



## New Orleans Pharmacy Museum and the Beginnings of Licensure

BY NED MILENKOVICH, PHARM.D, JD



### AUTHOR BIO

Ned Milenkovich, PharmD, JD, is chairman of the health care law practice at Much Shelist PC in Chicago and former vice chairman of the Illinois State Board of Pharmacy.

THE NEW ORLEANS PHARMACY MUSEUM sits in the Vieux Carré, the heart of the French Quarter.

This mid-19th century apothecary features exhibits of bloodletting, surgical instruments, and questionable medical practices then in use. Hand-blown apothecary bottles filled with crude drugs and medicinal herbs line the walls. Adding to the Pharmacy Museum's allure is the ghost of a former owner, dressed in a brown suit and matching top hat, who is said to haunt the premises.

The apothecary was constructed in 1823 for Louis Dufilho Jr, who, after having passed the first licensing exam ever instituted in the United States, became our nation's first licensed pharmacist in 1816. Prior to the enactment of this groundbreaking Louisiana licensing law, anyone could compound and sell concoctions without being subject to regulations or standards after having served a mere 6-month apprenticeship. This, of course, increased the risk that the public might receive

erroneous medications and incorrect doses. Dufilho was educated at the Paris College of Pharmacy and then apprenticed with his father and older brother, who were both local pharmacists in Louisiana. The history of American health care formally begins with Louisiana, the first state to institute licensure requirements for health care practitioners such as pharmacists.

Modern pharmacies are branching out into activities that range far beyond their traditionally licensed roles as local dispensers of prescription drugs to patients in their communities. As innovation and technology in the pharmaceutical field continue to evolve, the pharmacy profession is playing an ever-larger role in patient treatment that involves complex compounding methods, specialty pharmaceutical drugs, supply-chain issues, and new types of pharmacist-administered medications, such as vaccines. These areas of patient care may invite additional licensure requirements.

*One might be skeptical that a pharmacy such as the one in New Orleans could be haunted by a ghost, but no one can deny that a pharmacy can be haunted by imperfect adherence to licensing requirements.*

#### PHARMACY LICENSING

One area of due diligence for any dispensing pharmacy is to determine if it possesses the proper pharmacy licenses for the business activities in which it is engaged. Although this seems to be a basic regulatory compliance issue, pharmacies often overlook licensing requirements or fail to discover whether, or to what extent, a license is required for a particular area.

For example, a hypothetical retail pharmacy acts as a wholesale distributor of drug product that it sells to another pharmacy or to a health care practitioner without an identifiable patient at the time of the transaction. Depending on federal and state laws and the volume of the drug being distributed, such a pharmacy may be required to possess an additional wholesale distribution license apart from its state-issued pharmacy dispensing license.

Another example may involve what type of licensure a third-party logistics provider is required by law to have when picking, packing, and shipping products for a manufacturer or wholesaler. Such providers should consult with their legal advisors and the relevant oversight agencies to prevent violations of law.

Previously, state law typically drove licensure requirements in the drug supply chain. Today, the federal government has taken a more active role in addition to the various states. In short, pharmacy businesses engaged in dispensing/distribution activities as well as other interested parties should undertake a legal analysis to deter-

mine the licensure requirements for the business activities being practiced. If drug supply-chain activities cross state lines, then the laws and regulations of each state in question should be analyzed to ensure full compliance.

#### LACK OF LICENSURE CONSEQUENCES

If a business fails to maintain full licensure compliance, then an enforcement action may be undertaken by a federal government agency or a state board of pharmacy in response to an unauthorized pharmaceutical practice or the wholesale distribution of a drug. Depending on the severity of the unauthorized activity, disciplinary actions could involve monetary penalties, probation, suspension, or revocation of existing licenses. At a minimum, unless there is a valid reason for exemption, any such business activity is likely to be prohibited until the proper licensure is obtained.

A pharmacy can also be challenged by a third-party payer if a prescription drug was dispensed without possessing the required dispensing license. Many times, this may lead to a claw back of fees or could precipitate exclusion of the pharmacy from the payer network. In such cases, it behooves the pharmacy to seek the immediate advice of legal counsel.

Despite the existence of well-established government licensure requirements, pharmacy enterprises that engage in certain unauthorized business practices do not appreciate the severity of the possible consequences until they are sanctioned. One might be skeptical that a pharmacy such as the one in New Orleans could be haunted by a ghost, but no one can deny that a pharmacy can be haunted by imperfect adherence to licensing requirements.

In addition to being an icon of pharmacy history that every pharmacist should visit and explore, the New Orleans Pharmacy Museum reminds us that although the first pharmacy license was issued almost 200 years ago, the requirement persists to this day and no pharmacy enterprise should be haunted by doubts about its compliance responsibilities. ♦