

ACT 31 OF 2014 – INITIAL TRAINING AND CONTINUING EDUCATION IN CHILD ABUSE RECOGNITION AND REPORTING REQUIREMENTS

The Bureau of Professional and Occupational Affairs (BPOA), in conjunction with the Department of Public Welfare (DPW), is providing advance notice to all health-related licensees and funeral directors that are considered “mandatory reporters” under section 6311 of the Child Protective Services Law (CPSL) (23 P.S. § 6311), as amended, that EFFECTIVE JANUARY 1, 2015, all persons applying for issuance of an initial license shall be required to complete three hours of DPW-approved training in child abuse recognition and reporting requirements as a condition of licensure.

Additionally, EFFECTIVE WITH THE FIRST LICENSE RENEWAL AFTER JANUARY 1, 2015, all health-related licensees and funeral directors applying for the renewal of a license issued by the Board shall be required to complete at least two hours of Board-approved continuing education in child abuse recognition and reporting requirements as a condition of renewal.

Please note that Act 31 applies to all health-related licensees, regardless of whether they are subject to the continuing education requirements of the applicable board.

More information regarding this requirement will be posted on the BPOA website when it is available.

Act 31 may be reviewed at the following link:

<http://t.lt02.net/q/9bZXGNAaL2AraJke2cmeydHmM28y-Omj-Ona0wLX6hk65TXGh1U69ccLp>

Food and Drug Administration Issued A Final Guidance for Pharmacies that Compound Pursuant to a Prescription by Gayle Cotchen

In July 2014, the Food and Drug Administration (FDA) issued five documents as part of a News Release titled *"FDA outlines expectations for human drug compounders, including registered outsourcing facilities."* Since the title specifically mentions the term “outsourcing facilities,” it could have lead the reader to think the documents all applied to outsourcing facilities only – not to pharmacies. However, they don’t apply solely to outsourcing facilities. In particular, one of the documents was a Final Guidance for pharmacies that compound medications; it is available at the link below.

[Read More](#)

The Final Guidance lists 10 qualifications for the compounding of a drug product under Section 503A, such as compounding “for an identified individual patient based on the receipt of a valid prescription order” and “the drug product is compounded in compliance with the United States Pharmacopeia (USP) chapters on pharmacy compounding...” The Final Guidance also includes a description of “some of the possible enforcement actions FDA can bring against individuals or firms that compound drugs in violation of the FD&C Act.”

Background information from the federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Drug Quality and Security Act:

- Section 503A pertains to pharmacies that dispense compounded medications pursuant to prescriptions for individual patients or that compound medications based on a history of having received prescriptions previously.
- Section 503B pertains to outsourcing facilities, which are compounders that voluntarily register with the FDA and whose compounded drug products are not prepared pursuant to prescriptions for individual patients.

In conclusion, pharmacists who compound medications prescribed for specific patients should find the Final Guidance informative so they can compound in compliance with applicable FDA requirements.

U.S. Pharmacopeia Proposed Chapter 800

by Gayle Cotchen

In March 2014, the U.S. Pharmacopeia proposed Chapter 800, which “provides standards to protect personnel and the environment when handling hazardous drugs.” The proposed chapter is available at this link: http://t.lt02.net/q/vcZlguUnAvZL7bZX_QSyDXh0SUHMjXSGjXK_AObI-PGwzs9GZIN-i89Ks. Since the chapter addresses safety measures to be used by healthcare personnel (such as pharmacists and pharmacy interns) who handle hazardous drugs, the State Board of Pharmacy is including this brief article to draw attention to these standards.

The proposed Chapter 800 addresses risks associated with hazardous drugs during sterile and non-sterile compounding as well as risks associated with hazardous drugs that are commercially available. It addresses numerous aspects of handling, such as unpacking, storing, dispensing, transporting, and administering. Complying with the chapter minimizes exposure to hazardous drugs and the adverse consequences that can be associated with unprotected handling of these drugs.

Meet the Board

Gayle Cotchen, Pharm.D., R.Ph. (Acute Care Institutional Representative)

Gayle Cotchen is a Lead Pharmacist for Magee-Womens Hospital of University of Pittsburgh Medical Center (UPMC), where she has practiced pharmacy since February, 2005. In addition to performing clinical activities, her primary duties include medication safety activities as well as ensuring compliance with laws, regulations, and standards. Additional experience includes, but is not limited to, having served as Pharmacy Director for HealthSouth Rehabilitation Hospital and UPMC Rx Partners specialty pharmacies. A graduate of Duquesne University School of Pharmacy, Gayle resides in Gibsonia with her husband.

Robert Frankil, R.Ph. (Independent Retail Pharmacy Representative)

Rob is the President of Sellersville Pharmacy, Inc., which conducts business at two locations: Sellersville Pharmacy, Inc., a traditional community pharmacy, and Sellersville Pharmacy at Penn Foundation, a closed-door pharmacy on the campus of a mental health facility.

Rob served as President of the Pennsylvania Pharmacists Association in 2012-2013. Other professional affiliations include serving on the Steering Committee for National Legislative Affairs for the National Community Pharmacists Association, Board Member for the BucksMont Pharmacists Association, Board Member for the Philadelphia Association of Retail Druggists and a shareholder of Value Drug, as well as serving on Value Drug’s Regional Advisory Committee and PAC Committee.

He graduated from the Temple University School of Pharmacy in 1985 with a B.S. in Pharmacy degree and received the Temple University Alumni Association’s Distinguished Practitioner of the Year Award in 2014.

Rob is an avid golfer and a dedicated fan of the Eagles and Phillies. He has been married since 1986 to Eileen with whom he shares two daughters, Rose and Marcy.

Patrick M. Greene, Esq. (Consumer Protection Representative)

In May 2014, Mr. Greene was appointed to serve on the State Board of Pharmacy. He is employed as a Deputy Attorney General working in the Health Care Section of the Pennsylvania Office of Attorney General. Before his employment with the Pennsylvania Office of Attorney General, Mr. Greene served as a judicial law clerk for the Honorable Vito P. Geroulo in the Lackawanna County Court of Common Pleas. He earned his Juris Doctor from Penn State, The Dickinson School of Law in 2010. Mr. Greene is originally from Pittsburgh but now resides in south central Pennsylvania with his wife and son.

Janet Getzey Hart, R.Ph. (Retail Chain Pharmacy Representative)

Janet Getzey Hart received her B.S. in Pharmacy in 1984 from Duquesne University. She is currently employed by Rite Aid as a Director, Government Affairs. She has served as a past Board of Directors member for the Pennsylvania Pharmacists Association (PPA) and also served as Chairman of the Pennsylvania Association of Chain Drug Stores. She was the 2014 recipient of the PPA George S. Maggio Award for recognition of her work in legislative advocacy. Janet is very active in controlled substance issues on a national level and was recently awarded the President's Award at the National Association of State Controlled Substance Authorities for her work. Janet's hobbies include travel and tennis.

Terry Talbott, R.Ph. (Retail Chain Pharmacy Representative)

Terry Talbott, R.Ph. is a 1987 graduate of Duquesne University and a Regional Director of Government Affairs for CVS Health. She has been employed by CVS for 25 years, serving as a pharmacist and pharmacy supervisor in Northeast Pennsylvania prior to her current role. Terry is also a past president of the Pennsylvania Pharmacists Association and a recipient of the Bowl of Hygeia Award for community service.

Mark J. Zilner, R.Ph. (Independent Retail Pharmacy Representative)

Mark J. Zilner, R.Ph. is the owner of Diamond Pharmacy Services (institutional pharmacy), Diamond Drug Stores (retail pharmacy), Diamond Medical Supply (retail and institutional), RemedyRepack (FDA certified repackager and wholesaler), InnovaScript (mail order pharmacy) and SapphireHealth (EHR software). Mark serves as the COO and/or President of these companies and manages the operations and marketing. Mark is a 1991 graduate of Northeastern University and is a Board Member of the Indiana County Chamber of Commerce and the Indiana University of Pennsylvania Research Institute, as well as an Advisory Board Member of Value Drug and Indiana University of Pennsylvania Center for Family Business.

2015 Board of Pharmacy Meeting Dates

January 13
February 17
March 17
April 21
May 12
June 16
July 21
August 18
September 15
October 20
November 17
December 15

Board Meetings are open to the public and normally held at
One Penn Center, 2601 N. Third Street, Harrisburg, PA 17110.