

INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

Compounding Examination for Pharmacists

Word count: 1230

Spring 2015 Student Writing Competition

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4/20/2015

Current role of compounding pharmacy in the United States of America is polarized. Recent growth of drug manufacturing and distribution technology has revolutionized the way drugs are made and delivered, and more drugs are commercially available than ever. On the other end of the spectrum, the area of compounding pharmacy has been standing its ground to care for patients in the community and the institutions, and is expanding its horizons with the help of new delivery systems and sterile compounding technology. Today, pharmacy compounding is required in pharmacist licensing examinations of certain states, and therefore there is little training in compounding required for pharmacists. However, the demand for traditional and non-traditional compounding in pharmacy is increasing, and it is an essential skill in practicing pharmacy regardless of state. Therefore, the State Boards of Pharmacy should uniformly incorporate wet lab as part of their pharmacist licensing process to reduce inconsistencies of compounding practice among the states and to ensure that pharmacists acquire the critical skills and techniques of compounding through appropriate training. This will also open doors for pharmacists to be educated and trained about compounding, and become more involved in its art and science. It will contribute greatly advancing the profession of pharmacy in the ever-changing sphere of healthcare.

The importance of compounding examination is primarily demonstrated in situations where medications and formulations are not commercially available and must be used for a specific patient. According to USP 795, compounding is defined as “preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional

practice”.¹ Compounded medications establish personal relationships between healthcare practitioners and patients, which improves quality of care and the credibility of the healthcare practitioners. It is valuable for healing patients who have special needs for medication administration, and also improves compliance for patients who have difficulty adhering to their regimen. For example, quinidine sulfate (an antiarrhythmic drug) can be compounded as an oral suspension for arrhythmia patients who cannot swallow solid dosage forms such as tablets, as the drug is not commercially available in such formulation.^{2,3} Compounded quinidine sulfate oral suspension would improve the patient’s compliance, which is an important consideration in patients with chronic arrhythmias. This formulation also reduces the risk of medication-related adverse event such as aspiration, without having to resort to more expensive drugs. This shows that compounding is an essential part of individualized pharmacotherapy and medication cost management as well. It is clear that pharmacists properly trained in compounding will raise the standard of individualized patient care, and that incorporating the appropriate lab examination will help pharmacists and institutions to seek out more formalized and qualified training opportunities.

The role of compounding is also critical in institutional pharmacy. Pharmacists in hospital settings are expected to know about sterile and nonsterile compounding. There is constant need for various injectables or otherwise specially formulated medications for patients, such as chemotherapy or total parenteral nutrition, which are not always available commercially

¹ Pharmaceutical Compounding – Nonsterile preparations (definitions chapter 795). In: The United States pharmacopeia, Rockville, MD: The United States Pharmacopeial Convention, 2013:31-38.

² Quinidine. Lexi-Drugs Online [Internet]. Hudson (OH): Lexi-Comp, Inc. 1978-2015 [cited 2015 April 9].

³ Allen LV. Quinidine sulfate 10mg/mL Oral Suspension. *US Pharm.* 2015;40(2):62-63.

and difficult to acquire during drug shortages.⁴ Such demand requires pharmacists to have a minimum level of training and knowledge about the drugs involved in compounding, sterile compounding technique, the laws and regulations that pertain to sterile compounding, and the financial cost and benefit of compounding these formulations. The pharmacist must also be familiar with the ingredients and equipments used for such compounding. For example, in order to prepare chemotherapy regimen in the hospital pharmacy for an incoming patient, a pharmacist should be trained in the regulations of USP 797 for sterile compounding as well as the correct way to handle hazardous substances, the storage and stability requirements, and also the proper waste and disposal methods.⁵ The pharmacist should also be able to identify the most cost-effective method for preparing the regimen, because chemotherapy drugs are generally very expensive and difficult to acquire. Not all pharmacy programs offer hands-on training in the area of sterile compounding, however. In some cases, pharmacists rely on the knowledge of pharmacy technicians for compounding complex regimen of intravenous substances. This makes it difficult for the pharmacist to verify such regimen, and therefore does not parallel with the expanding role of pharmacists in institutions such as hospitals or long-term care facilities. If wet lab examination is implemented in the initial licensure, pharmacists will have a good understanding about how to go about verifying and handling compounding in institutional settings.

⁴ Drug Shortages: Current Drugs. American Society of Health-System Pharmacists. <http://www.ashp.org/DrugShortages/Current/>

⁵ Policies, Best Practices, and Guidelines. ©2015 American Society of Health-System Pharmacists. <http://www.ashp.org/menu/PracticePolicy/ResourceCenters/Compounding/Policies-Best-Practices-and-Guidelines.aspx>

Demand for compounded veterinary medicine has been rising steadily as well, as more herd, exotic, or companion animals require medical treatments.⁶ Many medications available for humans do not apply to the treatment of the similar diseases in animals. Manufactured veterinary medications are much less frequently available and also very expensive, which calls for the help of compounding pharmacies.⁷ Compounding pharmacies are often able to formulate drugs that tailor to the medical needs of the animal at a cheaper cost and with more consistency. During my advanced practice rotation at a compounding pharmacy, I had the first-hand opportunity to witness the compounding of various veterinary formulations. This includes a thyroid medication for a cat patient, which is not commercially available and also difficult to administer. These medications were compounded as transdermal gels to be applied in the ears of cats, where the drug is absorbed systemically. Such an example demonstrates the specialty and importance of compounding pharmacy in the field of veterinary medicine, which continues to expand and improve in quality with the help of appropriate technology. With good training and examination in the area of compounding, pharmacists will be able to prepare themselves in the face of this rising demand.

Compounding pharmacy is an essential but an undermined profession of pharmacy today. We encounter compounding in everyday practice, whether through compounding in the IV room of the hospital pharmacy or by looking up the concentration of an oral solution in a retail pharmacy. Compounding is a traditional art that the humanity has relied on for centuries. Throughout history, it has been the primary mode of practicing medicine and engaging in

⁶ Veterinary Compounding. Animal Health Institute, American Veterinary Distributors Association, American Veterinary Medical Association. Accessed on April 16, 2015 <http://www.ahi.org/wp-content/uploads/2011/04/Veterinary-Compounding-Brochure-2011finalversion.pdf>

⁷ Mark G. Papich. Drug Compounding for Veterinary Patients. The AAPS Journal 2005; 7(2) Article 29.

healthcare, and it continues to thrive as an essential, specialized area of pharmacy. We can enhance the practice of pharmacy by equipping our pharmacists with proper techniques and skills of compounding and improving the standard of patient care. This is only a beginning step, however. Educating and engaging pharmacists in the science of compounding will help pharmacists care for patients more effectively, and according to our Hippocratic Oath.