BSL BRIEF

Your source for legal news and government information.

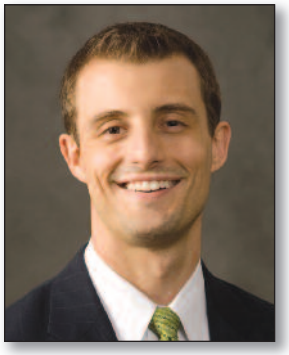
January, 2015

Bendin Sumrall & Ladner, LLC

Bendin Sumrall & Ladner, LLC

PHARMACY LAW & REGULATION PRACTICE GROUP

The Pharmacy Law & Regulation Practice Group at Bendin Sumrall & Ladner, LLC represents retail, compounding, and health system pharmacies in cases of alleged liability and disciplinary matters before the State Board of Pharmacy. The Group also counsels clients on best practices and handles issues of regulatory compliance at the state and federal level, frequently involving issues of 503(A) compounding pharmacy regulations, 503(B) outsourcing facility registration, Medicare billing and reimbursement, and FDA inspection and oversight.



Stephen T. Snow

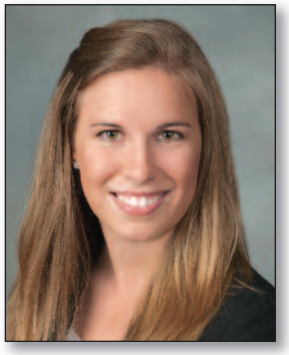
A partner at Bendin Sumrall & Ladner, LLC, Stephen practices in the areas of pharmacy compliance, construction litigation and insurance coverage. He is an experienced litigator who has presented cases in court and arbitration and has successfully argued before the United States Court of Appeals for the Eleventh Circuit. Stephen was honored as a Rising Star in 2012, 2013, 2014, and 2015 by Law & Politics and the publishers of Atlanta Magazine's Georgia Super Lawyers. Stephen graduated from Brigham Young University with a degree in Public Relations and a double-minor in Business and Korean. He earned his law degree from Temple University.

ssnow@bsllaw.net
(404) 671-3107

Robert W. Stannard

A partner at Bendin Sumrall & Ladner, LLC, Robert has a broad litigation practice with a focus on medical malpractice and healthcare law. He represents hospitals, physicians, allied health professionals, and pharmacies in cases of alleged liability, compliance and contract negotiation. Robert represents clients in trial and before Georgia's Medical and Pharmacy Boards. Robert graduated Magna Cum Laude from Hendrix College with a degree in philosophy and theology and a member of Phi Beta Kappa. He earned his law degree from The University of Georgia School of Law. Robert has an AV Peer Rating with Martindale Hubbell.

rstannard@bsllaw.net
(404) 671-3106



Jennifer C. Bellis

Jennifer Bellis is an associate at the firm and is a member of the Pharmacy Law & Regulation Practice Group. Jennifer earned her undergraduate degree in Environmental Studies at the University of North Carolina at Chapel Hill, where she graduated with honors and is a member of Phi Beta Kappa. While at UNC, Jennifer expanded her studies beyond Chapel Hill, researching sustainable development issues while living in the United Kingdom and on the coast of North Carolina. Jennifer earned her law degree from Emory University School of Law, where she graduated with honors.

jbellis@bsllaw.net
(404) 671-3113

FALLOUT FROM NECC CONTINUES

In 2012, the New England Compounding Center (NECC) made headlines for distributing contaminated methylprednisolone used for epidural steroid injections. At the epicenter of the tragedy are dozens of patients who died from fungal meningitis and hundreds of others who continue to suffer from illness and infection from the adulterated drugs. Two years after this tragedy, its aftershocks continue to reverberate through state and federal governments, as well as the health systems, hospitals, and pharmacies they regulate. On December 17, 2014, 14 executives and former employees of NECC were arrested and charged with crimes ranging from fraud and conspiracy to second-degree murder relating to distribution of contaminated drugs.

In the wake of political pressure for expanded federal oversight, Congress passed the Drug Quality and Security Act in November 2013. This Act remains in its implementation stages and ambiguity and confusion are more common than clarity when it comes to questions of compliance. States have been equally active in their legislative efforts in response to NECC. Last year, state lawmakers introduced 69 bills relating to oversight and regulation of compounded drugs in their respective states. This year, that number is over 70. State boards of pharmacy have also shown a renewed emphasis on enforcement and compliance, particularly with respect to compounding pharmacies. In Georgia, inspections and enforcement actions are on the rise and agents from the Georgia Drug and Narcotic Agency (GDNA) are undertaking thorough, purposeful inspections of pharmacies across the state. Inspectors have shut down some non-compliant pharmacies on the spot and have disciplined many others for infractions. Everyone – from legislators to field agents – is anxious to avoid another tragedy.

In the wake of the NECC crisis, health systems, physician practices, drug suppliers, and compounding pharmacies are now wading through a changing regulatory landscape and increased scrutiny from the public and governmental agencies. Hospital pharmacies, compounding pharmacies, physician practices, and drug suppliers will all be impacted by these changes.

Hospitals/Health Systems

Hospital pharmacists face a dilemma. Their responsibility to procure drugs to accommodate patients' needs presents a challenge in light of drug shortages or unavailability. The American Society of Health-System Pharmacists has identified more than 200 drugs currently subject to national shortages. Even commonly used compounds like intravenous fluids can be difficult to find.

Drug shortages compromise patient care and can contribute to medication errors. In the face of these concerns, health-system pharmacists must identify legitimate suppliers, obtain drugs in limited supply, and comply with tighter regulations governing the procurement process. This burden is substantial in light of the

Continued from page 3

questionable, if not misleading, marketing tactics employed by suppliers such as NECC.

NECC used the good reputation of its "sister pharmacy," Ameridose, to develop relationships with hospitals and clinics across the country. NECC's marketing materials described it as a state-of-the-art sterile compounder subjected to rigorous licensure processes that allowed it to legally do business in all 50 states. However, NECC's representations have not kept state boards of pharmacy from investigating pharmacists who ordered from NECC.

In the current regulatory environment, health-system pharmacies must take affirmative steps to protect themselves and their patients from unscrupulous suppliers and to ensure compliance with state and federal laws. Hospital pharmacists must familiarize themselves with their state's licensure requirements, particularly for non-resident suppliers. Such requirements often vary depending on whether an out-of-state supplier is considered a manufacturer, wholesaler, or compounding pharmacy. A supplier's assurance that it is properly licensed is not enough. Pharmacists responsible for purchasing drugs should independently verify their suppliers' licensure status at least annually, and should also take steps to verify that their suppliers have obtained the appropriate type of licensure. For further protection, pharmacists should insist on written assurance from their drug suppliers that they are licensed to sell drugs in Georgia and that they have obtained the appropriate license required for their business model, (i.e., manufacturer, wholesaler, or compounding pharmacy). This written verification should be signed and dated by a representative from the drug supplier. While obtaining written verification may not entirely shield a health system from disciplinary action by the Board of Pharmacy if the verification turns out to be false, taking these steps will help demonstrate diligence by the purchasing facility and may mitigate the adverse impact of an investigation.

Traditional Compounding Pharmacies

The recent changes in state and federal compounding laws have also had important implications for traditional compounding pharmacies. The FDA, the Georgia Board of Pharmacy, and the GDNA have each increased their scrutiny of compounding pharmacies in the wake of the NECC crisis. Pharmacies now face an increased likelihood of rigorous inspections. There are additional considerations regarding inspections by the FDA. Compounding pharmacies have historically been regulated by state boards of pharmacy. The FDA has inspection authority over compounding pharmacies, but that authority is limited. It is important to understand the permissible scope of an FDA inspection and how to properly assert the legal basis for preventing an inspector from overstepping his or her inspection authority.

Additionally, since the NECC crisis, the FDA is paying close attention to the volume of drugs produced by individual compounding pharmacies. Under Section 503A of the Food, Drug, and Cosmetic Act (FDCA) —the federal law setting the parameters for traditional compounding pharmacies—a compounding pharmacy may only prepare drugs for individually identified patients pursuant to a valid, patient-specific prescription, or in anticipation of receiving a valid, patient-specific prescription. Prior to the passage of the Drug Quality and Security Act in 2013, compounding pharmacies were also permitted to compound small quantities of drugs without a patient-specific prescription for use in a practitioner's office ("office-use compounding is not permissible at all for traditional compounding pharmacies"). However, the FDA now appears to hold the position that office-use compounding is not permissible at all. This is another area of uncertainty and ambiguity that has yet to be resolved. If the FDA determines that a compounding pharmacy is engaged in office-use compounding or is otherwise compounding drugs without a patient-specific prescription, then the FDA may decide to treat the compounder as a manufacturer, subjecting it to increased scrutiny during the inspection and requiring its compliance with the rigorous federal Current Good Manufacturing Practices (cGMPs). A facility that was operating as a

Continued from page 4

compounding pharmacy, but which is declared to be a manufacturer by the FDA, will almost certainly fail a cGMP inspection and receive a Warning Letter and potential fines from the FDA. Therefore, being aware of the limits placed on traditional compounding pharmacies and then operating within those limits are critical to avoiding enforcement action by the FDA. Advance preparation for an inspection can help protect your business. Examples of best practices include:

- Confirm that your facility has all required licenses and confirm they are current.
- Ensure that only staff members who are authorized to compound by the Georgia Pharmacy Act and Board rules are performing compounding functions.
- Ensure that staff members have completed all appropriate training and that this training is documented.
- Confirm that beyond use dates for your compounds are accurate and documented.
- Confirm you do not have products in your stock from unlicensed suppliers.
- Ensure that your facility and compounding practices comply with all requirements for sterile compounding in USP 797.
- Ensure that your facility performs all required record keeping.
- Prepare an "inspection response protocol" for your facility and follow it in the event of an inspection.

Understanding the areas where the GDNA and FDA have focused their attention in recent years can help ensure that your compounding pharmacy is in compliance and prepared for an inspection well in advance of the inspector's knock at your door. Likewise, familiarity with the inspection process can help improve the outcome of the inspection for your facility.

Beware of Medicare Fraud

Medicare fraud is a federal crime punishable by heavy fines and incarceration. Improperly billing for compounded medications or generic drugs under the billing codes for name-brand drugs constitutes Medicare fraud. Whether you submit improper codes intentionally or negligently, the U.S. Department of Justice is watching and prosecuting.

Protect yourself from fines and criminal prosecution by confirming that your office staff is submitting the proper codes for the medications that are administered to your patients. Only use the billing code for a name-brand drug if a name-brand drug was actually administered to the patient. If a generic version or a compounded form of the drug was administered, make sure to use the appropriate code.

UPDATES FROM THE GEORGIA BOARD OF PHARMACY

September 2014

- The Board adopted Rule 480-6-.02, which implements O.C.G.A. 26-4-114.1 and regulates non-resident pharmacies.
- National Association of Boards of Pharmacy President presented on efforts to establish a national inspection protocol.

October 2014

- The Board adopted new policy regarding the labeling of drugs with the name of the prescribing practioner, eliminating confusion caused by inconsistencies in the text of the Georgia Pharmacy Act.
- The Board offered clarification regarding Non-Resident Pharmacy Permits, including the application process and implications for in-state drug purchasers.

November 2014

- Presentation on new medication supply systems for use at subacute care facilities, and discussion of permitted use of these systems under current Georgia law.
- The Board discussed GDNA presence at pharmacy inspections and efforts by out-of-state agencies or entities to coordinate with GDNA prior to inspection.
- The Board discussed Rule 480-11-.02 and implications for compounding office-use medications for non-resident providers.

Compounding Pharmacy vs. Outsourcing Facility

Which Option is Right for Your Business?

As a part of its response to the NECC tragedy, Congress passed H.R. 3204, entitled the "Drug Quality and Security Act," which went into effect on November 27, 2013. H.R. 3204 made several key changes to the federal law regulating pharmacy compounding. Significantly, it created a new category of compounding pharmacy called an "outsourcing facility" under Section 503B of the Food, Drug, and Cosmetic Act (21 U.S.C.S. § 353B). It also reinstated statutory language concerning traditional pharmacy compounding under existing Section 503A, which was originally passed in 1997. H.R. 3204 also removed the advertising restriction in Section 503A that had been declared an unconstitutional limit on free speech.

With the advent of outsourcing facilities, many traditional compounding pharmacists, and some manufacturers, are considering whether it is in their best interests to register their current businesses as outsourcing facilities, or even to open completely separate outsourcing facilities. However, a great deal of confusion exists as to the distinction between traditional compounding pharmacies and outsourcing facilities and what regulations apply. The continually evolving federal law contributes to this confusion. In order to decide which type of entity is best for your business, it is critical to understand the differences between the two, the state and federal regulations that apply, and the costs associated with regulatory compliance.

Outsourcing facilities occupy a middle ground between traditional compounding pharmacies and larger drug manufacturing facilities. Unlike traditional compounding pharmacies, properly registered outsourcing facilities may produce large quantities of sterile drugs, with or without prescriptions for individually identified patients. Under H.R. 3204, the regulation of traditional pharmacy compounding is left to state boards of pharmacy, although the FDA has limited authority over their operations, including limited inspection authority. In contrast, outsourcing facilities voluntarily subject themselves to full FDA oversight and regulation. However, they are exempt from certain requirements typically imposed on manufacturers as long as the outsourcing facilities compound under specified conditions.

Some key similarities and differences between 503A compounding pharmacies and 503B outsourcing facilities that pharmacists should know and thoughtfully consider when deciding which type of facility is best for their business model are set forth below:

503A	503B
Exempts traditional compounding pharmacies from the FDCA's provisions regarding "new," "misbranded" and "adulterated" drugs.	Exempts outsourcing facilities from the FDCA's "new drug" provisions and requirements to label drugs with adequate directions for use.
Allows traditional compounding pharmacies to compound drugs pursuant to a valid, patient-specific prescription, or in anticipation of receiving a valid, patient-specific prescription.	Allows outsourcing facilities to compound drugs for non-patient specific orders, without first having obtained a valid prescription or basing its drug preparation on a history of receiving prescriptions for a particular patient.
Preserves historical regulation of compounding pharmacies by state boards of pharmacy.	Subjects outsourcing facilities to full inspection by the FDA.
Limits the FDA's inspection authority–the FDA cannot inspect "records, files, papers, processes, controls, and facilities" of a compounding pharmacy.	Requires outsourcing facilities to comply with a slightly modified version of the Current Good Manufacturing Practices codified at 40 C.F.R. §§ 211, *et seq*.
Requires drugs to be compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding.	Imposes additional labeling, registration, reporting, and fee requirements on outsourcing facilities.
Prohibits compounding "in inordinate amounts" drugs that are copies of commercially available, FDA approved drugs.	Prohibits compounding drugs that are copies of commercially available, FDA approved drugs.

Continued from page 6

Registration as an outsourcing facility may potentially open up new markets and business opportunities, because outsourcing facilities have the freedom to sell greater quantities of drugs, prepared without individual patient prescriptions, to various entities. The FDA plans to actively encourage health care providers and drug purchasers to obtain their compounded products only from outsourcing facilities in hopes it will become standard practice in the healthcare industry.

In deciding which type of facility is best for your business, you must weigh the financial advantages of the ability to engage in unlimited office-use compounding with the overhead costs and strict penalties associated with rigorous FDA oversight. Choosing to register your facility as an outsourcing facility comes with increased costs and regulatory burdens. A typical outsourcing facility must pay an annual registration fee of about $14,000, subject itself to FDA inspection, and pay a re-inspection fee in the amount of $15,000 if it fails the inspection. Outsourcing facilities must also register annually with the FDA and report a list of all drugs compounded to the FDA every six months. Additionally, the costs of bringing a traditional compounding pharmacy into compliance with the cGMP's may be significant. Maintaining cGMP compliance can also be quite costly. Moreover, FDA Warning Letters and other public enforcement actions arising out of even minor deficiencies in cGMP compliance may negatively impact an outsourcing facility's reputation among its customers.

Ultimately, deciding whether to register your traditional compounding pharmacy as an outsourcing facility is a business decision that is unique to each individual. The regulatory landscape governing both types of entities is constantly evolving and both involve different risks and opportunities. It is important to become fully aware of the applicable regulations for each entity and the costs associated with complying with those regulations before making the decision whether to remain a compounding pharmacy or to register as an outsourcing facility.

Other Practices

MEDICAL MALPRACTICE DEFENSE

The Medical Malpractice Group at Bendin Sumrall & Ladner, LLC represents hospitals, pharmacies, individual physicians and their practices, and other allied health professionals (including respiratory therapists, radiology technicians, CRNAs, DOs, and social workers) in cases of medical negligence and intentional torts. The Group also works extensively with medical entities in pre-litigation matters, risk management, and representation of medical professionals before their respective boards.

Outside the litigation setting, our attorneys speak to professional groups on a range of topics, including developments in medical practice and pharmacy law, risk management, and other important topics affecting medical professionals and hospitals.

CONSTRUCTION LITIGATION

The Construction Practice Group at Bendin Sumrall & Ladner, LLC represents builders and developers in all types of commercial and residential matters. In addition to working with general contractors and subcontractors on construction defect claims and contract disputes, our attorneys have expertise in areas that have increasing impacts on the work of Georgia construction entities. These include cases of environmental torts and storm water discharge, road construction and contractual relations with the Department of Transportation, and catastrophic losses. Our group also provides counsel to clients who specialize in high-rise office buildings, mixed-use facilities, parking structures, and large-scale residential developments. The attorneys at Bendin Sumrall & Ladner, LLC are available to speak to groups about matters frequently encountered in the construction industry, including subjects ranging from contractual obligations, insurance and indemnity, and risk aversion in construction settings.

GENERAL LIABILITY

While our General Liability Practice Group has substantial experience in litigating many types of civil matters, our representation most frequently relates to premises liability, product liability and contract disputes. We have developed particular expertise and have extensive experience representing banks, pharmacies, retailers, and product manufacturers who enjoy a national presence and call on our attorneys for advice, education, and representation in pre-litigation, mediation/arbitration, and trials. We also provide our clients with general counseling, presentations, and conduct training seminars on general torts and liability topics including commercial liability, security, and premises liability.

One Midtown Plaza
1360 Peachtree Street, NE
Suite 800
Atlanta, GA 30309
Main (404) 671-3100
Fax (404) 671-3080
www.bsllaw.net

Bendin Sumrall & Ladner, LLC

Medical Malpractice Defense | Pharmacy Law & Regulation | Healthcare Law | Construction Litigation | General Liability