NABP/AACP Annual Meeting & SE Officers Conference
Meeting Agenda

NABP/AACP Annual Meeting: August 2-5, 2014 • SE Officers Conference: August 2-4, 2014

Saturday, August 2, 2014

Moderator: Randall C. Rowen, PharmD, RPh; Interim Executive Dean, South Carolina College of Pharmacy

1:30 PM-2:00 PM **Attendees: SE Officers Only** **Ansonborough Room**

Welcome and Program Overview

- Craig Burridge, MS, CAE; CEO, South Carolina Pharmacy Association
- Patti Fabel, PharmD, RPh; President, South Carolina Pharmacy Association
- William Wynn, PharmD, RPh; President-Elect, South Carolina Pharmacy Association

2:00 PM-3:00 PM **Attendees: SE Officers Only** **Ansonborough Room**

Roundtable Discussion

- Moderator: Patti Fabel, PharmD, RPh; President, South Carolina Pharmacy Association

3:00 PM-3:15 PM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Welcome and Annual Meeting Overview

- Carole Russell, RPh, MHSA — Board Member, South Carolina Board of Pharmacy
- Lee Ann Bundrick, RPh — Administrator, South Carolina Board of Pharmacy
- Randall C. Rowen, PharmD, RPh — Interim Executive Dean, South Carolina College of Pharmacy
- Philip D. Hall, PharmD, RPh — Dean, South Carolina College of Pharmacy-MUSC Campus
- L. Clifton Fuhrman, PhD, RPh — Dean, Presbyterian College School of Pharmacy
- Curtis E. Jones, PhD, RPh — Dean, South University School of Pharmacy

3:15 PM-3:45 PM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Report of the National Association of Boards of Pharmacy

- Joseph L. Adams, RPh; NABP President

3:45 PM-4:15 PM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Report of the American Association of Colleges of Pharmacy

- Cynthia J. Boyle, PharmD, RPh; AACP President-Elect

4:15 PM-5:00 PM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Penn Center: Celebrating 150 Years of Education, Leadership & Service

- Victoria A. Smalls; Director of History, Art & Culture, Penn Center

5:00 PM-7:00 PM **Attendees: NABP, AACP & SE Officers** **Courtyard**

Welcome Reception

Sunday, August 3, 2014

Moderator: L. Clifton Fuhrman, PhD, RPh; Dean, Presbyterian College School of Pharmacy

7:00 AM-8:00 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Breakfast

7:00 AM-8:00 AM **Attendees: SE State Executives Only** **Wando Room**

State Executives Breakfast

8:00 AM-8:05 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Welcome to Charleston

- William A. Moody, Jr.; Mayor Pro Tem, City of Charleston

8:05 AM-10:05 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

The Emily Jerry Story: From Tragedy to Triumph: Preventing Future Tragedies Through Adoption of Technology & Best Practices (CE: 2 hours)

- Christopher S. Jerry; President & CEO, Emily Jerry Foundation

10:05 AM-10:15 AM **Break**

Meeting Agenda Cont.

Sunday, August 3, 2014 cont.

Moderator: L. Clifton Fuhrman, PhD, RPh; Dean, Presbyterian College School of Pharmacy

10:15 AM-11:15 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Panel: Update on Diversion/Prescription Drug Abuse (CE: 1 hour)

- Kaushik Kotecha, RPh; Director of Compliance & Controlled Substances, Smith Drug Company
- Lisa Thomson, RPh; Coastal District Director, South Carolina Department of Health & Environmental Control
- Gene Reeder, PhD, RPh; Professor of Pharmaceutical & Administrative Sciences, Presbyterian College School of Pharmacy
- Raymond Keith, RPh; Compliance Agent, Mississippi Board of Pharmacy
- Moderator: Rebecca Gillespie, PharmD, RPh; Board Member, South Carolina Board of Pharmacy

11:15 AM-12:15 PM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Panel: District III's Current State Issues (CE: 1 hour)

- J. Addison Livingston, PharmD, RPh; Chairman, South Carolina Board of Pharmacy
- Jay Campbell, RPh, JD; Executive Director, North Carolina Board of Pharmacy
- Mike Burleson, RPh; Executive Director, Kentucky Board of Pharmacy
- Moderator: Rob Hubbard, RPh; Board Member, South Carolina Board of Pharmacy

Monday, August 4, 2014

Moderator: Philip D. Hall, PharmD, RPh; Dean, South Carolina College of Pharmacy-MUSC Campus

7:00 AM-8:00 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Breakfast

8:00 AM-9:00 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

What's New & What's Next for Pharmacy Technicians (CE: 1 hour)

Everett B. McAllister, RPh, MPA; CEO & Executive Director, Pharmacy Technician Certification Board

9:00 AM-10:00 AM **Attendees: NABP, AACP & SE Officers** **Stono Ballroom**

Panel: Automation in Institutional, Mail Order & Long Term Care Pharmacy Practice (CE: 1 hour)

- Jeff Brittain, PharmD, RPh; Clinical Pharmacist, Medication Policy & Informatics, Medical University of South Carolina
- Daniel Bundrick, RPh; Vice President of Pharmacy Services, Agape Pharmacy
- Jennifer Spruill Russos, PharmD, RPh, MHA; Pharmacy Ambulatory Care Supervisor, Ralph H. Johnson Veteran's Affairs Medical Center
- Moderator: Carole Russell, RPh, MHSA; Board Member, South Carolina Board of Pharmacy

10:00 AM-10:15 AM **Break**

10:15 AM-11:00 AM **Attendees: NABP Only** **Stono Ballroom**

NABP Business Meeting

10:15 AM-11:00 AM **Attendees: AACP Only** **Harleston Room**

AACP Business Meeting

10:15 AM-1:30 PM **Attendees: SE Officers Only** **Ansonborough Room**

SE Officers Business Meeting & Closing Remarks

11:00 AM-12:00 PM **Attendees: NABP Only** **Stono Ballroom**

NABP Roundtable Discussions

Moderator: Lee Ann Bundrick, RPh; Administrator, South Carolina Board of Pharmacy

11:00 AM-12:00 PM **Attendees: AACP Only** **Harleston Room**

AACP Roundtable Discussions

Moderator: Philip Hall, PharmD, RPh; Dean, South Carolina College of Pharmacy-MUSC Campus

1:00 PM-3:00 PM **Sign up at registration desk** **Offsite**

Tour of Charleston CMOP ***Meet in lobby at 1:00 PM***

6:00 PM-9:00 PM **Ticket Required** **Offsite**

Tour of Charleston Harbor & Dinner Cruise (transportation provided) ***Meet in lobby at 5:15 PM***

Meeting Agenda Cont.

Tuesday, August 5, 2014

Moderator: Curtis E. Jones, PhD, RPh; Dean, South University School of Pharmacy

7:00 AM-8:00 AM **Attendees: NABP & AACP Only** **Stono Ballroom**
Breakfast

8:00 AM-8:15 AM **Attendees: NABP & AACP Only** **Stono Ballroom**
Memorium
- J. Addison Livingston, PharmD, RPh; Chairman, South Carolina Board of Pharmacy

8:15 AM-9:00 AM **Attendees: NABP & AACP Only** **Stono Ballroom**
NABP/AACP Joint Business Session

9:00 AM-10:00 AM **Attendees: NABP & AACP Only** **Stono Ballroom**
The Brutal Facts of Compounding Incidents & the Importance of Quality Systems (CE: 1 hour)
- Patricia Kienle, RPh, MPA, FASHP; Director of Accreditation & Medication Safety, Cardinal Health

10:00 AM-10:15 AM **Break**

10:15 AM-11:15 PM **Attendees: NABP & AACP Only** **Stono Ballroom**
Panel: Innovative Competency & Training Concepts for Compounding (CE: 1 hour)
- Bryan Ziegler, PharmD, RPh, MBA; Executive Director, Kennedy Pharmacy Innovation Center
- Carole Russell, RPh, MHSA; Pharmacist, Compounding Pharmacy, Medical University of South Carolina
- Varner Richards, PharmD, RPh; Owner & CEO, Intramed Plus, Inc.
- Moderator: Spencer Morris, PharmD, RPh; Board Member, South Carolina Board of Pharmacy

11:15 AM-11:30 AM **Attendees: NABP & AACP Only** **Stono Ballroom**
Closing

Continuing Education Information

Title: The Emily Jerry Story: From Tragedy to Triumph: Preventing Future Tragedies Through Adoption of Technology and Best Practices

Speaker:

- Christopher S. Jerry; President and CEO, Emily Jerry Foundation

ACPE UAN#: 0062-9999-14-099-L05-P **Contact Hours:** 2.0

Learning Objectives:

- Discuss the events surrounding the medical error that resulted in Emily Jerry's tragic death in 2006.
- Describe the important "lessons learned" from Emily's tragic death.
- Identify and discuss the qualities of a safety culture that enhance harm prevention.

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Title: Update on Diversion/Prescription Drug Abuse

Panelists:

- Raymond Keith, RPh; Compliance Agent, Mississippi Board of Pharmacy
- Kaushik Kotecha, RPh; Director of Compliance and Controlled Substances, Smith Drug Company
- Gene Reeder, PhD, RPh; Professor of Pharmaceutical and Administrative Sciences, Presbyterian College School of Pharmacy
- Lisa Thomson, RPh; Coastal District Director, South Carolina Department of Health and Environmental Control

Moderator:

- Rebecca Gillespie, PharmD, RPh; Board Member, South Carolina Board of Pharmacy

ACPE UAN#: 0062-9999-14-100-L04-P **Contact Hours:** 1.0

Learning Objectives:

- Describe current drug diversion issues from a state and federal perspective.
- List ways to identify and address abuse and diversion issues.
- Discuss practical concerns with the interpretation of "corresponding liability" for the pharmacist.
- Discuss how diversion and drug abuse are being integrated into pharmacy curriculum.

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Title: District III's Current State Issues

Panelists:

- J. Addison Livingston, PharmD, RPh; Chairman, South Carolina Board of Pharmacy
- Jay Campbell, RPh, JD; Executive Director, North Carolina Board of Pharmacy
- Mike Burleson, RPh; Executive Director, Kentucky Board of Pharmacy

Moderator:

- Rob Hubbard, RPh; Board Member, South Carolina Board of Pharmacy

ACPE UAN#: 0062-9999-14-101-L04-P **Contact Hours:** 1.0

Learning Objectives:

- Identify and discuss permit classifications for compounding pharmacies and non-resident pharmacies.
- Identify and discuss pharmacy technician requirements in respective states.
- Discuss status of advanced practice pharmacists in respective states.

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Title: What's New and What's Next for Pharmacy Technicians

Speaker:

- Everett B. McAllister, RPh, MPA; CEO and Executive Director, Pharmacy Technician Certification Board

ACPE UAN#: 0062-9999-14-102-L04-P **Contact Hours:** 1.0

Learning Objectives:

- Describe the impact recent changes within the profession will have on pharmacy technicians.
- Identify the evolving roles of pharmacy technicians and their opportunities in advancing care.
- Review the planned changes to the PTCB certification program.

Continuing Education Information

Title: Automation in Institutional, Mail Order and Long Term Care Pharmacy Practice
Panelists:
- Jeff Brittain, PharmD, RPh; Clinical Pharmacist, Medication Policy and Informatics, Medical University of South Carolina
- Daniel Bundrick, RPh; Vice President of Pharmacy Services, Agape Pharmacy
- Jennifer Spruill Russos, PharmD, RPh, MHA; Pharmacy Ambulatory Care Supervisor, Ralph H. Johnson Veteran's Affairs Medical Center

Moderator:
- Carole Russell, RPh, MHSA; Board Member, South Carolina Board of Pharmacy

ACPE UAN#: 0062-9999-14-103-L04-P **Contact Hours:** 1.0
Learning Objectives:
- Describe current trends in institutional pharmacy automation.
- Discuss how evolving technology may affect regulation.
- Discuss how automation is changing the prescription dispensing paradigm.
- Review automation quality assurance: testing the competency of equipment.
- Identify the safety risks and need to change the current system utilized by most skilled nursing homes for drug distribution.
- Describe how automation can be successfully implemented in a skilled nursing environment and the benefits realized.

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Title: The Brutal Facts of Compounding Incidents and the Importance of Quality Systems
Speaker:
- Patricia Kienle, RPh, MPA, FASHP; Director of Accreditation and Medication Safety, Cardinal Health

ACPE UAN#: 0062-9999-14-104-L03-P **Contact Hours:** 1.0
Learning Objectives:
- Summarize the evolution of the practice of sterile compounding.
- Discuss how the historical pharmacy-related contamination events shaped present-day pharmacy regulations.
- Explain current and upcoming national and state laws and standards as it pertains to compounding.

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Title: Innovative Competency and Training Concepts for Compounding
Panelists:
- Bryan Ziegler, PharmD, RPh, MBA; Executive Director, Kennedy Pharmacy Innovation Center
- Carole Russell, RPh, MHSA; Pharmacist, Compounding Pharmacy, Medical University of South Carolina
- Varner Richards, PharmD, RPh; Owner and CEO, Intramed Plus, Inc.

Moderator:
- Spencer Morris, PharmD, RPh; Board Member, South Carolina Board of Pharmacy

ACPE UAN#: 0062-9999-14-105-L04-P **Contact Hours:** 1.0
Learning Objectives:
- Describe competency requirements for non-sterile, sterile and hazardous compounding in a hospital ambulatory care center setting.
- Discuss competency requirements for hiring and maintaining employment in a community home infusion setting.
- List requirements for outsourcers regarding competency assessment of staff performing high risk compounding.
- Review education and training of pharmacy students in sterile compounding and how training is being incorporated into curriculum.

Speakers, Leaders and Panelists (alphabetized)

Joseph L. Adams, RPh, is the 110th president of NABP after serving one year terms as the Association's president-elect and treasurer. Prior to this, Mr. Adams served as a member of the NABP Executive Committee representing District 6 for 3 years. Mr. Adams was a member of the Louisiana Board of Pharmacy from 2000 to 2013 in addition to being a Walgreens Company employee since 1977. Mr. Adams has served as an active NABP member, serving on multiple committees and task forces. Mr. Adams earned his Bachelor of Science degree in pharmacy from Xavier University of Louisiana College of Pharmacy.

Cynthia J. Boyle, PharmD, RPh, is the 2014-2015 AACP President-Elect. Dr. Boyle is a Professor and Chair of the Department of Pharmacy Practice and Administration at the University of Maryland Eastern Shore. She has served in numerous capacities in the AACP, including Speaker of the House of Delegates. She has experience in community, institutional, and consultant settings. Dr. Boyle also served three terms of office in the APhA Academy of Pharmacy Practice and Management, as president of the Maryland Pharmacists Association and its foundation, as national president of Phi Lambda Sigma and as the chair of the Pharmacy Academy in the National Academies of Practice. She graduated from the University of Oklahoma College of Pharmacy and University of Maryland School of Pharmacy.

Jeff Brittain, PharmD, RPh, BCPS, is a Clinical Pharmacist in Medication Policy & Informatics at Medical University of South Carolina. He works in both inpatient and outpatient settings in his role at MUSC, supporting all medication-related information systems. He has been instrumental in a number of safety and practice initiatives including implementation of computerized provider order entry for both adult and pediatric hospitals, and most recently the conversion of the electronic medical record to a new platform. He is the recipient of the South Carolina Pharmacy Association's 2014 Distinguished Young Pharmacist award and serves as a SCCP preceptor. He received his PharmD from Wilkes University in 2005 and his BCPS in 2009. *Dr. Brittain discloses previous honorarium from Baxter for customer perspective.*

John Daniel Bundrick, RPh, has been a pharmacist for over 28 years, serving in long-term care and employee based settings. He currently serves as Vice President of Pharmacy Services at Agape' Pharmacy. He previously practiced at Lowman Home, Palmetto Senior Care and SCANA. He earned his Bachelor of Science in Pharmacy from the University of South Carolina in 1984. Mr. Bundrick has received numerous professional awards including the Institute of Safe Medicine Practices Safety Cheers Award in 2011, Upsher-Smith Excellence in Innovation Award for South Carolina in 2007 and Preceptor of the Year from SCCP in 2006 and 2010. *Mr. Bundrick declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Michael A. (Mike) Burleson, RPh, assumed the position of Executive Director of the Kentucky Board of Pharmacy in 2004. Mr. Burleson is a 1974 graduate of the University of Kentucky College of Pharmacy. Prior to assuming his positon with the Board of Pharmacy, Mr. Burleson worked for 30 years in a number of pharmacies. He is past president of the National Association of Boards of Pharmacy, the National University of Kentucky Alumni Association and the University of Kentucky College of Pharmacy Alumni Association. *Mr. Burleson declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Jack William (Jay) Campbell IV, RPh, JD, currently serves as the Executive Director of the North Carolina Board of Pharmacy. He serves as an instructor of pharmacy law at Wingate University School of Pharmacy and the University Of North Carolina Eshelman School Of Pharmacy. He is a frequent guest lecturer on law and ethics issues at Campbell University College of Pharmacy and Health Sciences. He received his Juris Doctorate from Vanderbilt University in 1997 and his Bachelor of Science in Pharmacy from the University of North Carolina at Chapel Hill in 1993. *Mr. Campbell declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Christopher S. Jerry created the Emily Jerry Foundation after losing his two year old daughter to a fatal medication error in 2006. After his tragic loss, he created the Emily Jerry Foundation to increase public awareness of the systems aspects of medicine as well as addressing key patient safety related issues by identifying technology and best practices to minimize "human error." Mr. Jerry is a committed patient safety and caregiver advocate, who works relentlessly for a change in the underlying "culture" of medicine in the US. His focus over the past eight years has broadened to include advocacy for caregivers. *Mr. Jerry declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Raymond L. Keith, RPh, is a compliance agent with the Mississippi Board of Pharmacy. Prior to his work with the Mississippi Board of Pharmacy, Mr. Keith worked as a pharmacist for almost 20 years in institutional and retail pharmacy settings. He is a former Mississippi Board of Pharmacy Member. He received his Bachelor of Science in Pharmacy from the University of Mississippi in 1986. *Mr. Keith declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Patricia Kienle, RPh, MPA, FASHP, is the Director of Accreditation and Medication Safety for Cardinal Health Innovative Delivery Solutions. She received her pharmacy degree from the Philadelphia College of Pharmacy and Science and a Masters in Public Administration from Marywood University. **(cont.)**

Speakers, Leaders and Panelists cont. (alphabetized)

Patricia Kienle cont. She completed an Executive Fellowship in Patient Safety from Virginia Commonwealth University and is an Adjunct Associate Professor at Wilkes University. Kienle is a Fellow of the American Society of Health-Systems Pharmacists, named Pharmacist of the Year by the PSHP and the recipient of the Distinguished Achievement Award in Hospital and Institutional Practice for the American Pharmaceutical Association Academy of Pharmacy Practice and Management. She is the author of *Compounding Sterile Preparations: ASHP's Visual Guide to Chapter <797>* video and *Companion Guide.* Patti has been a member or chair of multiple expert panels for USP and currently is a member of the USP Expert Committee on Compounding, and chair of the Subcommittee and Expert Panel on Hazardous Drugs. *Ms. Kienle declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Kaushik V. Kotecha, RPh, served as a police officer prior to his career in pharmacy. He graduated from the USC School of Pharmacy and worked as a pharmacist at Mary Black and oncologist pharmacist and manager at IntraCare. He joined the SC Department of Health and Environmental Control in 1993 as an inspector and was later promoted to Piedmont District Director. Upon retirement, he began his current career as the Director of Compliance and Controlled Substances with Smith Drug Company. *Mr. Kotecha declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

J. Addison Livingston, PharmD, RPh, represents the 2nd Congressional District on the South Carolina Board of Pharmacy. Dr. Livingston is the co-owner of a small chain of independent pharmacies in the Columbia, SC area. He serves as the PIC and compounding pharmacist at one of the facilities. He is the current chairman of the board and serves as the chairman of the non-resident review committee. He also serves on the legislative committee. *Dr. Livingston declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Everett B. McAllister, RPh, MPA, is the Executive Director and Chief Executive Officer for the Pharmacy Technician Certification Board. Mr. McAllister is responsible for the leadership of the nation's leading certifying body for pharmacy technicians. As Executive Director and CEO, his duties include management of testing for PTCB's 525,000 Certified Pharmacy Technicians nationwide, marketing new business development and being the spokesperson for the certification program. Mr. McAllister served in senior level positions within the United States Air Force and Department of Defense, retiring as a Colonel. He earned his Bachelor of Pharmacy degree from the University of South Carolina and a Masters of Public Administration from Auburn University. *Mr. McAllister declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Claiborne E. (Gene) Reeder, PhD, RPh, is a professor of Pharmaceutical and Administrative Sciences at the Presbyterian College School of Pharmacy. He also serves as Director in the Strategic Market Insights Group at Xcenda, an AmerisourceBergen health care consulting group. Prior to joining Xcenda, Dr. Reeder was a Professor of Pharmacoeconomics and Outcomes Research at the University of South Carolina College of Pharmacy where he now holds the title of Distinguished Professor Emeritus. Dr. Reeder holds a Bachelors and a Masters in Science in Pharmacy and a Ph.D. in Business Administration. Dr. Reeder is the recipient of multiple awards. In April 2011, the Foundation for Managed Care pharmacy presented it highest award, the Steven G. Avey Award to recognize his lifetime of service in managed care. Most recently, Dr. Reeder was awarded the 2014 Bowl of Hygeia Award by the South Carolina Pharmacy Association. *Dr. Reeder declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Varner R. Richards, PharmD, RPh, is the CEO and owner of Intramed Plus, Inc. and has been involved in the infusion industry for over 30 years. He has served in many settings including hospital, academia and home infusion management. He graduated from the College of Pharmacy at the University of Nebraska Medical Center in 1980 with a Doctor of Pharmacy and completed a two year General Pharmacy Residency at the University of Kentucky Medical Center. Dr. Richards currently serves on the South Carolina College of Pharmacy Leadership Advisory Board and the Kennedy Pharmacy Innovation Center Advisory Committee. He currently serves on the Board for the National Home Infusion Association (NHIA) and has participated in the NHIA Leadership Forums on an annual basis. *Dr. Richards declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Carole Small Russell, RPh, MHSA, is a pharmacist in the Compounding Pharmacy at the Medical University of South Carolina, as well as a clinical instructor at the MUSC campus of the South Carolina College of Pharmacy and an adjunct instructor at Trident Technical College, where she also chairs the Technician Advisory Committee. She has had multiple positions of leadership during her career, but her major emphasis over the past 10 years has been sterile compounding. She was appointed in 2011 as the representative from the 1st Congressional District to the SC Board of Pharmacy where she serves as chair of the Compounding Committee and as member of various other key committees. She received her Bachelor of Science in Pharmacy from the Medical University of South Carolina in 1977 and her Masters in Health Systems Administration from the Medical University of South Carolina College of Health Professions in 1992. *Mrs. Russell declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Speakers, Leaders and Panelists (alphabetized)

Jennifer Spruill Russos, PharmD, RPh, MHA, BCACP, is currently the Pharmacy Ambulatory Care Supervisor at the Ralph H. Johnson Veterans Affairs Medical Center. Prior to returning to clinical administration, she served as the Operations Program Manager at the Charleston Consolidated Mail Outpatient Pharmacy. She received her Doctor of Pharmacy degree from the University of Georgia in 2007 and Masters in Health Administration from Simmons College in 2014. She completed a PGY-1 Residency with an emphasis in Ambulatory Care and a PGY-2 Residency in Health System Administration at the Charleston VAMC. Dr. Russos is board certified in Ambulatory Care and holds certificates in Academic Preparation from SCCP, Lean Six Sigma from Vanderbilt University and Pharmacy Leadership from ASHP. *Dr. Russos declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Victoria A. Smalls is a native of St. Helena Island, SC. Penn Center brought Victoria on in 2012 as a consultant to coordinate Penn Center's Sesquicentennial Celebration. Penn Center soon noticed her talents and hired her as the Interim Director of History & Culture. In 2013, they promoted her to Director of History, Art & Culture for the National Historic Landmark District. In her spare time, Victoria is a visual artist who has been painting and selling her art professionally for 11 years. Victoria has strong ties to Penn Center, her father-- Elting Smalls was a student-athlete at Penn School and graduated in 1943. In addition, her Gullah father and white mother met on the historic grounds at a Baha'i' conference the summer of 1965 during the Civil Rights Movement. Due to the South's law on marriage, the couple could not marry in South Carolina and decided to marry in Michigan. Victoria proudly comes from a multi-racial family of 14 siblings that all grew up on their St. Helena Island farm, which happens to be the very land that her great-grandparents purchased in the late 1860's. She is also the proud mother of three: Christopher, a 21 year old Winthrop University graduate; Julian, a 6'6" 16 year old honor student and athlete, and Layla Love, a 9 year old who wants to sing like Candice Glover. Victoria feels a strong sense of place in working at Penn Center and loves to share its 152 year old story with all.

Lisa Thomson, RPh, is the Coastal District Director for the South Carolina Department of Health and Environmental Control. She has worked in retail pharmacy settings, served as a drug information specialist and a drug database coordinator. She received her Bachelor of Science in Pharmacy from the Medical University of South Carolina and is an honor graduate of the SC Criminal Justice Academy. *Mrs. Thomson declares no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.*

Bryan Ziegler, PharmD, RPh, MBA, is currently the Executive Director of the Kennedy Pharmacy Innovation Center and a Clinical Assistant Professor at the South Carolina College of Pharmacy-USC Campus. He received his PharmD from the University of South Carolina in 2001 and his MBA from the Moore School of Business at the University of South Carolina in 2006. He completed an Executive Residency with the National Community Pharmacists Association. He has had practical experience in hospital, chain and independent community pharmacy settings. Recently, Dr. Ziegler has be involved with the renovation of the Aseptic Compounding Experience Lab at SCCP and has been involved with developing and launching multiple training programs related to sterile compounding. *Dr. Ziegler discloses involvement with a sterile compounding certificate program offered by the Kennedy Pharmacy Innovation Center.*

Conference Planning Committee:

Sarah Braga, PharmD, RPh; Associate Professor of Pharmacy Practice and Director of Drug Information, South University School of Pharmacy

Lee Ann Bundrick, RPh; Administrator, South Carolina Board of Pharmacy

Laura Reid; Director of Events, South Carolina Pharmacy Association

Dock Henry Rose, RPh; Former Chairman, South Carolina Board of Pharmacy

Carole Small Russell, RPh, MHSA; Board Member, South Carolina Board of Pharmacy, 1st Congressional District

Julie Sease, PharmD, RPh, BCPS, CDE, BCACP; Assistant Dean for Academic Affairs and Professor of Pharmacy Practice, Presbyterian College of Pharmacy

Cynthia Voris, PharmD, RPh; Director, Continuing Education, South Carolina College of Pharmacy

Members of the planning committee declare no conflicts of interest or financial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holding and honoraria.

Continuing Education Instructions

The South Carolina College of Pharmacy Office of Continuing Education is proud to provide the Learning Management System for your use at the 2014 NABP/AACP District III Annual Meeting in Charleston, SC. This system will allow you to complete your evaluations, print your statements of credit and automatically report your credits earned to CPE Monitor to maintain your complete transcript for the continuing education attended during the conference. If you have any questions regarding your CE credits, please contact us at 803.777.9979.

Obtaining Your Statement of Credit

To avoid confusion, it is recommended that you have these instructions with you when you go online to claim your credit. While these instructions are very technical, they are written to walk you through the program, step-by-step, as you complete the process.

You will obtain your credit through the South Carolina College of Pharmacy's online learning management platform. If you have not used our online platform before, you will need to create an account. Please go to our website at: http://SCCP.learningexpressce.com. You can create a new account by clicking on "Create an Account." This is located to the right of the page, directly under the South Carolina College of Pharmacy logo. Be sure to enter your NABP ID and birth month and day into your profile. Once you have created your account, you will be logged in.

Now that you are logged in, you may complete your evaluations. To complete this action, click on "Complete Test/Evaluation." This is located to the left of the page, under the South Carolina College of Pharmacy banner. The "Programs and Pending CE" page will display. At the bottom of the page is a statement, "To access a private program, enter the registration code here." Enter the access code SE3 in the box next to this statement and ***click*** register (hitting enter won't work). This code is case sensitive. Your program details will display. Scroll to the bottom of the page.

Confirm your personal information, especially your NABP eID and birth month and day. Click on the blue "Register" button at the bottom. The program is now added to your "Programs and Pending CE" list. Choose the sessions you attended by clicking on the 'tick' boxes next to the appropriate sessions. Click Register. The program is now added to your program list. Click on the title: NABP AACP 2014 District Meeting. The sessions you chose will have plus signs next to them. Any sessions you did not choose will remain unchecked. Click on the plus sign next to the first session you attended. The box will expand to reveal the green "Complete Evaluation" button. Click on this green button. You will be prompted for the session's access code. Individual Session Access Codes are given out at the end of each CE. Enter the code into the box. This code is case sensitive. Click on the submit button. Complete the evaluation questions. Repeat until you have completed all evaluations. Once you have answered all of the evaluations, your certificate will display for printing or to save to your computer. It will also be in your account under "Completed CE" if you need to print it in the future.

Event Access Code: SE3 **Event Title:** NABP AACP 2014 District Meeting

Individual Session Access Codes will be given out at the end of each CE.

The South Carolina College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education. The program is accredited for a total of 8 live contact hours (0.8 CEUs). Participants must attend all activities for maximum credit. Registration codes for each day's CE activities will be announced at the end of each session. Participants must complete an on-line speaker and program evaluation in order for credit to be reported to the CPE® monitor. ACPE now requires that all completed pharmacy continuing education credits must be processed and claimed no later than 60 days from the date of the live activity. In order for us to meet the 60 day requirement for reporting, you are encouraged to complete your evaluation as soon as possible, but no later than 30 days after the activity. *This is a knowledge based learning activity.*

If you have any questions or comments, feel free to reach out to the following:

CE Questions:
Cynthia (Cindy) Voris
South Carolina College of Pharmacy
803.777.4219
vorisc@sccp.sc.edu

SE Officer Questions:
Laura Reid
SC Pharmacy Association
803.354.9977
laura@scrx.org

NABP, AACP or General Questions:
Carole Russell
South Carolina Board of Pharmacy
843.442.5276
smallcl@musc.edu
OR
Cindy Parham
North Carolina Board of Pharmacy
919.246.1050 ext. 202
cparham@ncbop.org

Emily Jerry
foundation
Let The Healing Begin

Our Mission

- We are determined to make our nation's medical centers safer for everyone—beginning with our babies and children.
- We are focusing on increasing public awareness of key patient safety-related issues.
- We are always striving to be an active part of the "solution" by identifying technology and best practices proven to minimize human error in medicine.
- Through our efforts, we are devoted to helping save lives every day.

Modification of Internal Systems & Processes in Medicine

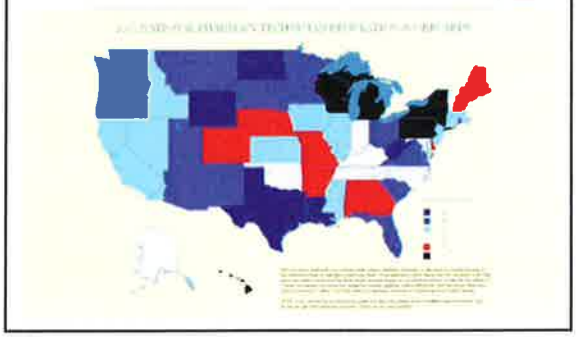
- Many caregivers have shared their fear that they could make an error without realizing it, a risk intrinsic to being human.
- Through the proper adoption and implementation of technology in medicine, coupled with new and improved best practices, we can lower the probability of the "human error" component of medicine.
- We now have the ability to manufacture millions of iPhones & other incredibly complex devices with almost "zero defects" by ingraining proven process improvement methods such as ISO Standards, Six Sigma principles, etc.
- ***We can do the same in Medicine!***

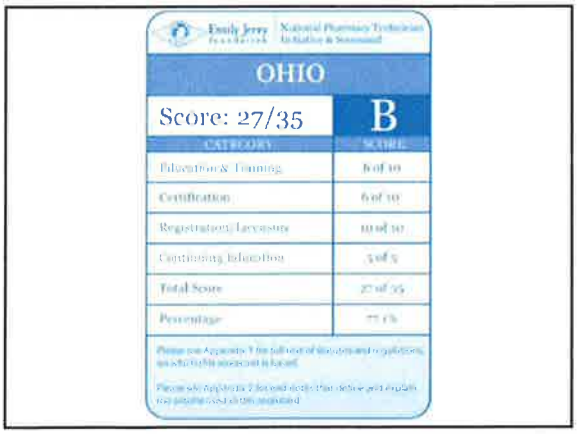
"To err is human; **to forgive, divine.**"

-Alexander Pope

[redacted]

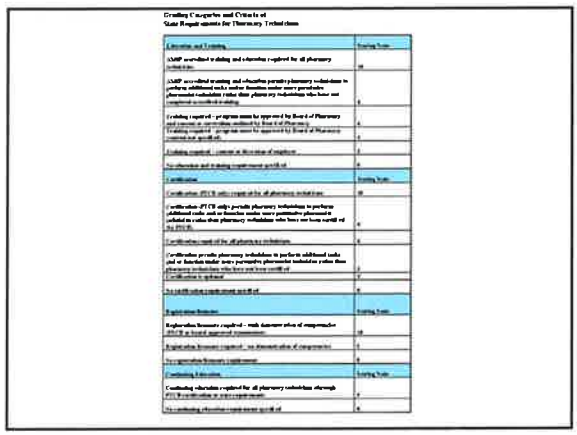
Emily Jerry Foundation
2014 Pharmacy Technician Scorecard





OHIO

Score: 27/35	B
CATEGORY	SCORE
Education & Training	8 of 10
Certification	6 of 10
Registration/Licensure	10 of 10
Continuing Education	3 of 5
Total Score	27 of 35
Percentage	77.1%



The
GUARDIAN ANGEL Pediatric Safe Label Program

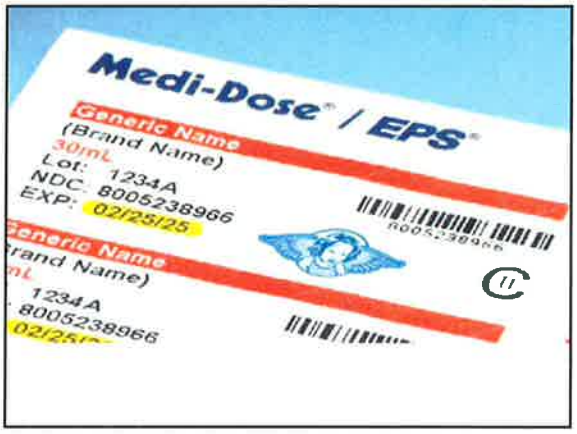
Emily Jerry foundation

The Problem

- Adverse drug events and medication errors are of particular concern with babies and children
- Dosing of pediatric medications must typically account for body weight and therefore usually requires special calculations

Our Plan:

- Guardian Angel logo is printed on ALL medication packaging intended for babies and children
- The logo serves as a reminder to all caregivers that the medication is designated for a child
- Caregivers are thereby alerted to pay extra attention to a medication that is to be given to a particularly vulnerable population



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DIVERSION IN PHARMACY

Raymond Keith RPh
Mississippi Board of Pharmacy
NABP/AACP District III

- Raymond Keith, RPh
- Mississippi Board of Pharmacy Compliance Agent for > 10 years
- Perform routine inspections of facilities permitted by the Board, and investigations of registrants, licensees, and permits as directed by our Investigative Review Committee
- We work closely with MBN and DEA Diversion

The Mississippi Board of Pharmacy

Calendar year 2013 Compliance Agents performed:

> 1,400 inspections

> 60 investigations

at least 6 audits performed:

> 4,500 dosage units C – II

> 69,000 Dosage units C – III

> 1,500 dosage units C – IV

> 50 pints of liquid controlled substances

19 voluntary surrenders

REASONS FOR DIVERSION:

- Greed / Monetary gain
  - ➢Affects RPh and technicians (and cashiers)
  - ➢More common in technicians and cashiers
  - ➢Takes effort, but can be verified w/ surveillance and daily counts / verification

REASONS FOR DIVERSION:

- Threats / Intimidation:
  - ➢Personal
  - ➢Family (especially children)
    - ❖Unknown person threatens family
    - ❖Child owes dealer

    More common with technicians and cashiers

REASONS FOR DIVERSION:

- Addiction:
  - – Can happen with anyone
  - – More common with RPh
    - ➢Stress
    - ➢Perceived lack of time for MD appointment
    - ➢Can't be away from pharmacy

REASONS FOR DIVERSION:

- Seduction:
  - Former crush or significant other
  - "Intriguing" new acquaintance
  - Sympathetic situation of significant other

DIVERSION: PREVENTION

Diversion: Prevention

- Awareness:
  - By RPh
  - By all employees
- Security Measures
  - Surveillance
  - Alarm Systems
  - Having ***and reconciling*** perpetual inventories
- And Most Important: (but hardest)

Diversion: Prevention

- ***TRUST BUT VERIFY !!!***

QUESTIONS??

Drug Diversion and Abuse: Coverage in the PharmD Curriculum

Gene Reeder, RPh, PhD
Professor of Pharmaceutical and Administrative Sciences
Presbyterian College
School of Pharmacy
Clinton, SC

Why Should Schools Be Teaching This Topic And Be Engaged with the Profession to Address The Problem?

Ten of the highest prescribing states in number of opioid Rxs per person are in the South.

SOURCE: IMS, National Prescription Audit (NPA), 2012
Morbidity and Mortality Weekly Report, Vol. 63, July 1, 2014

What Can Be Done? Some State Examples

SOURCE: : Vital Signs Morbidity and Mortality Weekly Report, Vol. 63, July 1, 2014.

Survey of District III Schools

- Three open-ended questions were emailed to a contact at each school in District III.
  1. Are drug diversion and drug abuse being integrated into the PharmD curriculum?
     - If so, how and to what degree (e.g. lectures in law or clinical classes; elective course; guest speakers; etc)
  2. Do you have a faculty member with a particular expertise or interest in this area?
  3. Are you engaged with pharmacists or regulatory agencies in the state regarding drug diversion and drug abuse?

Survey of District III Schools

- Most Schools cover this topic somewhere in the curriculum, although none reported a required course dedicated to the topic
  - ~ 4 lecture hours typical
- Guest lecturers were the most frequently reported method
  - State Controlled Substance Agencies
  - Board of Pharmacy
  - Regional DEA Office
  - Pharmacist Recovery Program

Survey of District III Schools

- Some Schools offered elective courses in drug abuse and misuse which included drug diversion
- Lectures are typically included in the Pharmacy Law Course but tend to focus on detecting and avoiding fraudulent CS Rxs
- Basic neurology of substance abuse and addictive behaviors are covered in clinical didactic courses
- Several Schools partner with Boards and Associations to offer CE courses

Corresponding Responsibility

What Should a Pharmacist Do?

Corresponding Responsibility

- Federal CS Regulations state that while "the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." (21 C.F.R. § 1306.04)
- Regulations further state, "the person knowingly filling such a purported prescription, as well as the person issuing it is subject to the penalties provided for violations of the provisions of law relating to controlled substances."
- Thus, a pharmacist is prohibited from filling a CS Rx "when he either knows of or has reason to know that the prescription was not written for a legitimate purpose."

Source: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/12/the-dea-opines-on-a-pharmacists-corresponding-responsibility-.html

Kaushik V. Kotecha, R.Ph.
Sr. Controlled Substance Director

9098 Fairforest Road
Spartanburg, SC 29301
Office 864-582-1216 Ext. 1204
Fax 864-591-0333
kkotecha@smithdrug.com

Introduction

- Spartanburg City Police Officer
- Graduate of USC School of Pharmacy
- Hospital Staff Pharmacist
- Oncology Pharmacy Manager
- Inspector with SC DHEC, Bureau of Drug Control
- Graduate of SC Criminal Justice Academy
- Regional Director with DHEC, Bureau of Drug Control
- Director and now Sr. Director of Controlled Substance Compliance with Smith Drug Company, March 1, 2012
- Investigator with the 7th Circuit Solicitor's Office

Simple Life

Life Today

DEA Statistics

- Rx drug trafficking in US is a $72.5 billion-a-year business
- More than 25% of all Rx drugs dispensed in US end up being re-sold on the street
- One-third of all illegal drugs sold are prescription drugs
- Rx drug abuse is often the gateway for children to illicit drugs such as cocaine and heroin

* Brian Goldman, M.D. (*How to Thwart a Drug Seeker*/ other sources)

Additional Stats

OD deaths increased from Opioid analgesics*:

- 1999 – 4,030
- 2009 – 15,597
- 2010 - 16,651, 60% of drug overdose involved pharmaceutical drugs

Recent data indicates that 4,091 people in Florida died from prescription drug OD in 2010 (Methadone, Oxycodone, Morphine and Benzodiazepine)

The number of babies addicted to prescription drugs has nearly tripled in the past decade (13,539)

Rx drug abuse is the fastest growing segment for illegal drug use in US, faster than cocaine, meth and heroin combined

Recent estimate is that 52 million people have used Rx drugs illegally (NIDA)

*cdc

DEA Registration Population as of 7-20-2014

Total Number of Registrants: **1,500,245**

- Practitioner – 1,168,919
- Mid-Level Practitioner - 232,136
- Pharmacy (all) - 68,907
- Hospital/Clinic - 15,921
- Manufacturer - 545
- Distributor - 959
- Researcher/Labs/ADS Machines - 9,25
- NTP - 1,319

More Senior Citizens Caught Selling Prescriptions

When police in Spartanburg set up a stakeout to catch a neighborhood drug dealer, the last person they expected to see passing pills was someone who looked like their grandmother.

But when a tiny, gray-haired 75-year-old woman took cash in exchange for her prescription drugs, they were forced to bring her in and charge her with unlawful distribution.

"She was getting methadone, Lortab and Valium and selling those drugs... to supplement her income," said Kaushik Kotecha, Piedmont district director of the state Department of Health and Environmental Control's Bureau of Drug Control.

Trial Continues for Campobello Woman Accused of Killing Baby Through Tainted Breast Milk

[redacted], Woman Who Gave Baby Morphine Through Breast Milk, Gets 20 Years


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Counter Measures For Pharmacy

Create a KYP for the prescribers of controlled substances

Check prescribers DEA registrations

- Valid https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp
- Privilege to prescribe schedule
- Registered address is in the state where the prescriber is licensed

Check state boards

- Valid license
- Sanctions
- Type of practice and/or board certification for the type of prescriptions

Patient

-Are they paying for with insurance/cash
-Are they traveling long distances to see the prescriber and/or your pharmacy
-Patients coming together and/or family members getting similar Rx
-Large population of patients from a prescriber(s) who considered to liberal prescriber. "Candy Man"

Counter Measures For Pharmacy

When accepting controlled substance prescription(s)

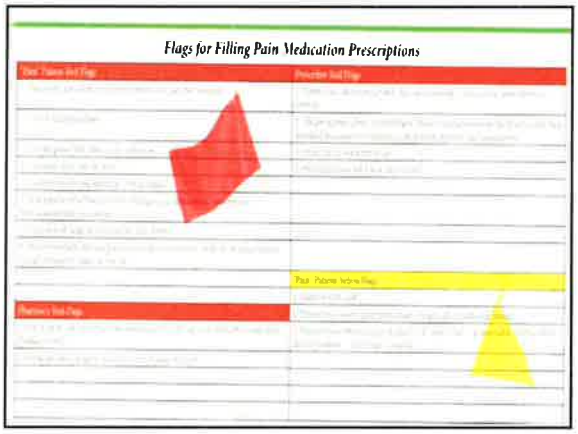
- Review the prescription before dispensing
- Check PMP
- Check for alteration
- Determine the appropriate quantity for the practitioner, ie. a dentist should not be prescribing 120 dosage units of hydrocodone
- Obtain a positive identification and make note of the person who obtained the positive identification

Counter Measures For Pharmacy

- Review your security procedures
- Make sure your alarm and surveillance recording are functional by conducting a quarterly test
- Make sure only authorized personnel are allowed to enter the dispensing area
- Call your local law enforcement agency to conduct a security risk management review and seek advice
- Develop a plan of action in case of robbery
- Develop a plan of action for forged prescription
- Develop a plan of action for employee theft (PIC and/or Owner)

Counter Measures For Pharmacy

- Keep track of your inventory
- Monthly invoices
- Monthly DEA 222
- Review monthly dispensing
- Review your purchasing
- Conduct internal audit
- Have a file on the prescriber
- Have Drug Diversion Policy



SC DHEC Bureau of Drug Control

Lisa Thomson, RPh
Director, Bureau of Drug Control
thomsola@dhec.sc.gov
Office 803-896-0636

SC DHEC
Bureau of Drug Control

WHO WE ARE
WHAT WE DO
WHERE WE DO IT

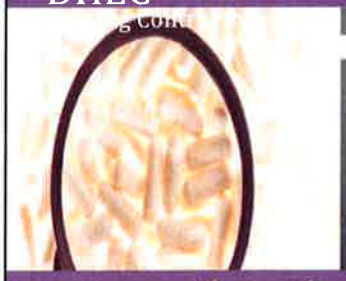
Who Regulates Controlled Substances?

DHEC is a regulatory agency with the goal of achieving and maintaining compliance with applicable laws and regulations through education.

The Bureau of Drug Control regulates the dispensing and administration of controlled substances. This is done through:

- Audits
- Inspections
- Educational Programs
- Investigations

DHEC



Duties of an inspector

- Regulatory
- Registrant inspections
- Accountability audits
- Education
- Law Enforcement
- Investigations/Arrests

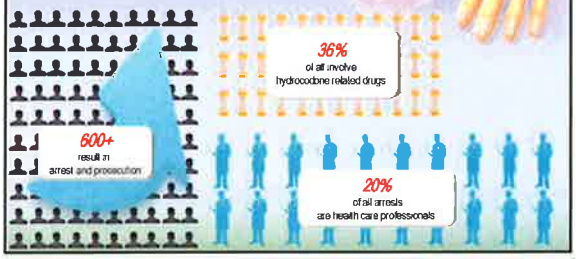
DHEC Drug Control Inspectors requirements:

- Licensed pharmacists
- Minimum of three (3) years working experience in pharmacy practice
- Complete SC Criminal Justice Academy training and become a commissioned law enforcement officer

What is the Problem?

750-1000 complaints received annually from:

- health care professionals
- concerned citizens
- state and local agencies
- inspectors



36% of all involve hydrocodone related drugs

600+ result in arrest and prosecution

20% of all arrests are health care professionals

Life Today

Enough Prescription Painkillers were prescribed in 2010 to medicate every American Adult around the clock for a month (4 times more prescription painkillers were sold in 2010 than in 1999).

In 2010, 1 in 20 people in the US (age 12 or older) reported using prescription painkillers for nonmedical reasons in the previous year.

Nearly 15,000 people die every year of overdoses involving prescription painkillers.

Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.

Nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

Source: CDC Vital Signs November 2011

We like our Prescription Painkillers…

Amount of prescription painkillers sold by state per 10,000 people (2010)

Drug Overdose Mortality Rates

(per 100,000 People 2010)

Methods of Diversion

Practitioners/Pharmacist
- Illegal distribution
- Self abuse
- Trading drugs for sex

Employee Pilferage
- Hospitals
- Practitioner offices
- Nursing homes
- Retail pharmacies
- Manufacturing/Distribution

Pharmacy/Other Theft
- Armed robbery
- Burglary
- In Transit Loss
- Smurfing

Patients
- Drug Rings
- Doctor shopping
- Forged/fraudulent/altered Rxs
- Photocopied Rxs
- Stolen prescription pads
- Internet
- Pain Clinics

The Last Line of Defense

CORRESPONDING LIABILITY

44-53-360 A prescription, in order to be effective in legalizing the possession of a controlled substance and eliminating the need for registration of the recipient, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **BUT A CORRESPONDING LIABILITY** rests with the pharmacist who fills and ultimately dispenses the prescription.

CORRESPONDING LIABILITY
SC Reg 61-4
Section 1002 Purpose of Issue of Prescription

A prescription for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner BUT A CORRESPONDING LIABILITY rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Drug Seeker or Patient?

Potential Red Flags

- Many customers receiving the same combination of prescriptions; cocktail
- Many customers receiving the same strength of controlled substances; no individualized dosing; multiple prescriptions for the strongest dose
- Many customers paying cash for their prescriptions
- Early refills
- Many customers with the same diagnosis codes written on their prescriptions
- Individuals driving long distances to visit physicians and/or to fill prescriptions
- Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician

Potential Red Flags

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctors prescription

Verification of legitimacy not satisfied by a call to the doctors office

SC Prescription Monitoring Program

- SC pharmacies began mandatory reporting in February 2008.
- It provides information for schedules 2,3,4 scripts that a patient has had filled for a specified period, and includes the prescriber who ordered it and the pharmacy that filled it
- Daily Reporting

OVERVIEW

- Describe the mission and function of the Pharmacy Technician Certification Board
- Describe the impact recent changes within the profession will have on pharmacy technicians
- Identify the evolving roles of pharmacy technicians and their opportunities in advancing care
- Review the planned changes to the PTCB certification program

PTCB

Self-Assessment Questions

- What has remained stable in the pharmacy profession over the last ten years?
  a. Job Market
  b. Practice Models
  c. Technology
  d. Need for Change
- Pharmacy technicians may assist pharmacists with:
  a. Supervising and training other technicians
  b. Database administration
  c. Overseeing compounding quality control
  d. All of the above

PTCB

Self-Assessment Questions

- Which of the following statements are false?
  a. PTCB published an updated exam in 2013
  b. Accredited education will be a requirement in 2020
  c. All states regulate pharmacy technicians
  d. Pharmacy technicians are positively impacting MTM and Transitions of Care services

About PTCB

Mission Statement

PTCB develops, maintains, promotes and administers a nationally accredited certification program for pharmacy technicians to enable the most effective support of pharmacists to advance patient safety.

Certification Council

NABP

APhA

PTCB

MPA

Key Contractors

PEARSON VUE

graphcom

Telecom, Inc.

COBALT

Exam Design Inc

PTCB Certification Program

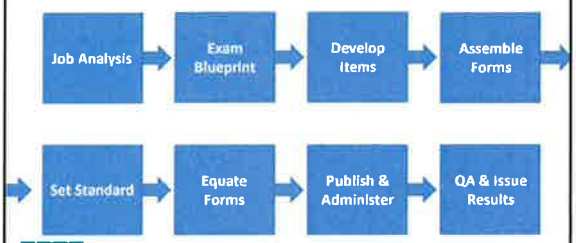
Pharmacy Technician Certification Exam (PTCE):

- Widely recognized and trusted throughout the profession
- Psychometrically sound
- 280,000 active certified pharmacy technicians
- 500K certifications since 1995

Current certification requirements:

- A high school diploma or equivalent
- Disclosure of all criminal and state board of pharmacy actions
- A passing score on the PTCE
- Recertification every two years

Assessment Process



Requirements to Work

- There are no standard nationwide requirements to work as a pharmacy technician
- Employers may require:
  - Formal pharmacy technician education
  - Prior experience
  - National certification (Certified Technician -- CPhT)
  - State registration
  - Continuing education
- Formal Education Programs
  - Approximately 750 programs in United States
  - 258 accredited by American Society of Health-System Pharmacists (ASHP)

Career (U.S. Bureau of Labor Statistics, Jan 2014)

- 2012, Median Pay $14.10 hr / $29,320 yr
- 2012, Number of Jobs 355,300
- Job Outlook, 2012 – 2022 20% growth rate
  - Employment increase much faster than average for all occupations
    - The average growth rate for all occupations is 11 percent
    - Projected numeric change is 70K

PTCE Candidate Demographics

- **Age of candidates**
  - < 21: 20%
  - 21-25: 34%
  - 26-30: 17%
  - 31-40: 15%
  - 41-60: 14%
- **Gender**
  - Female: 74%
  - Male 26%
- **Education Level**
  - HS Diploma/GED 45%
  - Associates 13%
  - Bachelor 15%
  - Masters 2%
  - Other 5%
  - Rx Tech Certificate/Diploma 20%

PTCB

Winds of Change

Over the past several years, the pharmacy profession has witnessed changes in. . .

- Regulatory Oversight
- Job Market
- Pharmacy Education
- Technology
- EHR/e-prescribing
- Pharmacy Practice Models

Transitions of the Profession

- Pharmacy profession under pressure to change
  - Medication Therapy Management
  - Affordable Care Act
  - Accountable Care Organization
  - Medical Home model
  - Medicaid expansion
  - Collaborative practice
  - Provider status

Pharmacy Technician Roles

- The roles of pharmacy technicians are changing as pharmacists move to more direct patient care
- Pharmacy technicians play integral roles in supporting pharmacists in all practice settings
- PTCB is focused on certification requirements to increase patient safety

Evolving Roles of Technicians

- Lead technician roles
- Compliance technicians
- Medication safety
- Pharmacy Benefit
- Immunization assistance
- Supply chain management
- Informatics
- Tech – check- tech
- MTM services/Transitions of Care

Growing Demand for Change

Joint Commission of Pharmacy Practitioners (JCPP)
Vision Statement

Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.

PPMI

PTCB
C.R.E.S.T. INITIATIVE

CERTIFICATION PROGRAM CHANGES

New PTCB requirements to become recertified:

- **2014**, one of the 20 required CE hours to be in patient safety, in addition to one already required in law
- **2015**, accept only *pharmacy-technician-targeted* CE
- **2016**, the number of CE courses allowed from college courses will be decreased
  - from 15 to 10 hours
- **2018**, the number of in-service hours allowed for CE will be phased out
  - from 10 to five in 2015, and from five to zero in 2018

CERTIFICATION PROGRAM CHANGES

New PTCB requirements to become initially certified:

- **2014**, Criminal background checks
- **2020**, Complete an ACPE/ASHP-accredited education program - *Pharmacy Technician Accreditation Commission (PTAC)*

Advanced Certification Programs in Development

The Way Forward

- Elevate standards within the profession to meet the demands of the growing healthcare system
- Improve patient care, outcomes & access
- Roles are evolving & scope of practice is expanding
- Provide platform to advance pharmacy technicians
  - Technicians must have education, training and credentials to advance with the pharmacy workforce

Self-Assessment Questions

- What has remained stable in the pharmacy profession over the last ten years?
  a. Job Market
  b. Practice Models
  c. Technology
  d. **Need for Change**
- Pharmacy technicians may assist pharmacists with:
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Self-Assessment Questions

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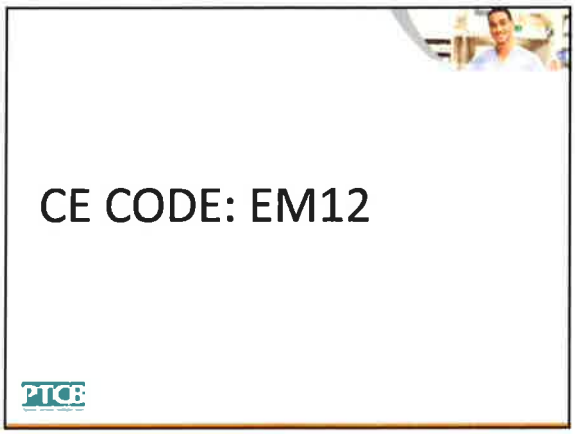


Department of Veterans Affairs: Consolidated Mail Outpatient Pharmacy (CMOP)

Annual Meeting of NABP/AACP District III
August 2014

Jennifer Spruill Russos, PharmD, MHA, BCACP

1

Objectives

- Pharmacy Automation – How it's changing the Prescription Dispensing Paradigm
- Automation Quality Assurance – Testing the "Competency" of Equipment

2

Department of Veterans Affairs
Consolidated Mail Outpatient Pharmacy

CMOP Mission

To honor our nation's Veterans by providing exceptional mail outpatient pharmacy service in support of the provision of care.

CMOP Vision

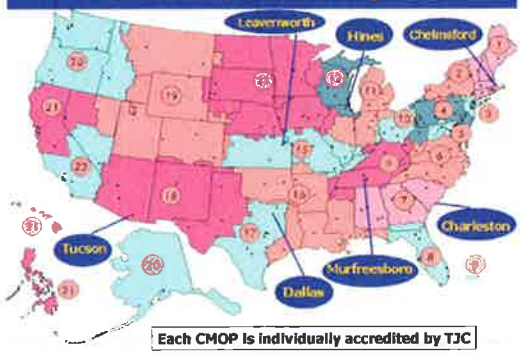
- Partner with VA Medical Center customers in the provision of integrated and seamless care.
- Continue vision of One VA by partnering with other government agencies (CHAMPVA, DoD, Indian Health Service, etc.).
- Continuously improve quality processes and provide exemplary services that are both patient centered and evidence based.
- Ensure the highest level of integrity and accountability within the CMOP workforce; promote a work environment that supports learning, discovery, and continuous improvement.
- Contribute as members of the VA Pharmacy community and as members of the Pharmacy profession.
- Be a visible component to our VA Medical Center customers yet transparent in the VA patient-centric pharmacy process.
- Continuously plan and prepare for response to emergent need both locally and nationally.
- Innovate, Automate, and Transform the provision of Prescription Benefit to veterans.

3

VA CMOP...

- Functions as a virtual extension of the VA Medical Center (VAMC) pharmacies
- Provides high-quality prescription service through automated processing and mail delivery of medications
- CMOP facilities individually accredited by The Joint Commission
- Focuses on accurate, timely, and cost-effective fulfillment of the dispensing portion of prescriptions

VA CMOP National System



Each CMOP is individually accredited by TJC

Evolution of VA CMOP

1950's
- VA first organization to routinely mail RXs

1974
- West LA VAMC consolidates RX mailing

1992
- GAO recommends consolidation of Veteran RX processing

- First automated VA consolidated mail outpatient pharmacy opens in Leavenworth, KS

1999
- 7 CMOPs implemented to provide nationwide service optimizing postal shipping

Since 1999
- Continued improvements in automation to increase quantity and quality

Why Automate?

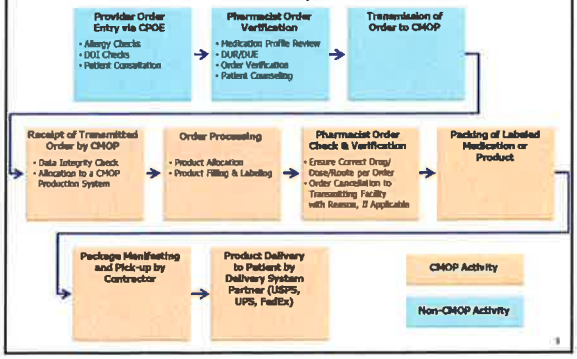
- Combat the pharmacist shortage
- Improve use of space
- Increase efficiency
- Lower operational and personnel costs
- Reduce errors
- Reduce repetitive motion injuries

Roles for VAMCs and CMOP in the VHA Outpatient Medication Fulfillment System

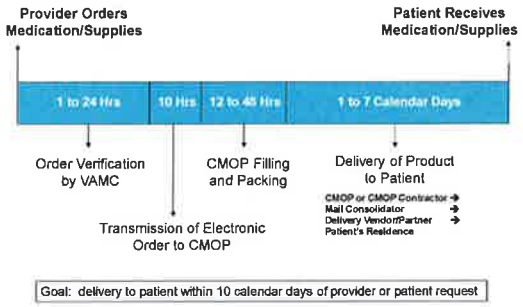
- Initial order review.
- Medication profile review.
- Therapeutic drug and laboratory monitoring.
- Patient consultation.
- Verification of patient address.
- Daily transmission of orders.
- Reporting of errors, close calls, and complaints.
- Notification of changes in product utilization.
- Verification of order transmissions.
- Accurate and timely processing of orders.
- Investigation, trending, and feedback for reported errors, close calls, and complaints.
- Cancellation of order with explanation to the Medical Center, when applicable.
- Proper inventory control.
- Provision of cost reports.

Medical Center | **CMOP**

Life of a VA CMOP Mail Outpatient Prescription

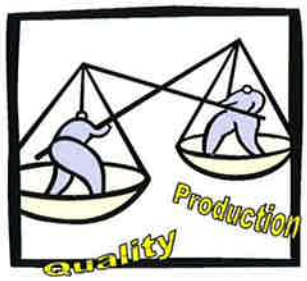


Timeline for a VA CMOP Mail Outpatient Prescription



Goal: delivery to patient within 10 calendar days of provider or patient request

The Great Balance



There's Safety in Automation

- *To Err is Human*
- One error is one error too many
- Nationally 1.5% to 4 % of prescriptions filled in error with potentially serious risk to patients
- Automated systems ensure each fill follows an identical process
- Significant dispensing error reduction with automation in U.S. correctional facility
  - 6.3 to 4.1 per 100,000 Rx's dispensed

Pharmacy Dispensing Errors

Retail Pharmacy

- 4,481 Rx evaluated
- 40 direction errors
- 9 quantity errors
- 2 order omissions
- 8 strength errors
- 6 wrong drug
- 1 wrong dosage form

Automated Mail Order

- 21,252 Rx evaluated
- 14 direction errors
- 1 quantity error
- 1 order omission
- 0 strength error
- 0 wrong drug
- 0 wrong dosage form

Teagarden JR, Nagle B, Aubert RE, et al. Pharmacotherapy 2005;25:1629-1635
Flynn EA, Barker KN, Carnahan BJ. J Am Pharm Assoc 2003;43:191-200

VA CMOP Vital Statistics FY13

National CMOP Program

- Workload 117.2 million (Rx), 79.6 million (Parcels)
- >465,000 prescriptions/work day
- >322,000 Veteran patients serviced/work day
- Budget $3.44 billion/year
- $13.8 million/work day
- 82% of all outpatient Rx filled in VHA

Charleston CMOP

- Workload 26.2 million (Rx), 18.2 million (Parcels)
- >104,000 prescriptions per workday (~11% CS)
- >72,000 Veteran patients service/work day
- Budget $696 million/year
- $2.8 million/work day
- 58 VAMC facilities and associated CBOCs served

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Charleston CMOP Production System Allocation-The New Business Model

Unit of Use Dispensers (24%)
SI Dispen-SI-Matic
- Prepackaged item dispensing

Tablet/Capsule Dispensers (59%)
RxAS ScriptCount
- Automatic tablet/capsule counting
- Dual count technology to reduce, detect, and auto-correct miscounts

Controlled Substances (11%)
Dual Random Chas Labeling System
- Complete inventory every 24 hrs
- Charleston and Murfreesboro

Bulk Dispensing (1%)
- Special shipping needs

Manual Dispensing (4%)
- Low use products

Outsource Contractors (1%)
- Large, heavy, or bulky non-drug products
- Data security compliant with VA standards

15

Monitoring CMOP Performance

- Ongoing assessment of core processes evaluated using data from internal CMOP production systems
- Patient-related occurrences reported by VAMCs via the CMOP National Web Application's quality assurance reporting function
- Metrics developed and regularly assessed to promote use of best practices and sustainable improvement

16

Unique Feature-Charleston AVS

- Multi-layered automated sig review system stores data on accepted and rejected sigs
- Provides local flexibility to identify problematic sigs and provide direct and timely feedback to sites
- Eliminates redundant review of accepted sigs to focus RPh attention to outliers

17

Unique Feature-Lean Six Sigma

Established 2007

- Current Penetration:
  - Master Black Belt (1)
  - Black Belt (1)
  - Black Belt Candidate (1)
  - Green Belts (5)
  - Green Belt Candidates (3)
- JIT Staff Training
  - All Lead Technicians trained FY2013
  - Area SIPOC Analysis accomplished
  - Small scale projects accomplished
- Expose Students and Residents

Goal: Full integration of a Lean Six Sigma culture

18

How is Charleston CMOP Unique?

- Newest Tablet Capsule Automation
- Automated and Semi-Automated Packing
- Formal Strategic Planning Which Includes All Levels of Staff
- Lean Six Sigma Program
- Auto-Verify Sig Program
- Development of CLS, RCLS, and DRCLS Automation
- Consolidated Controlled Substance Dispensing
- Preceptor Site for PGY2 Residents and Pharm.D. Candidates
- Staff Development Programs Including Technician Certification Prep and Onsite CE Programs

QUESTIONS

Current Trends in Institutional Pharmacy Automation

Jeff Brittain, PharmD, BCPS
Clinical Pharmacist, Medication Policy & Informatics
Medical University of South Carolina
Adjunct Assistant Professor
South Carolina College of Pharmacy

What is Automation?

The technique, method, or system of operating or controlling a process by electronic devices, thereby reducing human intervention

- Reproducibility
- Efficiency

Areas of Focus

- IV Workflow Automation
- Robotic IV Compounding Automation

IV Workflow Automation Offers

- Workload prioritization
- Preparation guidance for user
  - Drug
  - Concentration
  - Amount
- Remote verification
- Intelligent labeling
- Analyze trends
- Historical reference

How It Works

- Input via print-stream or HL7 interface
- Routing based on order characteristics
- Match presented products against input
- Provide ingredient-specific guidance
- Control progress of doses
- Present steps in logical order for verification
- Timestamp each step

How It Works

- *Qualitative* analysis of ingredients
  - Scanning a bar code
  - Image recognition
- *Quantitative* measure of components
  - Image/video capture
  - Gravimetric measurement
- Progression restricted until parameters satisfied

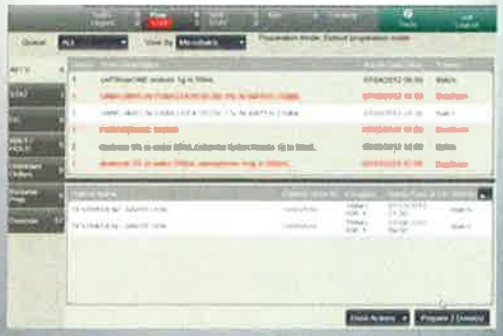
Gravimetrics

- Advantages:
  - Highest level of precision
  - Completes loop of verification
- Challenges:
  - Clinically significant precision
  - Conflict with device markings
  - Additional equipment in the hood
  - Additional time to weigh
  - Accurate gravimetric information

IV Workflow Automation Options

- DoseEdge® (Baxter)
  - http://www.baxa.com/doseedge/
- ChemoCato® (ChemoCato)
  - http://www.chemocato.com
- Pharm-Q® In The Hood (Envision Telepharmacy)
  - http://www.envision-rx.com/products-services/pharmq-ith
- Phocus-Rx® (Grifols)
  - http://www.healthmark.ca/2-30-PHOCUS-Rx-Camera-Verification-System-en.html?ProduitID=229
- IV Soft® (Health Robotics)
  - http://www.health-robotics.com/en/solutions/ivsoft/
- ScriptPro® TelePharmacy (ScriptPro)
  - http://www.scriptpro.com/Products/Telepharmacy/Sterile-Room-Med-Prep/

Workflow Prioritization



Guided Preparation

Side-By-Side Comparison

	ChemoCato	DoseEdge	i.v. SOFT	ScriptPro	Pharm-Q	Phocus-Rx
Gravimetric measurement	Yes	Yes	Yes	No	No	No
Bar code recognition	Yes	Yes	Yes	Yes	Yes	Yes
Image recognition	No	No	Yes	No	No	Yes
Still image capture / storage	No	Yes	Yes	Yes	Yes	Yes
Video capture / storage	No	No	Yes	No	No	No
Hazardous preparation	Yes	Yes	Yes	Yes	Yes	Yes
Non-hazardous prep support	No	Yes	Yes	Yes	Yes	Yes

Robotic IV Automation Options

- IntelliFill® (Baxter)
  - http://www.baxa.com/intellifill
- I.V. Station® (Health Robotics)
  - http://www.health-robotics.com/en/solutions/i-v-station/
- RIVA® (Intelligent Hospital Systems)
  - http://www.intelligenthospitals.com

IntelliFill®

- Output
  - Over 600 syringes/hr
- Accommodates
  - Specific 12mL syringe
  - Bandoleer-fed
  - Min vol = 0.5mL
  - Max vol = 11.5mL
- Non-hazardous only

I.V. Station®

- Output:
  - Up to 60 syringes or 24 bags/hr
- Accommodates:
  - 28 vials (1 to 100mL)
  - 25 IV bags (50 to 1000mL)
  - 42 syringes (1 to 60mL)
  - Min vol = 0.5mL
- I.V. Station® Onco for hazards

RIVA®

- Output (per run):
  - Up to 400 x10mL syringes
  - Up to 140 x 150mL bags
- Accommodates:
  - Bags from 25mL - 1000mL
  - Syringes from 1mL - 60mL
  - Min volume = 0.3mL in 1mL syringe
  - Min volume = 1.8mL in bag
- Hazards or non-hazards

Regulatory Scope

- Pharmacist vs engineer
- Who should operate?
  - Qualifications?
  - On-site vs remote management?
- Who should regulate?
- INsourcing

Current Trends in Institutional Pharmacy Automation

Automation in LTC

Daniel Bundrick, RPh
Vice President of Pharmacy Services, Agape'

Objectives

1. Identify safety risks and need to change the current system utilized by most skilled nursing homes for drug distribution
2. Describe how automation can be successfully implemented in a skilled nursing environment and the benefits realized

Disclosures:

- I have nothing to disclose

The Current System

Standard 30-day cycle 'bingo-cards' (see photo above) & emergency kits

- Creates waste & inefficiency due to large amounts of unused medications
- Creates greater opportunity for error and diversion of controlled substances
- Time-consuming and error prone narcotic counts at shift change
- Emergency kits create issues with billing and diversion
- Slow and inefficient medication prep and pass

Remote Dispensing System – Before & After

[Before]

[After]

Safeguards for Accuracy and Security

- System locked in a med room with video surveillance
- Narcotics are locked separately and only accessible by pharmacy
- Expiration dates and lots are tracked down to the packet
- Canisters are tested for accuracy each time they are filled
- A pharmacist checks each canister to verify the medication
- Microchip technology guarantees 100% restocking accuracy
- Approved personnel perform the '5 Rights' prior to administration

(Right patient, right drug, right dose, right route, right time)

Benefits to the Facility

- Provides access to medications 24x7
  - Emergency / STAT doses
  - First doses for new admissions (esp. late night/weekend)
- Reduces medication errors and prep/pass time
- Virtually eliminates medication waste
- Reduces inventory on the med cart
- Eliminates narcotics count at shift change
- Increases accountability and reduces diversion
- Allows approved personnel more time with patients

= Better Quality of Care

Benefits to the Pharmacy

- Increases accuracy
- Provides better inventory control
- Reduces delivery costs
- Reduces fill labor costs
- Provides better service to remote facilities
- Eliminates returns and drug destruction costs
- Allows pharmacists to focus on clinical functions
- Greatly enhances the pharmacists role and involvement in the medication administration process in the facility

= Better Service, Lower Cost

ISMP – 12 Core Processes

1. Provide ideal environmental condition for the use of ADCs (Automated Dispensing Cabinets)
2. Ensure ADC system security
3. Use pharmacy-profiled ADCs
4. Identify information that should appear on the ADC screen
5. Select and maintain proper ADC inventory
6. Select appropriate ADC configuration

ISMP – 12 Core Processes

7. Define safe ADC restocking processes
8. Develop procedures to ensure the accurate withdrawal of medications from the ADC
9. Establish criteria for ADC system overrides
10. Standardize processes for transporting medications from the ADC to the patient's bedside
11. Eliminate the process for returning medications directly to their original ADC location
12. Provide staff education and competency validation

#1 Provide Ideal Environmental Conditions for the Use of ADCs

- Each facility will have 1 or more Talyst systems that are close to the nurses station that will reduce excessive walking and work-arounds by staff
- The system will be located in a locked room that has limited foot traffic and is large enough to adequately open the doors of the ADC
- There will be sufficient lighting for the nurse to read the medication labels as well as adequate ventilation and temperature control within the room

#2 Ensure ADC System Security

- Each nurse will have his/her own password into the computer linked with each patients' MAR and the ADC
- Passwords will be changed quarterly in order to maintain system security
- All waste will be documented and will require 2 signatures for narcotics
- Random audits of medical records will be performed to verify that removed medications were administered and documented as dispensed
- Any discrepancies with the medication counts will be addressed immediately when they are discovered

#3 Use Pharmacy-Profiled ADC's

- Only a limited variety and quantity of medications in "non-profiled" ADCs will be stored
- Ensure that all ADCs in the facilities have pharmacy-profiling functionality.

#4 Identify Information that Should Appear on the ADC Screen

- The screen of the ADC will include patient demographics, including:
  - Complete patient name
  - A second Agape-approved identifier to be used before the medication is administered
  - Patient location

#5 Select and Maintain Proper ADC Inventory

- The P&T committee will have administrative control of drug availability in the ADC.
- No hazardous drugs or medications that require extensive dilutions or calculations will be part of the inventory
- Any medications that have low usage according to activity reports will be eliminated from the inventory
- Monthly pharmacy audits will be preformed of the inventory

#6 Select Appropriate ADC Configuration

- Each medication will be located in a separate container
- Matrix drawers will be used for floor-stock medications such as non-opiate analgesics and antacids
- Only medications will be held in the ADC (no personal items)

#7 Define Safe ADC Restocking Processes

- ADC will be restocked by a pharmacist when cartridges are low (daily, weekly, and permanently)
- Cartridges will be delivered to the facility from the main pharmacy pre-loaded
- Barcode scanning will be used during the restocking phase to ensure accuracy

#8 Develop Procedures to Ensure the Accurate Withdrawal of Medications from the ADC

- To limit the risk of wrong selections from the ADC, it will be configured to dispense in a pharmacy-profiled mode, which only allows medication retrieval after orders have been verified by a pharmacist
- Nurses must use their own password to access the ADC
- Any discrepancies between the ADC screen, the MAR, and the pharmacy or medication label will be investigated and corrected prior to the selection of the medication
- PRN medications will be separated in a different section of the ADC drug profile screen
- All medications will be returned to a common secure one-way return bin and not to an individual pocket or bin within the ADC

#9 Establish Criteria for ADC System Overrides

- An independent double-check with another licensed healthcare provider will be required when removing high-alert medications on override
- All override policies will be review and approved by the P&T Committee

#10 Standardize Processes for Transporting Medications from the ADC to the Patient's Bedside

- All medications will be transported in their original unit-dose package or kept on nurses mobile carts with labeled patient-specific draws and have the ability to lock if unattended
- The MAR will be available to support safe administration
- All medications transported from the ADC are in ready-to-use form for administration

#11 Eliminate the Process for Returning Medications Directly to their Original ADC Location

- All medications will be returned to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC

#12 Provide Staff Education and Competency Validation

- Staff with access to the ADC will be informed during orientation and annually through on-going education and competency validation, of the risks associated with drug selection
- Share with staff lessons learned from the regular review and discussion of ADC-related medication errors and near misses reports

THE BRUTAL FACTS OF STERILE COMPOUNDING

Patricia C. Kienle, RPh, MPA, FASHP
Director
Accreditation and Medication Safety
Cardinal Health
Innovative Delivery Solutions

DISCLOSURE

- Patricia Kienle is an employee and stockholder of Cardinal Health
- Patricia Kienle is an elected member of the USP Compounding Expert Committee, but is not speaking in that capacity or as a representative of USP

LEARNING OBJECTIVES

- Summarize the evolution of the practice of sterile compounding
- Discuss how the historical pharmacy-related contamination events shaped present-day pharmacy regulations
- Explain current and upcoming national and state laws and standards as it pertains to compounding

Study the past if you would define the future

Confucius

COMPOUNDING

- Art and science of preparing customized medications that are not otherwise commercially available
- Performed by or under the supervision of a pharmacist pursuant to an order from a licensed prescriber for an individual patient
- Essential element of pharmacy

HISTORY OF COMPOUNDING

- All states license pharmacists to compound
- Each state has varying degrees of regulations and oversight and enforcement of compounding practices
- Only 21 states require direct compliance with USP 797 after 10 years

USP <797>

- USP chapters numbered under 1000 are enforceable
- Until USP <797>, no consistent and enforceable compounding standard of practice existed

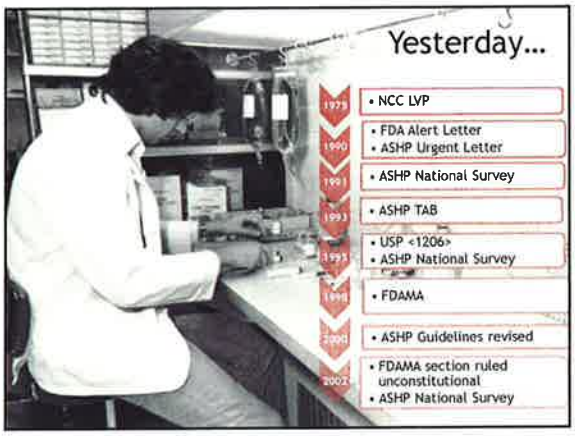
WHERE DO STUDENTS LEARN STERILE COMPOUNDING?

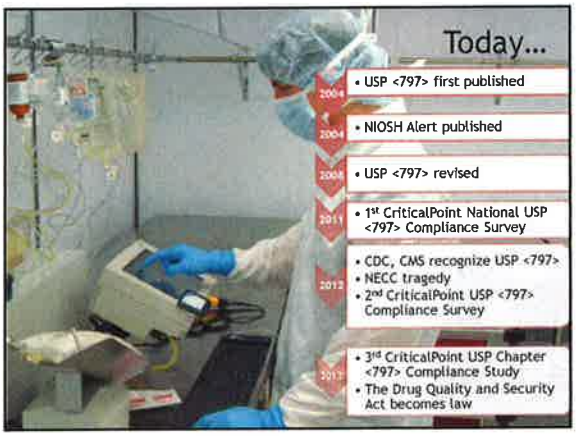
A. Mandatory course
B. Integrated in curriculum
C. On rotations
D. On-the-job training

COMPOUNDING

- Despite the chapter's uniform sterile compounding standards, schools of pharmacy may not always include sterile compounding
- Only 1 in 6 graduates are prepared for sterile compounding work

Hellums M, Alverson SP, Monk-Tutor MR. Instruction on compounded sterile preparations at U.S. schools of pharmacy. AJHP. Volume 64, Nov 1, 2007: 2267-74





USP <797>

- Pharmaceutical Compounding – Sterile Preparations
  - Facilities
  - Personnel training
  - Personnel monitoring
  - Environmental monitoring
  - Assignment of beyond-use dates

USP 797

USP <800>

- Hazardous Drugs - Handling in Healthcare Settings
  - Builds on elements of <797>
  - Containment of hazardous drugs
  - Protection of personnel

DRUG QUALITY AND SECURITY ACT

- Quality → Compounding
- Security → Track and trace
- Section 503
  - 503 A - Traditional compounding
  - 503 B - Outsourcing facilities

503A: TRADITIONAL COMPOUNDING

- Eliminates the unconstitutional provisions of 503A that **"...created uncertainty regarding the laws governing compounding."**
- Requires FDA to engage in **two-way** communication with state regulators - identified as a major deficiency in FDA's response to the meningitis outbreak.
- Preserve and protect the practice of **traditional pharmacy** compounding in community pharmacies

MAJOR DIFFERENCE

OVERSIGHT OF MEDICATIONS

Pedigree	Oversight
Manufacturer	FDA
Outsourcing Facility	FDA and SBOP
Compounding Pharmacy	SBOP
Patient Specific Non Patient Specific	
Nuclear Pharmacy	SBOP

May include carve in or carve out in state regulations

"OUR PATIENTS HAVE NEVER HAD A PROBLEM"

BRUTAL FACTS

Year	State	Description
1990	Nebraska	4 patients died of a bacterial infection from non-sterile cardioplegia solution compounded in a hospital from multiple lots of
1990	Pennsylvania	2 patients lost their vision after becoming infected by Pseudomonas aeruginosa found in indomethacin eye drops compounded in a drug store even though commercial non-steroidal drops were available at the time
1998	California	11 children became septic—10 tested positive for Enterobacter cloacae bloodstream infections associated with contaminated prefilled saline syringes
2001	California	11 patients contracted Serratia marcescens infections following the injection of betamethasone compounded at a community pharmacy

BRUTAL FACTS

Year	State	Description
2001	Missouri	4 children contracted Enterobacter cloacae infections from IV ranitidine compounded in a hospital pharmacy
2002	North Carolina, South Carolina	5 patients developed Exophiala infections from contaminated injectable methylPREDNISolone that was prepared by a compounding pharmacy; one patient died
2002	Michigan	Pharmacy preparing injectable methylPREDNISolone and baclofen recalled the products because of contamination with Penicillium mold, Methylobacterium, and/or Mycobacterium chelonae
2003	Missouri	Bacteria contamination with Burkholderia cepacia found in at least 2 batches of a compounded inhalant solution used by 19,000 patients with chronic lung diseases

BRUTAL FACTS

Year	State	Description
2004	Texas, New York	36 patients developed Pseudomonas bloodstream infections after receiving heparin/saline flushes from multiple lots of prefilled syringes
2005	New Jersey, California	Up to 25 patients contracted Serratia marcescens infections due to contaminated magnesium sulfate mini-bags prepared by a compounding pharmacy
2005	Minnesota	2 patients were blinded after receiving a compounded trypan blue ophthalmic injection contaminated with Pseudomonas aeruginosa and Burkholderia cepacia; the injectable product is a commercially available product
2005	California	Sterile talc vials with unwashed stoppers were not sterility tested before distribution from an outsourcing compounding pharmacy

BRUTAL FACTS

Year	State	Description
2005	Maryland	10 patients died after exposure to cardioplegia solution from 2 lots contaminated with gram-negative rods
2006	Nevada	1 baby died from a 1,000-fold zinc overdose (mcg and mg zinc sulfate confused) compounded in a hospital pharmacy
2006	Ohio	1 child died after a compounding error led to administration of chemotherapy in 23.4% sodium chloride injection instead of 0.9% sodium chloride
2007	Washington, Oregon	2, possibly 3, patients died after receiving an intravenous colchicine product compounded at a concentration higher than standard (4 mg/mL vs. 0.5 mg/mL) in a compounding pharmacy

BRUTAL FACTS

Year	State	Description
2009	Florida	21 horses died after receiving a compounded substitute vitamin supplement containing vitamin B, potassium, magnesium, and selenium (product not approved in the US)
2010	Illinois	1 child died after receiving more than 60 times the amount of sodium chloride prescribed due to a compounding error in a hospital pharmacy
2011	California, Florida, Tennessee	16 patients being treated for wet macular degeneration developed severe eye infections due to contamination of AVASTIN (bevacizumab) during compounding; one patient blinded, another patient developed brain infection
2011	Alabama	9 patients among 19 died when PN solutions that were administered were contaminated with Serratia marcescens during compounding using non-sterile components to prepare amino acids

BRUTAL FACTS

Year	State	Description
2012	California	9 patients developed fungal endophthalmitis after use of the compounded product Brilliant Blue-G (BBG) or receiving injections of triamcinolone-containing products dispensed from the same compounding pharmacy

New England Compounding Center (NECC) Meningitis Outbreak	
Date	September 21, 2012- October 23, 2013 (no further CDC updates expected)
Location	USA (20 States)
Cause	Fungal meningitis contamination of steroid medication
Injuries	751 total case count; 384 meningitis and spinal infection; 7 stroke; 325 paraspinal/spinal infection; 33 peripheral joint infection; 2 spinal and peripheral joint Some patients recovering from the meningitis are falling ill again. Sufferers of the new infection are now coping with epidural abscesses and infections near the injection site.
Death(s)	64
Litigation	More than 20 lawsuits filed against NECC

SCOPE OF THIS ISSUE

- The scale of the meningitis outbreak makes this event the worst among a series of fatal or harmful infections and overdoses linked to pharmacy compounding practices in the US rivaling other key drug safety issues in the past that have led to substantial drug safety legislation.

BRUTAL FACTS CONTINUE

Year	State	Description
2013	Connecticut	FDA announced that a compounding pharmacy in New Jersey was voluntarily recalling all of its products after a Connecticut hospital reported that 5 bags of magnesium sulfate from the pharmacy were contaminated with mold. The pharmacy has since been closed by the NJ Division of Consumer Affairs
	Georgia, Louisiana, South Carolina and Indiana	A compounding pharmacy in Augusta, Georgia, is voluntarily recalling 79 lots of bevacizumab-filled syringes (Avastin, Genentech) intended for retinal injections because of the risk for eye infection, the US Food and Drug Administration (FDA) announced yesterday.
	Texas	A batch of compounded IV Calcium Gluconate found to be contaminated with Rhondococcus equii. 15 infected patients, 2 deaths (relationship to drug not known)

AND IT CONTINUES …

- JAMA: Response to mold contamination of intravenous magnesium sulfate produced by a compounding pharmacy

Boyce, JM et al. Response to Mold contamination of Intravenous Magnesium Sulfate Produced by a Compounding Pharmacy. *JAMA Intern Med.* Published online February 03, 2014. doi:10.1001/jamainternmed.2013.13772 retrieved on February 18, 2014 at http://archinte.jamanetwork.com/article.aspx?articleid=1819572

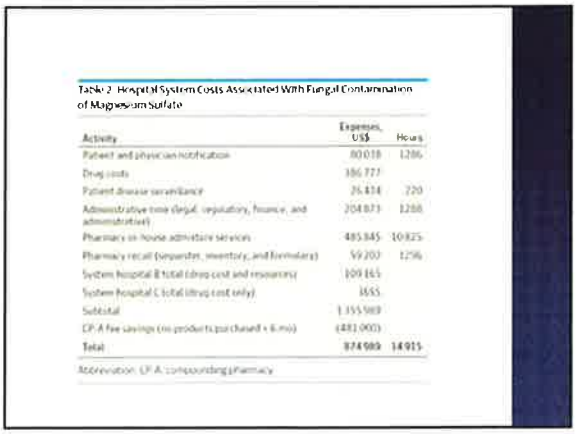


Table 2. Hospital System Costs Associated With Fungal Contamination of Magnesium Sulfate

Activity	Expenses, US$	Hours
Patient and physician notification	80 018	1286
Drug costs	186 777	
Patient disease surveillance	26 434	720
Administrative time (legal, regulatory, finance, and administrative)	204 873	1288
Pharmacy in-house administrative services	485 845	10 825
Pharmacy recall (inspection, inventory, and termination)	59 202	1256
System hospital B total (drug cost and resources)	109 865	
System hospital C total (drug cost only)	3655	
Subtotal	1 155 569	
CP-A fee savings (no products purchased × 6 mo)	(481 000)	
Total	674 989	14 915

Abbreviation: CP-A, compounding pharmacy.

MOST RECENT EVENTS

- Outbreak of Burkholderia contaminans linked to intravenous fentanyl from an institutional compounding pharmacy
  - 7 patients affected
  - Prepared drug from bulk Active Pharmaceutical Ingredient (API): High-risk compounding
  - Report published in JAMA
  - Available online: JAMA Intern Med. Published online February 03, 2014. doi:10.1001/jamainternmed.2013.13768

FDA ACTIONS

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

WHAT IS THE BIGGEST PROBLEM?

A. Leadership
B. Facility design
C. Personnel
D. Monitoring

WHAT WENT WRONG?

- Leadership
  - Inactive and ineffective oversight
- Education, competence, proficiency
  - Untrained employees
  - Lack of competency and proficiency evaluation systems
- Hand hygiene and garbing
- Environmental control and monitoring
  - Inadequate for intended activities
  - Improper use

WHAT WENT WRONG?

- Process control failures
  - Quality
  - Measurement and weight
  - Maintenance or achievement of sterility
  - Potency
  - Recall procedures
- Cleaning and disinfecting practices
- Preventive maintenance

WHAT WENT WRONG?

- Inadequate policies and procedures
- Equipment
  - Improper use of sterilizing equipment
  - Failure to validate systems
- Documentation
- Lack of compliance with federal and state regulations

2014

STATE OF PHARMACY COMPOUNDING

Regulatory Inspections

Patient Incidents Involving Compounding Errors by Facility Size

PHARMACY

EDUCATORS: WHAT CAN YOU DO?

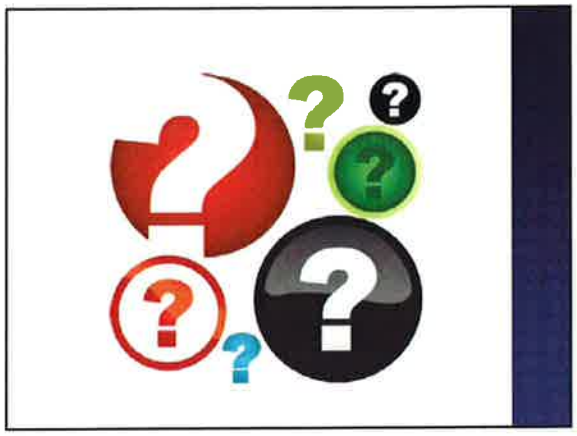
- Recognize the need for education of students and practitioners
  - Didactic
  - Practical
- Teach contemporary practices
- Elevate compounding to a level needed for today's and tomorrow's practice

REGULATORS: WHAT CAN YOU DO?

- Be familiar with contemporary compounding practice issues
- Adopt USP compounding chapters
  - Patient safety depends on the symbiotic relationship of all the elements of <797> and proposed <800>
- Achieve a comfort level to identify in- and out-of scope traditional compounding

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. "

Michael Cohen, MS, FASHP
Institute for Safe Medication Practices (ISMP)



HOME INFUSION ENVIRONMENT

Varner Richards, Pharm.D
CEO / Owner
Intramed Plus

Challenges – Home Infusion Setting

Patient Safety

- Non-Medical Environment
- Self – administration of IV Medications
- Storage

Patient Safety

Home Setting

Challenges – Home Infusion Setting

- Stability – preparation of CSP for extended period of time
  - 7 days
  - 10 days
  - 30 days
- Sterility – varied parameters affecting sterility
  - Drug Delivery Device
  - Temperature
  - Varied storage
- Risk Level - Low & Medium Risk Level
- Beyond Use Dating (BUD)

Drug Delivery Devices

Employee Requirements

Pharmacy Technicians

- Excellent USP 797 working knowledge
- Excellent sterile technique
- Efficient / methodical / alert
- Strong work references – if available

Pharmacists

- Excellent USP 797 working knowledge
- Knows / practice proper sterile technique
- IV Compounding experience - Hospital Setting
- Proper supervisory knowledge of sterile compounding activities

Pre-employment Requirements

Accredited school / training program
Experience – previous CSP activity / level / experience
Background & Pre-employment drug screening

CSP Qualifying Requirements
- USP 797 Working knowledge
- Personal Cleansing & Garbing Process Compliance
- Media Fill Testing
- Gloved Finger Sampling (GFS)
- Observation

CSP Qualifying

Media Fills	3 batches x 3 consecutive days
GFS	3 Samples x 3 consecutive days
Observation	Compounding technique Work attitude Focused / Alert

Qualifying results

Pass	No Growth No observed CSP technique issues 14 days - before compounding any products for patient use Continued observation / training during 1st weeks of work performance
Fail	Growth (CFUs) in Media Fill or GFS Repeat x 1 with close observation Failed again - not hired

Ongoing – Training / Education

Quarterly	CE Focus Review testing results
6 months	Facility Certifications Review testing results
Annually	Media Fill & Glove Finger Samples
Ongoing	New drug therapies CSP Requirements

Patient Safety!!!!!

Compounding Training in an Academic Medical Center/Outsourcing



Carole Small Russell, RPh., MHSA
Medical University Hospital Authority
Clinical Assistant Professor, SC College of Pharmacy
Adjunct Instructor, Trident Technical College

1

Disclaimer

Although I am a member of the South Carolina Board of Pharmacy, I am speaking today in my individual capacity and not as a member of the Board.

The views and opinions presented do not necessarily reflect the views of the Board, nor should they be construed as an official interpretation of the S. C. Practice Act

2

Objectives

Describe competency requirements for non-sterile, sterile and hazardous compounding in a hospital/ambulatory care academic medical center setting.

Describe competency requirements for outsourcers under cGMP

3

Medical University of S.C. Hospital Authority

Charleston, S.C.

- Est. 1824
- 700 bed comprehensive academic medical center
- 80 acres
- 13,000 employees, students, faculty

MUSC Health

Prior to 2004

- "Home-grown" program: 1970s-1980s
  - slide deck
  - cassette tape audio
  - skill check-offs



Prior to 2004

- ASHP tools[1]: 1990's - 2004
  - VHS tape/DVD
    (viewed annually)
  - Workbook
  - Written test
    (home-grown + ASHP)
  - Annual skills check-offs
    (home-grown)

1. ASHP.ORG

Current Model

- Upon hire:

1. View *Basics of Aseptic Compounding*[1] (on Department Web page)
2. Complete CBT/test on non-sterile, sterile, hazardous compounding and hazardous disposal
3. Attend Intro to Sterile Compounding live lecture
4. Complete written test in class
5. Begin hands-on training, complete skill check-off, media fill (5 bags) and glove fingertip test (3 sets)

1. ASHP.ORG

Current Model

- Annually *(every 6 months for high-risk compounders)*:

1. Complete CBT/test on non-sterile, sterile, hazardous compounding and hazardous disposal
2. Attend Annual Non-Sterile, Sterile, Hazardous Compounding live lecture
3. Complete skill check-off, media fill (1 bag) and glove fingertip test (1 set) under supervision of "trained trainer"
4. Total ACPE CE credit = 5 hours (timing is everything!)
5. Facts and tools drive compliance

1. ASHP.ORG

You Want Me to Do What?

Gaining Staff Buy-In for Unpopular Assignments

Carole Small Russell, RPH, MHSA
Medical University of S.C.
December 6, 2005

Cleaning the Room



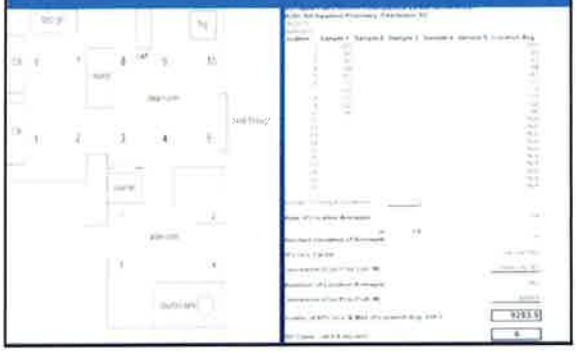

For the Floors....


Sterile Water for Irrigation!

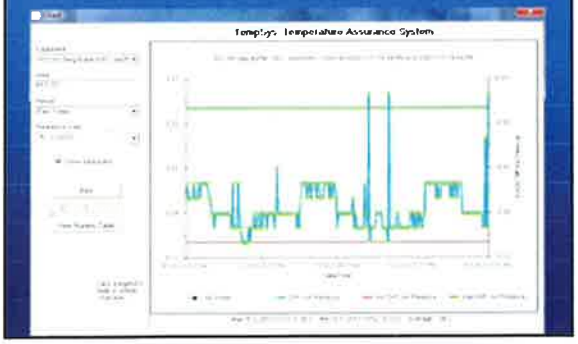
Drive Compliance with Facts: We are the Dirtiest Part of Compounding

- The human body harbors an average of 150-200 different classes of bacteria
- Hands have an average of 100,000 organisms / sq mm
- The body sheds 5 grams of skin fragments each day along with shedding 1 layer of skin every 5 days (size range 10 to 300 micron = 1000th of a mm)
- Role of make-up, jewelry, nails

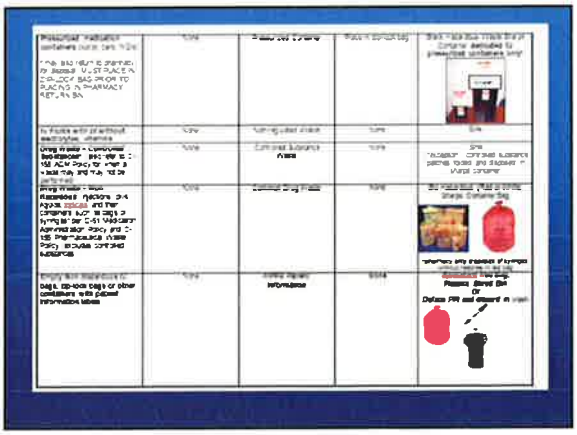
Facts: Where to Sample



Facts: Pressure Control




Clean Room Garbing
Shoe Covers
Head Cover
Beard Cover/ Mask
Clean Nails/ Wash Hands
Gown
Alcohol Gel
Sterile Gloves
Sterile



Don't Assume…

- Balances
- Liquid Measurements
- Syringes & Droppers
- Spatulas
- Weighing Papers & Boats
- Mortors & Pestles
- Water Sources: *what is purified?*

It's All About YOU

- **Gloves, Gloves, Gloves**
  - Powder free, nitrile, neoprene labeled as chemo gloves (sterile): one under, one over the gown cuff
  - Double glove for handling hazards (two pairs of chemo gloves)
  - Change every 30 minutes
  - Remove outer glove after prep and decon of product, and before removing garb
  - Keep inner glove on while removing garb

Gowns, Gowns, Gowns

- Disposable, coated for chemo use
- Wear no more than 3 hours
- Remove with care using inner gloves, dispose of as a hazard
- Wash hands after removing

It's All About YOU

Eye/Respiratory Protection

- face shield, safety glasses, N-95 mask (must be fit tested)

Shoe and Hair Covering

- remove with inner gloves
- discard in plastic bags and then as hazardous waste

It's All About YOU!

Closed System Transfer Devices
- required when negative pressure room not available
- must also use BSC or CACI

Competency Training for Outsourcers

- CGMP: current good manufacturing practice training
  - scheduled, ongoing
  - as a result of a deficiency
  - business process redesign
  - update/change in SOP
  - refreshers in regulations, ethics, OSHA, etc.
  - content driven by business risk assessment

"Developing a continuing CGMP training program," Journal of GXP Compliance, Vol. 13, No. 4, Fall 2009, pp. 88-96

Competency Training for Outsourcers

- FDA: *CGMP training shall*
  - be conducted by qualified individuals (as defined by SOP)
  - be conducted on a continuing basis (as defined by SOP)
  - address CGMP requirements applicable to them

Developing a continuing CGMP training program," Journal of GXP Compliance, Vol. 13, No. 4, Fall 2009, pp. 88-96

What Are "Applicable Requirements"?

- 21 CF 211: *QC, sanitation, equipment cleaning and maintenance, sampling and testing, stability testing, records and reports…*
  - Sterile Drug Production: *aseptic technique, cleanroom behavior, microbiology, hygiene, gowning, aseptic SOPs*
  - FDA Warning Letters: *posted at fda.gov*
  - Own documentation of deviations, investigations, product quality complaints

Developing a continuing CGMP training program," Journal of GXP Compliance, Vol. 13, No. 4, Fall 2009, pp. 86-96

Questions?

Innovative Workplace Competency and Training Concepts for Compounding

Focus on Pharmacy Student Training

KENNEDY

Pharmacy Student Training

Instruction on compounded sterile preparations at U.S. schools of pharmacy

KENNEDY

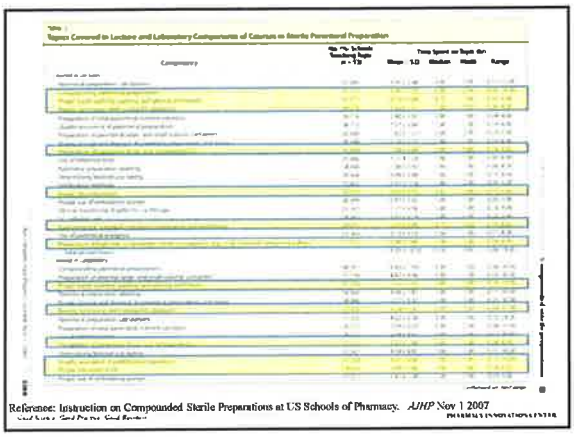
Table 1
Characteristics of Instruction in Compounded Sterile Preparations at U.S. Schools of Pharmacy (n = 53)

Characteristic*	No. (%) Respondents*
Course structure	
Both a didactic and a laboratory component in CSPs are offered	51 (96)
CSP topics are incorporated into other courses	45 (85)
A standalone course in CSPs is offered	10 (21)
Only a didactic component in CSPs is offered	2 (4)
Only an experiential component in CSPs is offered	1 (2)
Compounding environment	
CSPs are made within a laminar airflow hood (biological safety cabinet, or isolator	40 (75)
Hood is not located in a room designed for making only CSPs	27 (51)
Students gown and glove before making CSPs	30 (57)
CSPs are made inside a cleanroom	20 (38)
Students practice making CSPs, but not within a laminar-airflow hood	13 (25)
Compounding experience	
Students make CSPs as individuals	37 (70)
Students make CSPs both as individuals and in groups	10 (19)
Faculty demonstrate but students do not make	
CSPs at all	5 (9)
Students make CSPs but only in a group	4 (8)

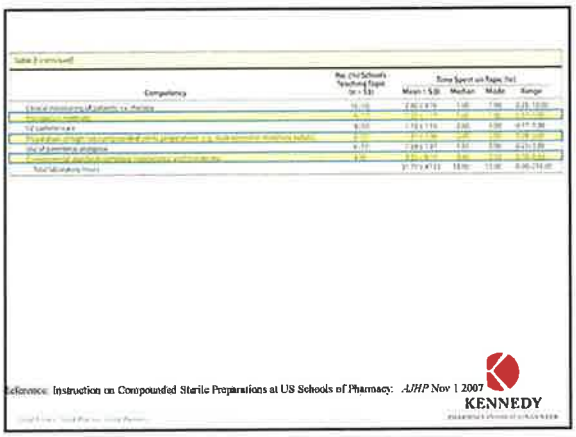
CSP, a compounded sterile preparation.

eference: Instruction in Compounded Sterile Preparations at U.S. Schools of Pharmacy. *AJHP* Nov 1 2007

KENNEDY



Reference: Instruction on Compounded Sterile Preparations at US Schools of Pharmacy. *AJHP* Nov 1 2007



Reference: Instruction on Compounded Sterile Preparations at US Schools of Pharmacy: *AJHP* Nov 1 2007

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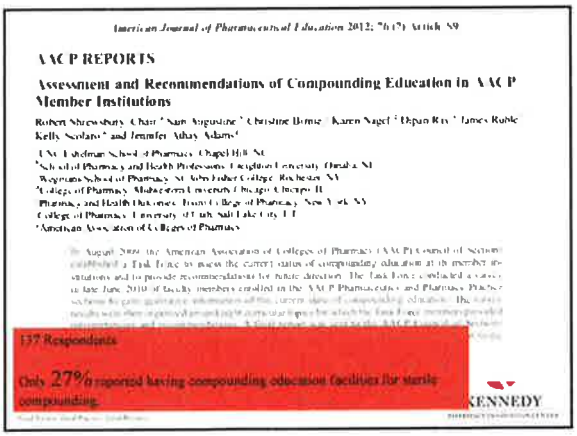

American Journal of Pharmaceutical Education 2012; 76 (7) Article 89

AACP REPORTS

Assessment and Recommendations of Compounding Education in AACP Member Institutions

137 Respondents

Only 27% reported having compounding education facilities for sterile compounding

KENNEDY

ACPE Standards

- Current standards released 2006, minor updates 2011
  - Next comprehensive review 2013-2014
- Curriculum Standards related to Ster. Cmpd
  - Std #9: The Goal of the Curriculum
    - …."curriculum must prepare graduates with the professional competencies to enter pharmacy practice in any setting to ensure optimal medication therapy outcomes and patient safety…."

Reference ACPE Accreditation Standards & Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Version 2.0 Feb 2011

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ACPE Standards

- Std #11.5
  - "….Outcomes which are not appropriate for distance study (such as physical assessment or compounding skills) should be taught using other educational methods."
- Std #14.4
  - "….IPPE must account for not less than 300 hours….must be balanced between community pharmacy and institutional health system settings."

KENNEDY

ACPE Standards

- Std 27.1 (Physical Facilities)
  - "laboratories dedicated to professional curriculum instruction and practice simulation that are reflective of contemporary pharmacy practice and standards, including facilities for extemporaneous preparation of intravenous and other medications."

KENNEDY

ACPE Standards

- Appendix B – Add'l Guidance on Science Foundation
- Extemporaneous Compounding/Parenteral/Enteral
- USP guidance on compounding & FDA Compliance policy guidance
- Sterile admix techniques
  - USP chapter <797>
  - Stability and sterility testing and dating
  - Clean room requirements
  - Infusion devices and catheters

KENNEDY

ASHP-ACPE Task Force Report: Fall 2010

Competency #6

Demonstrate essential techniques and describe processes and facilities needed to provide sterile compounded parenteral solutions, including the basic requirements of USP 797.

- Didactic lecture
- Practice lab
- IPPE/APPE
- Exams
- Preceptor Assessments

Reference: Entry-level Competencies Needed for Pharmacy Practice in Hospitals and Health-Systems. ASHP-ACPE Task Force Report Fall 2010

KENNEDY

Challenges in Training Students

- Training facilities
- Increased number of students to train
- IPPE/APPE challenges
- Training focused on core concepts of USP 797 and aseptic technique
  - Cleaning gaps
  - Environment management/monitoring gaps
  - Focus primarily on low/med risk CSPs

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SC College of Pharmacy

Previous

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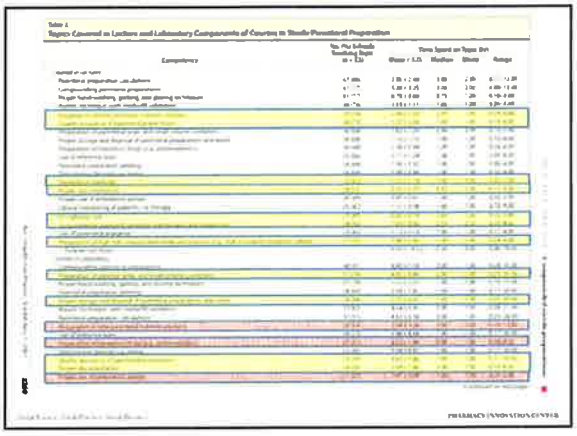

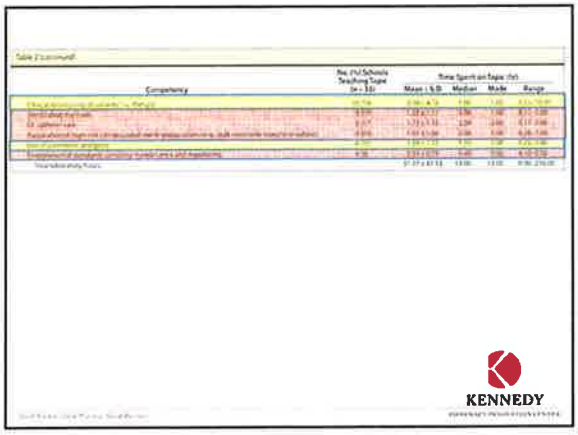

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SC College of Pharmacy/KPIC

Now

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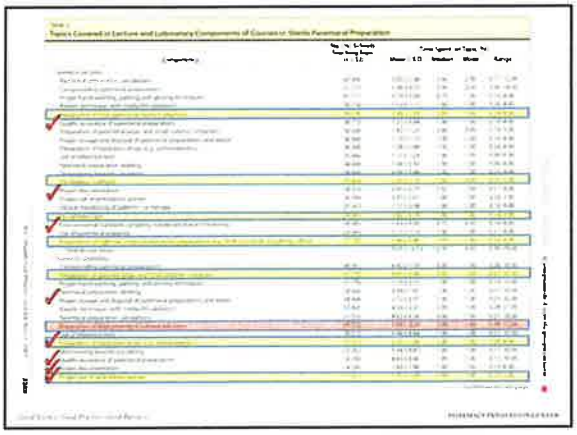

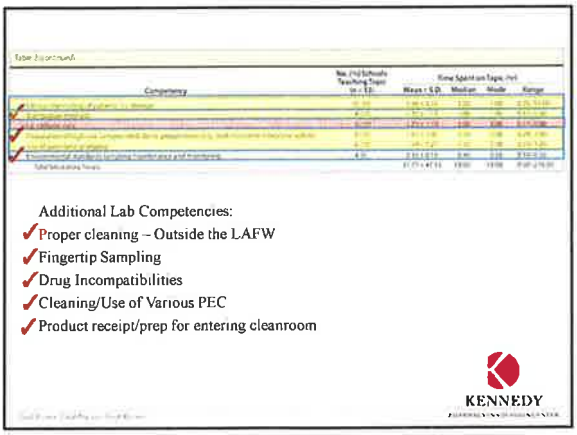

Additional Lab Competencies:

- ✓Proper cleaning – Outside the LAFW
- ✓Fingertip Sampling
- ✓Drug Incompatibilities
- ✓Cleaning/Use of Various PEC
- ✓Product receipt/prep for entering cleanroom

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SC College of Pharmacy/KPIC

ACE Aseptic Compounding Experience LAB

KENNEDY


KENNEDY