The PBA Health Care Law Committee Newsletter

Vol. 3 No. 1

Message from the Chair
By Clifford A. Rieders

We hope to have another good year, considering the many health law changes that will be affecting the public, our clients and attorneys in general. On Jan. 10, President Obama enacted into law legislation that will have a major effect on Medicare subrogation issues. We will attempt to familiarize our committee members with changes in the law, as well as upcoming regulations.

We need to stay abreast of state legislative affairs. I strongly encourage you to submit topics to present at the next Pennsylvania Bar Institute Health Law Institute in March 2014 (see below). The Patient Safety Authority in Pennsylvania is active and expanding. We need to be in touch with that organization and to appreciate its impact on our clients and on our practice of the law.

The PBA Health Care Law Committee will meet Thursday, April 11 at the Radisson Hotel in Camp Hill, as part of the PBA Committee/Section day. We hope to see you all there.

Request for Proposals for PBI’s Health Law Institute in March 2014

Have an idea for a great, timely topic you would like to present at the PBI Health Law Institute in 2014? If you do, simply e-mail a short abstract (50-100 words) outlining your proposed topic and possible co-presenters to Carolyn Wepfer, staff attorney, at PBI at cwepfer@pbi.org. The deadline for submitting proposals is Wednesday, July 31.

Join your colleagues for Pennsylvania’s premier health law event.

19TH ANNUAL
Health Law Institute
It’s the best way to be updated on everything new in health law.

Tues & Wed., March 12-13, 2013
Philadelphia • Pennsylvania Convention Center
What is Pharmacy Compounding?

By Roseann B. Termini

Pharmacy compounding usually involves a small quantity of custom-made prescriptions. However, this has changed over the years to what some term large-scale production.

By way of illustration, in the later part of 2012, the U.S. Food and Drug Administration (FDA) was forced to confront the issue of pharmacy compounding on a large scale due to deaths associated with compounded drug products linked to fungal meningitis and involving the New England Compounding Center (NECC). The NECC distributed contaminated pain injections that caused serious adverse events, including approximately 32 deaths. Subsequently, FDA Commissioner Margaret Hamburg testified before Congress and specifically recommended that Congress enact legislation to provide the FDA with enforcement authority.

In 2002, an FDA inspection had revealed a contamination issue with the same steroid; however, the FDA had to defer to Massachusetts state authorities. Traditionally, with pharmacy compounding, state pharmacy boards maintain regulatory oversight. Further, as mentioned, traditionally compounding pharmacies fill special orders from physicians for an individual patient. NECC is an illustration of where thousands of doses of drugs were shipped to several states.

Commissioner Hamburg proposed a two-tier system in which traditional compounding pharmacies would continue to be regulated at the state level and larger pharmacies would be subject to FDA oversight. According to Dr. Hamburg, these non-traditional pharmacies that operate on large-scale compounding would have to register with the FDA, as well as undergo regular inspections. Further, these large-scale compounding pharmacies would be obligated to meet the more rigorous manufacturing standards required of pharmaceutical companies.

Previous FDA attempts to regulate large-scale operations have been stymied; however, that should change. For example, Ameridose LLC, managed by the same parties who managed NECC, voluntarily recalled all of its unexpired products in 2012 due to FDA sterility assurance concerns. The recall was conducted for preventive measures, not because of reports of adverse events such as infections.

As background, when the U.S. Supreme Court decision of Thompson v. Western States, was decided in 2002, the FDA then clarified that the agency would continue to use enforcement action against those who compounded drugs that are actually attempts to illegally manufacture drugs. The FDA released a Compliance Policy Guide (CPG) section 460.200 [Pharmacy Compounding] on May 29, 2002, following the Thompson decision. The continued on Page 3
What is Pharmacy Compounding?
(Continued from Page 2)

CPG sets forth a list of factors that the FDA considers in determining whether to take enforcement action when the scope and nature of a pharmacy’s activities raise the kind of concerns ordinarily associated with drug manufacturing. For example, the FDA would consider enforcement action against pharmacists who compound medications that are commercially available in the marketplace, those that use bulk ingredients that are not components of FDA-approved drugs or those pharmacists who use commercial-scale manufacturing or testing equipment.

Thompson v. Western States involved a challenge by a group of licensed pharmacies who based their claims on constitutional principles that the 1997 Food and Drug Administration Modernization Act (FDAMA) provisions under 21 U.S.C. sections 353a (a) and (c) violated the First Amendment. These sections of the FDAMA permitted compounding by license but restricted the advertisement of compounding. Pharmacies, licensed pharmacists or licensed physicians were prohibited from advertising or promoting the compounding of any particular class of drug or type of drug. The Western States decision by the U.S. Court of Appeals, 238 F.3d 1090 (9th Cir. 2001), focused on First Amendment free speech issues and determined that FDAMA’s limitations on advertisements for compounded prescriptions were unconstitutional because the restrictions were overly broad and violated the free speech clause of the First Amendment. The FDA had argued that the restrictions were necessary to prevent pharmacists from engaging in the major manufacture of unapproved drugs. The U.S. Supreme Court affirmed the appellate court ruling. The dissent in the Thompson opined that the decision against the FDA would undermine the agency’s authority to protect the public health and safety under the federal Food, Drug and Cosmetic Act. As a result of this decision, the FDA uses its enforcement discretion for compounding reasonable quantities of drugs. However, the FDA remains concerned about large-scale production of pharmacy compounding.

EDITORIAL COMMENT
Following the fungal meningitis outbreak caused by the New England Compounding Center in Framingham, the Massachusetts Department of Public Health conducted unannounced inspections of 40 sterile compounding pharmacies across Massachusetts. The findings are available at www.mass.gov/eohhs/gov/newsroom/press-releases/dph/update-on-unannounced-pharmacy-inspections-announced.html.

c. Roseann B. Termini, Esq. All rights reserved. This article is from Volume V of the new 2013 sixth edition of Food and Drug Law: Federal Regulation of Food, Drugs, Biologics, Medical Devices, Cosmetics, Dietary Supplements, Veterinary and Tobacco Products Regulation.

The new complete 2013 sixth edition of Food and Drug Law: Federal Regulation of Food, Drugs, Biologics, Medical Devices, Cosmetics, Dietary Supplements, Veterinary and Tobacco Products Regulation by Roseann B. Termini, is available in print or in 12 separate subject-specific ebook volumes at www.fortipublications.com or Amazon.
Pennsylvania is seen as a national leader in the effort to eliminate health care-acquired infections (HAIs) based on the comprehensive framework for HAI reduction established by Act 52 of 2007 (P.L. 331, No. 52). The General Assembly modified the MCARE Act (P.L. 154, No. 13), which is the Patient Safety Authority’s authorizing legislation, in order to implement a framework of HAI surveillance, quality improvement and transparency. The Authority’s approach to HAI prevention — as with other issues in patient safety — is based on data analysis, education and collaboration. The Authority’s role is non-regulatory and non-punitive.

Infections related to health care can be devastating for patients. For example, when an artificial joint becomes infected, it may have to be removed, leaving the patient unable to walk. The Authority works with clinicians to better comprehend how infections related to health care delivery are acquired. The Authority’s access to infection-event reports provides valuable insight into the systems of care that cause harm. The Authority’s analysis of HAI events helps to identify trends and signals in order to direct infection-prevention activities and to develop appropriate interventions on behalf of the patient.

The Authority addresses HAI prevention to avert patient harm and excess treatment costs. It pursues several avenues in order to provide frontline staff, clinicians and administrators with data to help direct their infection-prevention activities. This integrative approach with current clinical practice through collaboration gives the Authority the ability to develop resources and tools designed for overall prevention of HAIs.

In order to develop comprehensive infection-prevention resources, the Authority works closely with the Pennsylvania Department of Health, and the Pennsylvania Health Care Cost Containment Council. The Authority also collaborates with the Hospital and Health System Association of Pennsylvania, the Association for Professionals in Infection Control and Prevention, the Health Care Improvement Foundation, the Pennsylvania Health Care Quality Alliance and other government agencies and professional associations across the spectrum of health care delivery.

As required by Act 52 of 2007, the Authority has developed a 15-member panel of infection-control experts to help implement the act. The HAI Advisory Panel provides advice and guidance to the Authority in the implementation of HAI legislation.

The advisory panel recommends guidelines to the Authority and other state agencies on HAI reporting requirements for various health care settings, plans for analyzing infection-related data from covered health care settings, evidence-based practices in the control and prevention of HAIs, and educational needs for various facilities and health care workers. The advisory panel also provides guidance on the review of infection-related advisory content, methods for calculating statewide and national HAI rates, reasonable goals for HAI reduction and other goals as identified over time.

The HAI panel recently convened to discuss and provide guidance on several important issues regarding changes in infection-reporting criteria. The HAI panel strives to involve experts ultimately affected by the changes to infection reporting in the decision-making process. The involvement of a panel of expert clinicians and active collaboration between health care agencies is essential to eliminate confusion and set forth guidance that is realistic and grounded.

Specific examples of collaborative efforts for reporting critical issues are available on the PA Patient Safety Authority website at http://patientsafetyauthority.org/Pages/Default.aspx.
Managing Entity Subject to Vicarious Liability

By John C. Cameron, Vice Chair, PBA Health Care Law Committee

In Hall v Episcopal Long Term Care, 2012 PA Super 205, the Superior Court of Pennsylvania held that a managing entity of a nursing home could be found vicariously liable for the negligent acts of its employees since the managing entity was responsible for the full operation and management of the facility.

The estate of the deceased had brought a survival claim for corporate negligence against the nursing home, Philadelphia Nursing Home, as well as the nursing home’s managing entity, Episcopal Long Term Care. The parties stipulated to the discontinuance of the claims against the nursing home. The trial court granted Episcopal’s motion for a directed verdict with regard to the estate’s claim for punitive damages.

On appeal, the Superior Court rejected the nursing home’s claim that a corporate negligence cause of action against it was not sustained by the evidence. In the Hall decision, President Judge Correale F. Stevens opined that the record was replete with evidence that the nursing home was chronically understaffed, management was aware of the understaffing and patients, including the deceased, received improper patient care due to the inadequate staffing levels. Following its opinion in Scampone v Grane Healthcare Co., 2010 PA Super 124, 11 A. 3d 967 (PA. Super. 2010), appeal granted, 609 Pa. 264, 15 A. 3d 427 (2011), the Superior Court indicated that the evidence supported the conclusion that the managing entity had actual or constructive knowledge of the understaffing, which created harm to the deceased, and that negligence was a substantial factor in bringing about harm to the patient.

Based on the evidence of various short-comings and numerous failures of patient care, the Superior Court affirmed the judgment as it related to the jury’s award of compensatory damages. The Superior Court concluded that the trial court erred in refusing to submit to the jury the question of whether an award of punitive damages was appropriate and remanded for further proceedings to determine whether the nursing home’s negligence would rise to the level of reckless disregard.

Contribute to the PABAR-PAC!
The PABAR-PAC’s Success Depends on Your Support

The PBA Legislative Department lobbies for legislation that is important to lawyers in their day-to-day practice so that they may provide efficient and effective legal services to their clients. For instance, during the 2011-12 legislative session, the PBA lobbied for and was instrumental in shaping legislation that provides for better protection with regard to guardianship issues that involve multiple states, a new form of business entity known as the benefit corporation and improvements in the discovery process involving multiple jurisdictions.

The PABAR-PAC is the political action committee of the Pennsylvania Bar Association. The PABAR-PAC can only maintain its level of support of the PBA’s legislative program through a commitment by lawyers such as you. The PBA encourages you to contribute to the PABAR-PAC today and make a difference in how effective its legislative program can be on your behalf. Simply complete this form and e-mail to the PBA. Be sure to use your NON-CORPORATE credit card.

For more information or to donate, visit www.pabar.org/public/legislative/PAC/pabarpacform.asp.
State Legislative Update

By Steven Loux, PBA Legislative Counsel

The PBA Legislative Department seeks to inform section members about adopted or pending legislation that affect our practice areas. The Committee encourages members to express opinions regarding any pending legislation’s importance or impact by contacting the PBA Legislative Department or the leaders of the Committee. To obtain copies of any bill cited below, please e-mail PBA Legislative Counsel Steve Loux at steven.loux@pabar.org, call him at 800-932-0311, Ext. 2246, or directly access bills and other legislative information online at www.legis.state.pa.us.

NEW LEGISLATIVE SESSION

In January, the Legislature began its two-year session, which will end in the fall of 2014. There are a number of House and Senate Committees (all controlled by the Republicans) that could be of interest to the Committee, as follows:

<table>
<thead>
<tr>
<th>House Committee</th>
<th>Chairs</th>
<th>Senate Committee</th>
<th>Chairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judiciary</td>
<td>Ron Marsico (R)</td>
<td>Judiciary</td>
<td>Stewart Greenleaf (R)</td>
</tr>
<tr>
<td></td>
<td>Thomas Caltagirone (D)</td>
<td></td>
<td>Daylin Leach (D)</td>
</tr>
<tr>
<td>Insurance</td>
<td>Nicholas Micozzie (R)</td>
<td>Banking and Insurance</td>
<td>Donald White (R)</td>
</tr>
<tr>
<td></td>
<td>Anthony DeLuca (D)</td>
<td></td>
<td>Michael Stack (D)</td>
</tr>
<tr>
<td>Health</td>
<td>Matthew Baker (R)</td>
<td>Public Health and Welfare</td>
<td>Patricia Vance (R)</td>
</tr>
<tr>
<td></td>
<td>Florindo Fabrizio (D)</td>
<td></td>
<td>Shirley Kitchen (D)</td>
</tr>
</tbody>
</table>

LEGISLATION

Below find bills of relevance to the Health Care Law Committee, listed by topic. Reference to a committee means a House committee for House bills, a Senate committee for Senate bills, except where specified otherwise. The PBA has no position on the bills and is providing each summary for informational purposes only. All dates refer to 2013.

Health Care Benevolent Gesture

HB 57, sponsored by Rep. Keith Gillespie (R-York), amends Title 42 (Judiciary & Judicial Procedure) adding that a benevolent gesture or admission by health care provider or assisted living residence or personal care home prior to the commencement of a medical professional liability action shall be inadmissible as evidence of liability or as evidence of an admission against interest. The bill was referred to the Judiciary Committee on Jan. 10. SB 379, sponsored by Sen. Patricia Vance (R-Cumberland and York), amends the Medical Care Availability and Reduction of Error (MCARE) Act adding a new section providing that in any liability action, any benevolent gesture, or admission made prior to the commencement of a medical professional liability action by a health care provider or assisted living residence or an officer, employee or agent of the provider or residence to a patient or resident or the patient’s or resident’s relative or representative regarding the patient’s or resident’s discomfort, pain, suffering, injury or death, regardless of the cause shall be inadmissible as evidence of liability or evidence of an admission against interest. The bill received first consideration in the Senate on Feb. 5.

Liability Issues

HB 512, sponsored by Rep. Sheryl Delozier (R-Cumberland), amends Title 35 (Health and Safety) and 42. The Uniform Emergency Volunteer Health Practitioners (UEVHP) Act, added to Title 35, establishes a system for the use of volunteer health practitioners and provides safeguards to assure that health practitioners are appropriately licensed.

continued on Page 7
State Legislative Update

(Continued from Page 6)

and regulated to protect the public’s health. The act applies to volunteer health practitioners registered with a registration system and who provide health or veterinary services in Pennsylvania for a host entity while an emergency declaration is in effect. Title 42 is amended to include a section limiting civil liability for volunteer health practitioners: Subject to the exclusion that follows, a volunteer health practitioner who does not receive compensation that exceeds $500 per year for providing health or veterinary services pursuant to 35 Pa.C.S. Ch. 79 (relating to uniform emergency volunteer health practitioners) is not liable for damages for an act or omission relating to that operation, use or reliance unless the act or omission is an intentional tort or is willful misconduct or wanton, grossly negligent, reckless or criminal conduct. Finally, in addition to the protections specified above, a volunteer health practitioner providing health or veterinary services pursuant to the UEVHP is entitled to all the rights, privileges or immunities provided by other applicable provisions of this subchapter (subchapter C, relating to immunities generally). The bill was referred to the Veterans Affairs and Emergency Preparedness Committee on Feb. 5.

HB 525, sponsored by Rep. Matthew Baker (R-Bradford and Tioga), amends the Public School Code, in school health services, to provide definitions and mandate school employees be trained in diabetes care and management. The legislation provides for definitions and five sections, § 1414.2 (relating to training of school employees in diabetes care and management), § 1414.3 (relating to diabetes care in schools), § 1414.4 (relating to possession and use of diabetes medication and monitoring equipment), § 1414.5 (liability), and § 1414.6 (diabetes care in nonpublic schools). Section 1414.5 provides, “Nothing in sections 1414.2, 1414.3 or 1414.4 shall be construed to create, establish or expand any civil liability on the part of any school entity or school employee.” In addition, subsection (b) of § 1414.6 provides “No nonpublic school employee or nonpublic school employee shall be liable for civil damages as a result of the activities authorized by sections 1414.2, 1414.3 and 1414.4, except that an employee may be liable for willful misconduct.” The bill was referred to the Human Services Committee on Feb. 5.

Miscellaneous

SB 428, sponsored by Sen. Jay Costa (D-Allegheny), amends § 7799.3 of the Probate, Estates and Fiduciaries Code to allow for some of the residual funds from a beneficiary’s account within a pooled trust to be distributed upon the beneficiary’s death to other individuals with disabilities in need of services. Currently, a trust may retain up to 50 percent of the remaining balance for the benefit of other beneficiaries. The remaining 50 percent must be reimbursed to the commonwealth and any other state that provided medical assistance up to an amount equal to the total amount of medical assistance paid on behalf of the beneficiary. This bill adds the phrase “or other individuals with disabilities” to the provision for the portion the trust is permitted to keep and would not affect the portion that

continued on Page 8
State Legislative Update
(Continued from Page 7)

go back to the commonwealth. The bill received first consideration in the Senate on Feb. 12.

HB 21, sponsored by Rep. Glen Grell (R-Cumberland), amends the Mental Health Procedures Act, in criminal justice determinations, to allow a licensed psychologist to perform an exam to determine whether a defendant is mentally competent to stand trial. The bill was referred to the Judiciary Committee on Jan. 16.

HB 86 and SB 194, sponsored, respectively, by Rep. Nicholas Micozzie (R-Delaware) and Sen. Mike Folmer (R-Berks, Chester, Dauphin, Lancaster and Lebanon), amend the MCARE Act by repealing § 743 requiring a report to the Insurance Commissioner by basic insurance coverage insurers and self-insured participating health care providers on certain specified claims information. The legislation also repeals the requirement that a copy of the report be submitted to the House Insurance and Senate Banking and Insurance Committees. HB 86 passed the House 201-0 on Feb. 5, and was then referred to the Senate Banking and Insurance Committee. SB 194 received first consideration in the Senate on Feb. 5.

HB 563, sponsored by Rep. Phyllis Mundy (D-Luzerne), the Quality Management in Health Care Act provides a 20 percent discount on the health care provider’s assessment if the health care provider implements a quality management system to the satisfaction and approval of the Department of Health (DoH). Application to the DoH for approval of the plan is provided and the Act states the DoH shall provide the provider with a certificate of implementation once approved. The DoH is given powers and duties and is required to submit a report on the success of the program. Penalties for noncompliance are provided. The bill was referred to the Health Committee on Feb. 8.

Lance v Wyeth Tracking
Pending Resolution of a Conflict

On March 15, 2011, the Pennsylvania Supreme Court granted petitions for allowance of appeal in a product liability suit against the manufacturer of a prescription drug to decide whether to apply Restatement (Second) of Torts or Restatement (Third) of Torts as the appropriate standard in this matter. See Lance v Wyeth, 15 A.3d 429 (Pa. 2011). The case raises the question whether Pennsylvania law would recognize a negligent design defect claim, a negligent failure to test action, a negligent marketing tort and a negligent failure to withdraw from the market claim for a prescription drug. The case has been argued and is currently in active status but no decision has been made as of this date. The PBA Health Care Law Committee will report the anticipated ruling in this case on its website and in this newsletter.
Help With Your PBA Health Care Law Committee Listserv

The following instructions should assist in your effective use of your Committee’s listserv.

To subscribe, log in on the PBA website with your PBA member username and password, select the “Committees/Commissions” tab, then the “Health Care Law Committee” tab, then the “Listserv Sign-Up” tab. The subscription form can also be accessed directly at www.pabar.org/public/listserv_form.asp.

Once subscribed to the listserv, you will get the following confirmation message:
“File sent due to actions of administrator traci.raho@pabar.org.”

To send a message to members of the listserv, address your email to health@list.pabar.org.

To reply only to the sender, hit “Reply,” and type your personal reply to the sender. This response will only go to the sender, not to the entire listserv membership. You can manually add other recipients outside of the sender or the membership.

To reply to the entire listserv membership, hit “Reply to All,” and type your response. This response will go to the sender and to the entire listserv membership.

To unsubscribe, send a message to listserv@list.pabar.org with “unsubscribe health” in the body.

For customer service, contact Traci Raho, PBA internet coordinator, 800-932-0311, ext. 2255.

Contact Resources

PA Department of Health, Office of Legal Counsel
(717) 783-250
Karin Simpson, Regulatory Coordinator
ksimpson@pa.gov
James T. Steele Jr., Deputy Chief Counsel
jsteele@pa.gov
Yvette Kostelac, Contracts Coordinator
ykostelac@pa.gov

Erie County Health Department
Ronald DiNicola, County Solicitor
140 West Sixth Street
Erie, Pa. 16501
(814) 451-6344

Dauphin County Human Services
Joseph Curcillo, County Solicitor
2 South Second Street, Fifth floor
Harrisburg, Pa. 17101
(717) 780-6300

Allegheny County Health Department
Henry Miller III, Solicitor
3333 Forbes Ave.,
Pittsburgh, Pa. 15213
(412) 578-8008
hmiller@achd.net

Philadelphia Dept. of Public Health
Lynda Moore, Chief Deputy City Solicitor
(215) 683-5300
lynda.moore@phila.gov

Department of Health and Human Services Office of General Counsel — Region III
Public Ledger Building, 150 South Independence Mall West Ste. 418, Philadelphia, Pa. 19106
James C. Newman, Chief Counsel, Region III
(215) 861-4456

Assistant Regional Counsels:
Lynda R. Dennis, (215) 861-4497
Alan C. Horowitz, (215) 861-4670
Diane C. Howel, (215) 861-4749
Maureen U. Kane, (215) 861-4464
Constance A. Kossally, (215) 861-4455
Jan M. Lundelius, (215) 861-4463
Noreen O’Grady, (215) 861-4420
Suzanne K. Yurk, (215) 861-4454