4th edition

Compounding Sterile Preparations

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This edition is dedicated to the victims of the fungal meningitis outbreak of 2012, who serve as an enduring reminder of the consequences of poor compounding practice.

E. Clyde Buchanan
Philip J. Schneider
Ryan A. Forrey

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Acknowledgments

Every day many pharmacists and pharmacy technicians participate in compounding sterile preparations. In the vast majority of cases, their preparations are accurate, stable, pure, and sterile. We salute these health professionals who maintain essential high standards. Such work requires great attention to detail and genuine care for patients.

We are grateful to Ruth Bloom, Beth Campbell, Kristin Eckles, and the many other ASHP staff members who reviewed and edited each chapter of this text. We express special gratitude to Jack Bruggeman, former ASHP Director of Special Publishing, who began working with us on this book in 2014. Without his encouragement and support, our work would not have been possible.

Finally, to our family members and friends who gave us the space and emotional support to finish, we express our heartfelt appreciation.

E. Clyde Buchanan
Philip J. Schneider
Ryan A. Forrey

Preface

This professional reference for pharmacists and pharmacy technicians who compound sterile preparations also will serve well as a textbook for student pharmacists and pharmacy technicians. To assist with classroom use, ASHP plans to publish learning objectives and review questions and answers for each chapter. There is a robust list of references at the end of each chapter for those scholars who wish to dig deeper into this rich material.

Since the current version of USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations became official in June 2008, much has happened in the world of sterile compounding. Perhaps the most significant event, as well as the most tragic, was the multistate outbreak of fungal meningitis and other infections that occurred in 2012 (www.cdc.gov). The Centers for Disease Control and Prevention (CDC) counted 753 infected patients in 20 states, and 64 of those infected patients died. Contaminated steroid injections compounded at the New England Compounding Center in Framingham, Massachusetts, caused these infections. As a direct consequence, in 2013 the U.S. Congress passed the Drug Quality and Security Act (DQSA) to be enforced by the Food and Drug Administration. The meningitis outbreak also sparked concerns about compounding pharmacies and prompted an investigation by the Office of the Inspector General (OIG) regarding the use of compounding pharmacies by hospitals and oversight of hospital compounding by the Centers for Medicare & Medicaid Services (CMS) and its accrediting organizations (OIG report OEI-01-13-00400). The OIG recommended that accreditation surveyors be trained on standards for safe compounding practices and that CMS amend its interpretive guidelines to address hospitals' contracts with standalone compounding pharmacies. In October 2015, CMS did so. In May 2016, one of the CMS accreditation agencies, the Healthcare Facilities Accreditation Program, published updates to its pharmaceutical standards. These standards identify extensive and specific requirements for compounded sterile preparations. The other agencies that accredit pharmacies and healthcare organizations will update their pharmacy standards too.

In February 2016, the *United States Pharmacopeia* finalized USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. This enforceable chapter applies to all healthcare personnel and entities that handle hazardous drugs. *Compounding Sterile Preparations, Fourth Edition*, updates all chapters for DQSA and USP Chapter <800> but refers to the 2008 version of USP Chapter <797>, which is current as of this publication. The fourth edition does not cover USP Chapter <797> proposed in late 2015 which is still under review and revision. When a new, final USP Chapter <797> becomes available, ASHP will publish a revised edition.

All previous chapters have been updated, and several new chapters and chapter authors have been added. New chapters include the following:

- Imperative for Change: Adverse Sterile Compounding Events
- Immediate-Use Compounding
- Special Considerations in Pediatric Compounding

- Special Considerations in Compounding Biologicals
- Microbiological Issues in Compounding Sterile Preparations
- Sterile Compounding Technology

New authors include Craig A. Boyce, Todd W. Canada, Richard C. Capps, Bruce A. Erickson, Ryan A. Forrey, Kathleen M. Gura, Patricia C. Kienle, Mark G. Klang, Jeannell M. Mansur, Linda F. McElhiney, Richard B. Osteen, Kelley Reece, Ryan K. Roux, Keith H. St. John, Susan Spivey, Mary Ann Stuhan, Radhakrishna S. Tirumalai, and Angela W. Yaniv. All chapter authors are listed with their credentials in the front matter and anyone who compounds sterile preparations will recognize the experts assembled for this work.

With all the new material, we needed another coeditor, so we are fortunate to welcome Ryan A. Forrey and his expertise. Having served as the Associate Director of Pharmacy and Infusion Services at the Ohio State University Wexner Medical Center and as the Director of Pharmacy at Emory University Hospital Midtown, he is now Senior Manager, Market Development for Hazardous Drug Safety at Becton, Dickinson and Company. Dr. Forrey is also on the Compounding Expert Committee for the *United States Pharmacopeia*.

Many challenges face the pharmacy staff members who compound sterile preparations. Let us meet those challenges by providing our patients with the safest compounded sterile preparations possible and protecting the healthcare employees who handle hazardous drugs. Our professional reputation depends on it.

E. Clyde Buchanan
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