASE COUNTS ARE NOT ANTICIPATED AT THIS TIME.



<http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>

Why do we care about USP <800>?

- ▶ USP 800 is written to identify safe handling of hazardous drugs for the protection of staff and patients.
- ▶ It is also written to apply to all healthcare settings.
- ▶ Once USP 800 becomes official (December 2019) , it is federally enforceable.
- ▶ Practices that are not compliant with USP 800 standards could face a loss of market share, adverse publicity, or enforcement obligations.

Implementation 2018

- ▶ The general chapter is going to go into effect December 1, 2019, following revision of <797> in late 2018 and early 2019
- ▶ Final Chapter is available for purchase: A good GAP Analysis and SOPs will match line by line
- ▶ Read carefully
- ▶ Consider Impact on your practice
- ▶ Consider messaging re enforcement and court of public opinion

2013 Drug Quality and Security Act

Triggers FDA
Enforcement Activity!

- ▶ Introduced 9/27/2013 and signed by President on 11/27/2013 in reaction to the Fungal meningitis contamination in MA.
- ▶ Distinguishes compounders engaged in traditional pharmacy practice from those making large volumes of compounded drugs without individual prescriptions
- ▶ Defines the FDA's role in oversight of outsourcing facilities
- ▶ Offers providers and patients better information about compounded drugs
- ▶ Clarifies current federal law regarding pharmacy compounding
- ▶ Establishes nationwide drug serial numbers

USP and Law Enforcement

- ▶ USP is non-governmental, private, independent, and science-driven;
- ▶ USP standards are enforceable by law if written into a local law, but USP itself has no enforcement capability or apparatus;
- ▶ Law enforcement authorities do not set standards, but have the power to enforce standards set by USP...
 - ▶ Food and Drug Administration (FDA) (federal government)
 - ▶ State Boards of Health, Medicine, Pharmacy, and Nursing (state government)
- ▶ Civil law suits can be based on failure to comply with USP standards. (negligence per se)

Recent Enforcement

- ▶ 4 hospital cancer centers
- ▶ 1 private practice
- ▶ In NH, Board of Pharmacy got involved with medical practice drug preparation
- ▶ FDA "Form 483"
 - ▶ Issued at conclusion of an FDA inspection where conditions are observed that may violate the Food Drug and Cosmetic Act and related Acts
 - ▶ Not all inclusive
 - ▶ Intended to trigger a response and correction
 - ▶ Will be considered as FDA determines if any further action is appropriate to protect public health

FDA Form 483 Issued to Private Oncology Practice - “Producer of Sterile Drug Products”

- ▶ **5 days after patient caregiver posts negative post regarding mold in office and care concerns on social media, FDA arrives for surprise inspection**
- ▶ “OBSERVATION #1 - The cleaning, disinfecting and upkeep of the equipment used to produce and prepare sterile drug products are inadequate. Specifically:
 - ▶ Non sterile wipes are used to clean and wipe down the surfaces of the Class II
 - ▶ An unknown concentration is used to clean the Class II.....
 - ▶ Apparent brownish soiled material was observed on the inside bottom edges of the Class II.....
 - ▶ The certification of the Class II....was not performed and the certification raw data fromwere not available for review
- ▶ “OBSERVATION #2 - Inadequate aseptic techniques demonstrated by the operators who prepare and handle sterile drug products. Specifically, during the simulation performed by the operators it was observed that
 - ▶ Non sterile gloves were used in the preparation of sterile drug products inside the Class II
 - ▶ The operators have never received any training nor have been qualified to prepare sterile drug products.
- ▶ OBSERVATION #3 - Inadequate facility design to prevent microbiological contamination of sterile drug products. Specifically,
 - ▶ The Class II... is located next to the main refrigerator and in close proximity of the Area without any air quality control in the surrounding area.
 - ▶ A sink is located approximately five feet away from the Class II....
- ▶ OBSERVATION #4 - Drug products purporting to be sterile are not tested to determine conformance to such requirements. Specifically,
 - ▶ The IV flush bag containing....does not bear an expiration date determined by appropriate stability data to assure it meets applicable standards of identity, strength, quality and purity at the time of use, which could be used on patients for over a period of On average until the inventory has been depleted.
 - ▶ There is no sterility testing performed on the IV flush bag containing to assure sterility after multiple withdrawals from the IV bag ports.
 - ▶ Expired sterile injectables were stored in the cabinet, including but not limited to Heparin....., Lidocaine.....and.....

USP and the Practice of Clinical Medicine

- ▶ Do USP standards govern the practice of medicine?
Yes.
- ▶ Has clinical oncology strictly adhered to pertinent USP standards to date?
No.
- ▶ Have there been serious consequences to oncology for ignoring USP standards?
No.
- ▶ Might there be serious consequences for ignoring USP standards in the future?
Yes.
- ▶ Which USP Standards are most pertinent to the Practice of Oncology?
General Chapter <797> and Proposed General Chapter <800>

Looking at USP <797> in detail

Sterile product compounding

- ▶ Does the typical oncology practice compound sterile products according to the previous definitions of CSPs?

Yes. Every day.

- ▶ Is there any way to practice clinical oncology without compounding sterile products?

Not in today's care delivery model.

- ▶ Should clinical oncology begin to gain compliance with USP <797>?

Place your bets.

Personnel Cleansing and Garbing Order

▶ Prior to entering buffer area or segregated compounding area

- ▶ Remove all personal outer garments
- ▶ Remove cosmetics
- ▶ Remove jewelry from hands, wrists, or any other visible body parts
- ▶ No artificial nails allowed
- ▶ Don PPE in the following order:
 1. Dedicated shoes or shoe covers
 2. Head and facial hair covers
 3. Face masks/eye shields
 4. Perform hand cleansing procedures
 5. A non-shedding gown

▶ Upon entering buffer area or segregated compounding area

1. Antiseptic hand cleansing with surgical scrub
2. Don sterile powder-free gloves

Facility Design Requirements

- ▶ Must have an ISO Class 5 environment as a Primary Engineering Control (PEC) for critical site exposure. Laminar airflow work-benches (LAFW), BSCs, CAIs, and CACIs are common ISO Class 5 environments.
- ▶ •The compounding area must be separated from activities not essential to CSP preparation and must be a controlled (particle, temperature) environment.
- ▶ •Must have an ISO Class 7 environment for buffer area or cleanroom.

Facility Design Requirements - Continued

- ▶ For non-hazardous compounding, you must have an ISO Class 8 environment for ante areas. You must have an ISO Class 7 ante area for Hazardous Compounding .
- ▶ •For non-hazardous compounding -buffer areas physically separated from ante areas must have a positive pressure differential; For hazardous compounding buffer areas physically separated from ante areas must have a negative pressure differential.
- ▶ •PECs must be physically located within an ISO Class 7 buffer area.

Environmental Testing

- ▶ •Environmental monitoring must be routinely performed to prove that the compounding environment is properly maintained. Documentation that proves control is required.
- ▶ •Nonviable and viable airborne particle testing programs must be part of the facility's quality management program.
- ▶ •Total particle counts must be conducted at a minimum of every 6 months for PECs, buffer areas, and ante-areas. Counts must also be obtained if the PEC is relocated or if physical alterations are made to the buffer or ante-areas.

Environmental Testing - Continued

- ▶ Viable airborne particle sampling plans of the PECs, buffer areas, ante-areas, and segregated compounding areas at greatest risk of contamination must be developed and adhered to using electronic volumetric collection devices. Sampling should occur at least every 6 months.
- ▶ •Must conduct regular surface sampling to test for adherence to cleaning and disinfecting procedures.
- ▶ •Follow growth media specifications and incubation times specific to the type of sampling. Corrective actions should be based on microbial contamination action levels and micro

Cleaning Procedures

- ▶ There must be detailed cleaning and sanitizing procedures for ISO Class 5 PECs in order to maintain the cleanliness of the direct compounding area.
- ▶ •Buffer area and ante-area ceilings, walls, and shelving must be cleaned monthly, while counters, work surfaces, and floors must be cleaned daily.
- ▶ •Visual observation of cleaning and disinfecting techniques for all compounding and non-compounding personnel must occur at specified intervals

Example: Microbial Cleaning Overview

This will include a three tier process starting with cleanroom grade industrial detergent / surfactant agent. Then you must sanitize all surfaces with quaternary ammonium compound / sporicidal agent by spraying the entire room and contents and letting it sit for the appropriate contact time for the sporicidal agent that is being used, then removal of residue after appropriate contact time by wiping or mopping with Sterile Filtered Isopropyl Alcohol to the following areas:

▶1. Areas Included in Cleaning

- ▶a. Walls
- ▶b. Doors
- ▶c. Ceilings
- ▶d. Counters
- ▶e. Interior of cabinetry
- ▶f. Shelving Surfaces
- ▶g. Tables and/or carts
- ▶h. BSC

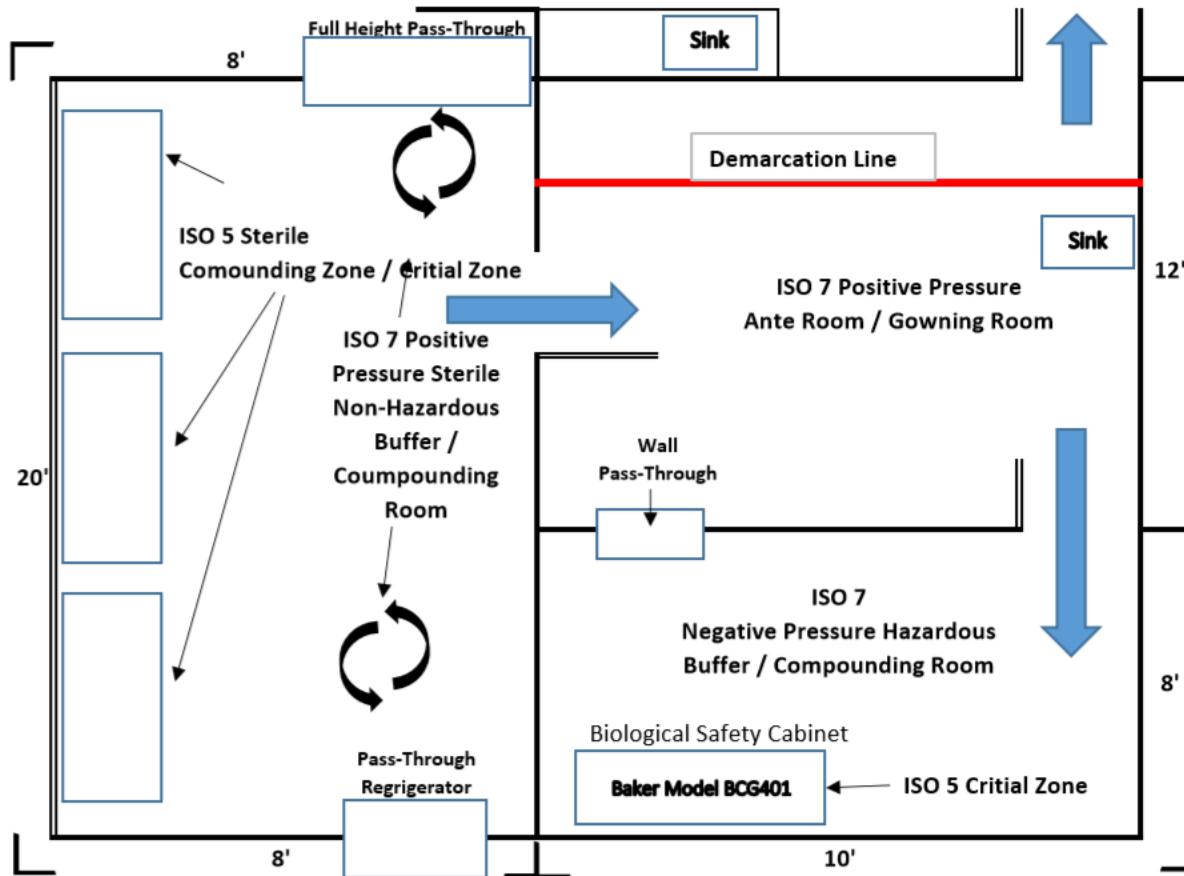
▶2. Materials for sanitizing/cleaning include

- ▶a. Step Stools
- ▶b. Specialized Wipes
- ▶c. Mops and covers
- ▶d. Sterile gloves
- ▶e. Bunny suits, hair nets and masks for workers
- ▶f. Sprayers,
- ▶g. Sporicidal agent
- ▶h. Sterile filtered isopropyl alcohol

Examples of GAPS

- ▶ Walls, Ceiling, Shelving
- ▶ Cardboard
- ▶ Standard Operating Procedures
- ▶ Training and Monitoring
- ▶ Environmental Testing
- ▶ Media Fill Kit Testing
- ▶ Garbing and Gowning
- ▶ Doors
- ▶ Air Exchanges
- ▶ Air Pressure
- ▶ HEPA Filters
- ▶ Vent to Exterior

USP 797 Sterile Compounding Pharmacy



USP General Chapter <800>

- ▶ The focus of Chapter <800> is *Handling of Hazardous Drugs*
- ▶ USP <800> does not specify particular drugs - it addresses the drugs on the NIOSH List of Hazardous Drugs
- ▶ USP <800> *does not replace* <797>
- ▶ USP <800> supplements and modifies <797>
- ▶ Both chapters will co-exist exist and both will be binding after 2019

Impact of Chapter <800>

- ▶ Clinical Oncology has been slow to comply with <797>, but has paid no significant price for that so far
- ▶ However enforcement has changed in the wake of NECC...
 - ▶ FDA much more heavily involved
 - ▶ State government much less complacent, much more proactive
 - ▶ Greatly increased numbers of inspectors - inspectors better trained and much more qualified
- ▶ DOJ enforcement strategies - Headline-making prosecutions and civil actions
- ▶ FDA enforcement - Post-NECC “drop-ins” - they HAVE visited at least one medical practice and written a 483 Report

Chapter <800> revokes <797> waiver

- ▶ In current version of <797> - *“In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.”*
- ▶ This waiver sentence caused many organizations to place their containment PEC (BSC or CACI) inside their positive-pressure clean room. They counted on that waiver to remain in place.
- ▶ Chapter <800> specifically revokes that waiver language and will require organizations to relocate their containment PECs to a negative-pressure ISO 7 space.

Chapter <800> revokes <797> waiver

- ▶ This requirement will be costly for the health care system
- ▶ It is very bad news if you have a C-PEC placed inside a positive-pressure ISO 7 space (clean room)
- ▶ If you have a positive-pressure ISO 7 space and you do no compounding of non-hazardous drugs, you could potentially rebalance the airflow and convert it to a negative pressure clean room
- ▶ If you have no clean room, it's possible that your first clean room should be a negative-pressure clean room
- ▶ OR - You could also ignore <800> and wait to see if anyone gets "speeding tickets"

Governments ill-prepared to inspect/enforce

- ▶ Even if the current version is published as Chapter <800>, neither Feds, nor most state governments have the expertise or resources to enforce.
- ▶ More likely than inspection, the Feds will look for a high profile professional to prosecute in mainstream media headlines (encouraging self-policing by us)
- ▶ Some more able states may take on high levels of enforcement (Florida, California, Texas)

Not just for clinical staff....

Chapter <800> is not limited just to clinical personnel

Every worker in the floor space of your practice must be shielded and protected from exposure to the drugs, including:

- Those who unpack drug totes from the wholesalers
- The patient-facing support staff (receptionists, secretaries, aides, etc.)
- Any billing/business people who might be exposed
- Janitorial/Cleaning/Maintenance personnel
- Delivery drivers or other distributors of hazardous drug products

Both <797> and <800> are not just about clean rooms

Space (Working and Storage)

Training and Oversight

Standard Operating Procedures

Monitoring and Testing

Sterile and Non-Sterile Compounding

Continuous Quality Improvement

A Typical GAP Analysis

Conduct GAP Analysis including:

- Understanding of USP <797> and <800>
- Compounding Staff Responsibilities
- CSP Microbial Contamination Risk Levels
- Risk Level Quality Assurance
- Media Fill Risk Levels and Personnel Training and Evaluation
- CSPs: Immediate Use, Containers, Hazardous Drugs, Radiopharmaceuticals,
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Patients and Caregiver Training, Monitoring and Adverse Events Reporting
- Continuous Quality Improvement Program (CQI)
- Review monitored data - compare and contrast with SOP requirements. Topics include:
 - Cleaning and disinfection
 - Certifications of SEC(s) and PEC(s)
 - Assess Quality Management process
 - Examine root-cause analyses
 - Review evidence of training and competency demonstrations of staff

Review labeling and storage practices

<800> Compliance Basics

- ▶ Facilities - Receipt Storage, Buffer, Anteroom, Non-Sterile, Sterile
- ▶ Environmental Wipe Sampling
- ▶ Personal Protective Equipment (PPE)
- ▶ Hazard Communication Plan
- ▶ Personnel Training- Right To Know
- ▶ Disinfection and Decontamination
- ▶ Receipt, Handling and Storage
- ▶ Labeling, Dispensing and Transport
- ▶ Non-Sterile Compounding
- ▶ Hazardous Drug Administration - Must use Closed System Transfer Device (CSTD) for IVs and injectables
- ▶ Cleaning Processes in Hazardous Drug Areas, Spill Control
- ▶ Disposal of Hazardous Drugs
- ▶ Medical Surveillance

Strategies for Improvement, and Continuous Quality Management

- ▶ Following the GAP Analysis
- ▶ Detailed plan to close GAPS
- ▶ Implement and LIVE Standard Operating Procedures (SOPs)
- ▶ Continuous Quality Management Process

Adopt a Pharmacy Perspective, not Oncology

- ▶ This is a journey not a single event
- ▶ Understand your gaps and options, and develop a plan for best possible and reasonable compliance
- ▶ Understand the political and enforcement environment of CT
- ▶ Secure good counsel that understands both oncology and the pharmacy details of USP and FDA and state agencies
- ▶ Bootcamp for auditors all based upon pharmacy interpretations
- ▶ Competency Testing and Monitoring
- ▶ Differences in Perspective can affect GAP analysis interpretations: risk levels

CT Regulations and Links

- ▶ <http://portal.ct.gov/DCP/Drug-Control-Division/Commission-of-Pharmacy-Licenses/Drug-Control-Division-Inspection-Forms#PCY>
- ▶ <http://portal.ct.gov/-/media/DCP/migrated-docs/USP797InspectionFormversion2pdf.pdf?la=en>
- ▶ http://portal.ct.gov/-/media/DCP/pdf/drug_control_pdf/SterileCmpding20170428InspectionChecklistpdf.pdf?la=en
- ▶ <http://portal.ct.gov/DCP/Drug-Control-Division/Commission-of-Pharmacy/Pharmacy-Commission-Meetings>
- ▶ https://www.cga.ct.gov/current/pub/chap_370.htm

Thank You, and Good Luck

Dawn Holcombe, MBA, FACMPE
DGH Consulting
33 Woodmar Circle
South Windsor, CT 06074

860-305-4510
860-644-9119 fax
dawnho@aol.com
www.dghconsulting.net