

# **Legal Handbook for Pharmacy Technicians**

*Diane L. Darvey, Pharm.D., JD  
Alexandria, VA*

*Editorial Content Advisor  
W. Renee' Acosta, R.Ph., M.S.  
Clinical Assistant Professor  
Pharmacy Practice Division  
College of Pharmacy  
The University of Texas at Austin*

**American Society of Health-System Pharmacists  
Bethesda, MD**

Any correspondence regarding this publication should be sent to the publisher, American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814, attention: Special Publishing.

The information presented herein reflects the opinions of the contributors and advisors. It should not be interpreted as an official policy of ASHP or as an endorsement of any product. The information contained in this publication is to be used as guidance.

Because of ongoing changes in laws and regulations, the information and its applications contained in this text are constantly evolving and are subject to the professional judgment and interpretation of states and the circumstances of pharmacy practice. The editors, contributors, and ASHP have made reasonable efforts to ensure the accuracy and appropriateness of the information presented in this document. However, any user of this information is advised that the editors, contributors, advisors, and ASHP are not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the document in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this document and will bear no responsibility or liability for the results or consequences of its use.

Director, Special Publishing: Jack Bruggeman  
Acquisitions Editor: Hal Pollard  
Senior Editorial Project Manager: Dana Battaglia  
Project Editor: Johnna Hershey  
Cover Design: Jim DeVall  
Page Design and Composition: Carol Barrer

#### Library of Congress Cataloging-in-Publication Data

Darvey, Diane L.

Legal handbook for pharmacy technicians / Diane L. Darvey.

p. cm.

ISBN 978-1-58528-159-6

1. Pharmacy--Law and legislation--United States. 2. Drugs--Law and legislation--United States. 3. Pharmacy technicians--Legal status, laws, etc.--United States. 4. Pharmacy technicians--United States--Handbooks, manuals, etc. 5. Pharmacists--Legal status, laws, etc.--United States. 6. Privacy, Right of--United States. I. Title.

KF2915.P4D357 2008

344.7304'16--dc22

2008005251

©2008, American Society of Health-System Pharmacists, Inc. All rights reserved.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, microfilming, and recording, or by any information storage and retrieval system, without written permission from the American Society of Health-System Pharmacists.

ASHP is a service mark of the American Society of Health-System Pharmacists, Inc.; registered in the U.S. Patent and Trademark Office.

ISBN: 978-1-58528-159-6

# Dedication

---

To my friends and colleagues:

“Education is the best provision for old age.”  
—Aristotle



## Preface

---

The practice of pharmacy is growing steadily more complex. Medications have become increasingly essential to treating disease, and each year brings the introduction of ever more sophisticated drugs. Pharmacists have an essential role in medication use through counseling patients on proper medication use; advising physicians, nurses, and other health care providers on medication therapy management; and working collaboratively with physicians. It is no surprise that pharmacy is one of the most highly regulated health professions.

As pharmacists take on expanded roles in the health care system, the importance of pharmacy technicians is highlighted too. They have a key role in supporting pharmacists. Today, technicians do many of the tasks that only a few years ago were performed by the pharmacist.

Like the pharmacy profession itself, the laws and regulations of pharmacy are complex and changing. Each state has its own set of pharmacy laws and regulations. The sheer magnitude of all these laws and regulations makes it impossible to specifically address all of them. In this book, I have taken the approach of providing examples of state laws and regulations that illustrate those found in most states. This approach should provide a foundation for pharmacy technicians, or persons studying to become technicians, to understand how their particular state regulates pharmacy and pharmacy technicians. In the pages that follow, you will read about the laws and regulations applicable to pharmacy technicians such as whether pharmacy technicians must be registered as well as the qualifications to become a pharmacy technician.

For the pharmacy technician, understanding the laws and regulations of pharmacy is an essential part of doing your job and doing it well. The fact that pharmacy is so highly regulated is a clear sign of the importance of your job and the importance of the pharmacy profession to the health and well being of patients.

*Diane Darvey  
December 2007*

## **Disclaimer**

This publication has been prepared by the author for general informational purposes only and is not intended to contain all laws and regulations that relate or may relate to the practice of pharmacy, including but not limited to pharmacy technicians. This publication and the materials therein are not provided in the course of an attorney–client relationship and are not intended to provide legal or other advice. Such advice should only be rendered in reference to the particular facts and circumstances appropriate to each situation by the appropriate legal professionals and/or consultants selected by the person. Any references or links to information or to particular organizations or references are provided as a courtesy and convenience, and are not intended to constitute any endorsement of the linked materials or the referenced organizations or materials by the author or publisher. The content and views on such links and of such organizations are solely their own and do not necessarily reflect those of the author or publisher. The author of this publication, Diane L. Darvey, prepared this publication on her own behalf, not as a representative of the National Association of Chain Drug Stores (NACDS). NACDS did not review or approve this publication, and its contents do not necessarily represent the views of NACDS.

# Table of Contents

---

Dedication .....	iii
Preface .....	v
Disclaimer .....	vi
Chapter 1. U.S. Legal and Regulatory System.....	1
<i>Learning Objectives</i>	
<i>Introduction</i>	
<i>Role of Laws and Regulations</i>	
<i>Role of Pharmacy Professional Practice Standards and Ethical Principles</i>	
<i>Violations of Pharmacy Laws and Regulations</i>	
<i>Summary</i>	
<i>Self-Assessment Questions</i>	
<i>Appendix 1-1. Code of Ethics: Pharmacy Associations</i>	
<i>Appendix 1-2. Code of Ethics for Pharmacy Technicians: American Association of Pharmacy Technicians (AAPT)</i>	
Chapter 2. Development of Laws and Rules or Regulations .....	15
<i>Learning Objectives</i>	
<i>Introduction</i>	
<i>Federal Laws and Rules or Regulations</i>	
<i>State Laws and Rules or Regulations</i>	
<i>Role of State Boards of Pharmacy</i>	
<i>Summary</i>	
<i>References</i>	
<i>Self-Assessment Questions</i>	
Chapter 3. Federal Laws and Regulations for Drugs.....	27
<i>Learning Objectives</i>	
<i>Introduction</i>	
<i>Food, Drug, and Cosmetic Act: Purpose, History, and Enforcement</i>	
<i>Poison Prevention Packaging Act</i>	
<i>Omnibus Budget Reconciliation Act of 1990</i>	
<i>Medicare Modernization Act of 2003</i>	
<i>Summary</i>	
<i>References</i>	
<i>Self-Assessment Questions</i>	
Chapter 4. Food and Drug Administration.....	39
<i>Learning Objectives</i>	

*Introduction*

*The Organization*

*Federal Approval of Drugs*

*Brand Name Drugs and Generic Drugs*

*Generic Drug Substitution*

*Prescription Drug Labeling and Package Inserts*

*Over-the-Counter Drug Labeling*

*Expiration Dates, Beyond-Use Dates, and Lot Numbers*

*Summary*

*References*

*Self-Assessment Questions*

**Chapter 5. Controlled Substances Laws ..... 53**

*Learning Objectives*

*Introduction*

*Controlled Substances Laws*

*Drug Enforcement Administration*

*State Prescription Monitoring Programs*

*Restrictions on Sales of Products Containing Ephedrine, Pseudoephedrine, and Phenylpropanolamine*

*Summary*

*References*

*Self-Assessment Questions*

**Chapter 6. State Laws and Regulations for Pharmacy Practice ..... 69**

*Learning Objectives*

*Practice of Pharmacy*

*Pharmacies and Pharmacists*

*Pharmacy Technicians*

*Quality Improvement Programs*

*Patient Counseling*

*Summary*

*References*

*Self-Assessment Questions*

*Appendix 6-1. NABP Model Act Article IV—Discipline*

*Appendix 6-2. State Boards of Pharmacy*

**Chapter 7. Privacy of Patient Health Information ..... 129**

*Learning Objectives*

*Introduction*

*Federal Protections for Patient Health Information*

*State Laws Protecting Patient Health Information*

*Summary*

*Self-Assessment Questions*

**Self-Assessment Answers ..... 137**

**Index ..... 141**