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Pharmacy Administration and Innovation: Best Practice Showcase: Impact of a Compounding Compliance Committee Across an Integrated Health System

Hiren Shah, PharmD
Pharmacy Operations Manager, AdventHealth

Jessica Wendler PharmD, BCSCP, CPh
Pharmacy Coordinator, AdventHealth

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Disclosure

Hiren Shah and Jessica Wendler do not have a 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 this presentation (within the last 12 months).

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Presentation Objectives

- Describe the best practices model as it fits within the complex healthcare organization.
- Examine legal or regulatory requirements that impact this model.
- Evaluate personnel and staffing requirements necessary for implementation of the best practice.
- Summarize the impact of the best practices model on quality, regulatory or other indicators.

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Topics We Will Cover

- The governance and decision-making structure of a system-wide compounding compliance committee.
- Strategies for standardizing compounding practices across multiple facilities.
- Structured communication improves transparency and closed loop decision making.
- Centralized oversight improves safety, efficiency, and stewardship of health IT resources.

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AdventHealth - Overview

1973 AdventHealth was established
9 million+ Patients served annually
105,000+ Team members
56 Hospital campuses
9 States
10,900+ Licensed beds
58 Urgent care facilities
27 Offsite EDs

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AdventHealth - Florida

West Florida Division	Central Florida Division	East Florida Division
15 Hospitals	10 Hospitals	7 Hospitals
1,231,672 Outpatient visits	1,656,139 Outpatient visits	650,832 Outpatient visits
125,157 Inpatient visits	176,045 Inpatient visits	89,075 Inpatient visits
485,714 Outpatient ED registrations	514,731 Outpatient ED registrations	292,442 Outpatient ED registrations
2,698 Beds	3,289 Beds	1,403 Beds

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Why This Matters

- In 2017, more than 40 adverse events and one death were reported linked to compounded medications prepared in Texas and California.
- Compounded medications provide access to care when:
 - Customized doses are required
 - A commercially available product is unavailable
 - A patient is allergic to a component of an FDA-approved drug product
 - Drug shortages occur
- Compounding medications must be balanced with minimizing associated risk.
- Much of the patient harm is preventable

Woodcock J, Dehn J. Toward Better Quality Compounded Drugs: An Update from the FDA. N Engl J Med. 2017 Dec 28;377(26):2509-2512. doi: 10.1056/NEJMp172905. PMID: 29288577. Liu, D. [Guidelines for Pharmacy Compounding](#), US Pharm. 2021;46(1):8-12.

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Pharmacy Leads Compliance Efforts

- Health system pharmacy teams uniquely positioned to lead compounding safety efforts
- Value in positioning a layer of oversight outside of the daily pharmacy operations as it offers an independent viewpoint on implementation of regulatory requirements
- A multidisciplinary approach to USP <797> and <800>; VA study
 - Improves communication
 - Increases engagement
 - Ensures completion of action items

Brude W, Chaffee, Jamie C, Tharp, John S, Clark, Stanley Kent, A compounding compliance team at an academic medical center, American Journal of Health-System Pharmacy, Volume 77, Issue 11, June 2020, Pages 883-891, <https://doi.org/10.1093/ajhp/afz053>
Wroeschawski CE, Park HK. Leveraging a multidisciplinary oversight committee to ensure USP <797> and <800> compliance at a Veterans Affairs health system. Am J Health Syst Pharm. 2022 Feb 15;179(2):105-109. doi: 10.1093/ajhp/afz053. PMID: 35725548.

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AdventHealth's Multi-Site Challenge

- Challenging to standardize compounding requirements across a health-system when implementing facility-level responsibility
 - Over 50 hospitals across 9 states
 - Fragmented decision-making
- Large organizational changes occurring concurrently
 - Adoption of a single compounding compliance documentation application
 - Conversion to a new electronic health record system
- Established an enterprise-wide compounding committee that:
 - Sets standards through shared decision-making
 - Drives improvement across all hospitals
 - Implements cohesive processes in a traditionally fragmented area

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Committee Framework

- Multidisciplinary Team
 - Non-operational committee leadership (non-voting)
 - Policy & regulatory experts
 - Microbiologist
 - Supply chain representative
 - Pharmacy informatics representative
 - Regional representatives (voting members)

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Our Journey: Centralized Pharmacy Governance Model

The timeline shows the progression of the Centralized Pharmacy Governance Model from 2022 to 2024. Key milestones include: Initial Recipe Review / Master Formulation Record (MFR) creation (Q3 2022), Standard Setting Policy and CSP Development (Q1 2023), Ongoing Recipe/MFR Review (Additions/Edits/Deletes) & Ongoing Policy Development and Evaluation (Q1 2023 - Q4 2024), Standard Compliance Software Implementation (Q1 2024), and Aseptic Technique (Q3 2024).

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Program Impact on Health System

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Expansion of Technician Roles in Pharmacy Leadership

- Strengthened a culture that recognizes and leverages technician expertise
- Elevated technician role (Voting members)
- Expertise in compounding
 - Recipe & SOP development
- Qualified evaluators

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Improved Operational Efficiency

- Oversight committee eliminates operational bias
- Standardized compounding decision approval process & defined electronic health record (EHR) build pathway
- Leveraged regional representation to ensure experienced system-wide input

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Enhanced Patient Safety

- Institute for Safe Medication Practices (ISMP) Sterile Compounding Guidelines recommend MFRs are:
 - Double checked using independent double check prior to use
 - Changes or additions to IV workflow software data are validated
 - Access to compounding software to minimize unauthorized changes
- Prior to committee development, compounding recipes were independently managed with variations in process
- Committee structure ensures compliance with ISMP recommendations and introduces redundancies as a risk mitigation strategy
- Elimination of site-based record management reduces variability and risk

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Interdisciplinary Awareness and Compounding Compliance

- USP <797> updates require specific competencies for pharmacy and all disciplines that compound
- System wide multidisciplinary approach to education & competency documentation
 - Nursing
 - Anesthesia
 - Surgery
 - Respiratory

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Standardization Maintenance

The committee's standardization efforts require maintenance tools to prevent deviation

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Beyond Use Date Assessment Guide

Consider available stability information in medication labeling for medication, diluent, concentration, final container, and storage conditions.

If exact stability information for medication, diluent, concentration, final container, and storage conditions does not exist review the following:

- Consider recommendations from national organizations
- Consider information on medication, diluent, and storage conditions
- Consider any relevant excipient information impact on medication
- Consider container type impact on medication
- Consider related literature for: leaching, sorption, light exposure, pH, degradation, precipitation, permeation, incompatibility, preservatives, stabilizers, etc.

Propose a final recommendation to the committee based on available information: If compounding is proposed, the most conservative BUD based on availability stability information, the literature assessment, and USP <797> is recommended.

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Labor Reduction and Stewardship of Resources

Presented by:



Danecka K. Tsibul, PhD



Meier J. PhD

Presented to:



AHIMA



Health Information Workforce Survey Results

Presented at:



AHIMA



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Labor Reduction and Stewardship of Resources

- Post committee implementation assessment revealed:
 - Fifty recipes assessed, double checked, and built in a 12-month period
 - Previous process would have yielded 297 individual EHR builds
 - Reduction in ticket volume by 83%
 - Average ticket time ~15 hours
 - Saved 3,705 hours of RPh/IT analysts labor annually
 - Median US Pharmacist salary: \$66.10/hr
 - Generated \$245,000/yr cost savings in healthcare IT resource labor



Electronic Health Record (EHR) Builds
In a 12-month period
after Compounding Committee Creation

Category	Value
Number of Potential Builds WITHOUT Centralized Review	297
Reduction	-83%
Number of Builds WITH Centralized Review	50
Hours of healthcare IT labor saved annually	3,705
Associated labor cost savings	\$245,000

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, OOH Data Access and Republishing Information, at <https://www.bls.gov/occupational-outlook-handbook-11-18>



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Demonstrations of Improvements

Committee Impact on Compounding Compliance Software Adoption

New region/facilities acquired by the organization

# Committee Meetings	Percent Adoption
0	70
5	70
10	70
15	70
16	70
20	80
25	85
30	75
32	86
34	95
36	97
38	98

Compliance Software Adoption

- Enhanced accessibility & traceability of compounding documents
- Improved regulatory compliance
 - Retrievable records for patient compounds
 - Automatic prompts of regulatory tasks
- Established a scalable approach for onboarding newly acquired facilities

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Library Reduction

- Reduction of redundant and unnecessary recipes
- Reviewed 457 recipes to ensure appropriateness, accuracy & consistency
 - Recipe reduction of 9%
 - Clearer, more consistent design
 - Limited options / minimized selection error
 - Improved end user experience
 - Align with formulary and system standards

Initial Review of Recipes for MFR

Category	Count	Percentage
Deleted Upon Review	40	9%
Added to MFR	417	91%

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Alignment with Advancing Pharmacy Practice

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Pharmacy Technicians in Advanced Roles

- Pharmacy technicians should participate in advanced roles in all practice settings to promote efficiency and improve access to patient care**
- Key member of the committee
- Company wide decision making
- Developed qualified evaluator role
 - Empowers technicians to train and evaluate staff
 - Expanded technician leadership within pharmacy operations
 - Optimized pharmacists' time and resources

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Qualified Evaluator Requirements

Criteria for Consideration

- Successfully completed sterile compounding general training.
- Not trained/selected by a designated person.
- ≥ 12 months sterile compounding experience with demonstrated excellence.
- Policy and procedure training.
- Good communicator with the ability and desire to teach others.

Demonstrates

- Proper aseptic preparation of compounded sterile preparation using media fill challenge and surface sampling lab.
- Ability to aseptically collect a surface sample from a Primary Engineering Control (PEC) and gloved fingertip (GFT) samples.
- Proper hand hygiene and garbing.
- Proper material transfer of supplies into compounding suite from unclassified spaces into a PEC using proper dwell times.
- Proper cleanroom behaviors.
- Desire to teach others and commitment to provide correctly prepared products to patients (strict adherence to compounding SOPs).
- Knowledge of referencing correct SOPs and WIs when teaching the above.
- Knowledge of different PECs and horizontal and vertical airflow AND demonstrates skills to maintain aseptic technique.
- Knowledge and ability to properly clean and maintain a clean compounding environment.

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Subject Matter Experts and Specialty Certification

- Pharmacists practicing in specialty areas should be board-certified through the Board of Pharmacy Specialties or other appropriate body**
- Committee led by board-certified sterile compounding pharmacists (BCSCP)
- Integrated additional BCSCP-certified members into voting roles to guide decision making
- Ensured compounding oversight is grounded in evidence-based practice & regulatory standards
- Strengthened organizational confidence through expert-driven, standardized decisions

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Technology in Compounding

- **Pharmacy departments should use technology to ensure the safe compounding of sterile products**
- Increased compliance software adoption by 30%
- Transitioned facilities to electronic documentation and increased regulatory compliance
 - Reduced risk of incomplete records
 - Auto alerts set up to ensure record completion
 - Electronic records
 - Readily retrievable
 - Improved traceability
 - Audit trail for compliance and investigations
- Preapproved, prebuilt recipes in the EHR prompting standardized work:
 - Component scanning for accurate product selection
 - Capture images

American Society of Health-System Pharmacists, Inc. | RSI recommendations ASHP: <https://www.ashp.com/pharmacy-practice/rsi/rsi-recommendations> Accessed July 3, 2025.

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Takeaways

- Centralized compounding oversight improved safety, consistency and system-wide standardization
- Strengthened workforce through expanded technician leadership and expert-driven decision making
- Enhanced interdisciplinary collaboration and alignment with ISMP and USP standards
- Achieved measurable impact: \$~245K annual savings, reduced redundancy and near 100% software adoption
- Established a scalable, replicable model for advancing compounding compliance across health systems

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Recognitions

This work is presented by Hiren Shah, PharmD and Jessica Wendler, PharmD on behalf of the AdventHealth Pharmacy Department recognizing work that was originated and continuously led by Mandy Wollitz, Executive Director of Pharmacy Regulatory and Quality Affairs

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Questions?



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