

Issue Brief

S.B. 161 Pharmacy Practice Act Revisions

On February 1st, 2012, State Senator Curtis Bramble submitted a bill that aims to amend the Utah Pharmacy Practice to include the following provisions:

1. Define cancer drug treatment regimen
2. Exempt an oncologist from the Pharmacy Practice Act when the oncologist provides a cancer drug treatment regimen to a patient
3. Exclude Schedule I, II, and III drugs from the drugs an oncologist may provide a patient under the exemption from the Pharmacy Practice Act
4. Include assistants to the oncologist who are under the general supervision of the oncologist in the exemption from the Pharmacy Practice Act

The Utah Society of Health System Pharmacists (USHP) is a non-profit, professional organization that represents pharmacists in Utah who practice in a variety of patient care settings, including hospitals, clinics, outpatient pharmacies, and infusion centers. As an organization of members whose primary focus is the safe delivery of optimal medication therapy regimens to the patients of Utah, USHP strives to advocate for legislation that will further this goal. It is with this purpose, that we submit comments regarding S.B. 161.

Licensure of Practices and Individuals Protects the Public

First and foremost, the Pharmacy Practice Act exists to maintain public health, safety, and welfare by regulating the manner in which medications are acquired, stored, and dispensed and/or administered to patients. It also regulates the training and licensure necessary for all those involved in the practice of pharmacy, recognizing that improper or inadequate training of anyone who handles prescription medications puts patients at risk. Furthermore, through licensure of both practices and professionals involved in the handling and dispensing of medications, regulations can be enforced. Without licensure of both the practices and those involved in handling medications, no regulatory agency would be in a position to sanction individuals and/or practices who fail to meet the provisions in the Pharmacy Practice Act and associated rules.

Pharmacists are highly-trained healthcare professionals with unique expertise in the area of medication therapy design and monitoring, and patient counseling. Since the mid-1990s, the entry-level degree for a pharmacist is at a Doctorate-level. Pharmacists take very seriously the responsibility to ensure that patients are properly educated on their medications (dosing, storage and administration, side effects, interactions and contraindications, monitoring and follow-up, etc.). This proposed legislation would allow an oncologist to delegate this function to “assistants”, with no requirements for their training or competence in the area of medication management, patient counseling, proper drug handling, etc. This puts the patients of Utah at risk. Additionally, it puts “assistants” of oncologists at risk of being asked to perform functions for which they may have no formal training.

Pharmacists Ensure All Medications Dispensed are Safe and Appropriate

Patients with cancer take a large number of medications, all of which are currently dispensed by a pharmacist- usually a single pharmacist or pharmacy. By taking a portion of these medications and allowing a physician to dispense them, patients would have two outlets for medication, so the pharmacist who is dispensing the majority of their medications no longer is able to get a “complete” picture of what the patient is taking. This prevents pharmacists from being able to adequately assess the patient’s medication regimen for drug/drug interactions,

contraindications, duplications of therapy, overdose, etc. All patients deserve the opportunity to receive this service prior to obtaining medications. It is part of the “dispensing” process, and is provided for in the Utah Pharmacy Practice Act. Creating an exemption for oncologists to dispense cancer medications from their office will not alleviate the need for patients to visit their pharmacy to obtain their non-cancer related medications. The net result of physician dispensing would be an increased risk of error due to incomplete information at the pharmacy and/or the dispensing oncology practice while not drastically reducing the number of trips that a patient or family member must make to the pharmacy.

Independent, Double-Checks Improve Safety and Quality

The American Society of Clinical Oncologists and the Oncology Nursing Society jointly publish “Standards for Safe Chemotherapy Administration”, which details a total of 31 practice standards for chemotherapy administration. Standard #12 states that a second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) independently verifies each order for chemotherapy before preparation, including confirming two patient identifiers, drug names, drug doses, drug volumes, rate of administration, route of administration, calculations for dosing, and treatment cycle and day of cycle.ⁱ While the standard does not state that a pharmacist should be the only healthcare professional assigned independent checking responsibility, USHP asserts that pharmacists are the most qualified healthcare professional to perform medication therapy reviews. Pharmacists are best positioned to ensure that medications are used rationally and safely.ⁱⁱ

Proper Handling of Chemotherapy Medications Protects Patients and Employees

Medications prepared for intravenous administration are subject to the United States Pharmacopoeia National Formulary (USP-NF), chapter 797 (USP-797). USP-797 aims to reduce the number of infections associated with pharmaceuticals and protect staff that prepare and administer medications. State Boards of Pharmacy are largely responsible for enforcing these standards. In the state of Utah, the Division of Occupational and Professional Licensing maintains this responsibility. Exemption from licensure removes any recourse that the Division might have to ensure that these medications are handled safely.

Chemotherapy agents are known carcinogens, and have other extremely toxic properties when not handled appropriately. Employees who handle these medications must maintain safe handling practices, and the oversight of the Division of Occupational and Professional Licensing by enforcing the Pharmacy Practice Act ensures that safe handling practices are upheld. Removing the requirement of licensure to oncology practices who handle medications that are hazardous removes a major mechanism to protect not only the patients of these practices, but the practice employees who come in contact with these agents on a daily basis.

Summary

USHP has a number of serious concerns about this proposed legislation. As an organization of pharmacists with responsibility for ensuring the accuracy and safety of medications, we fully understand and appreciate the great effort that is required when handling, storing, preparing, dispensing, and disposing of chemotherapy medications. These medications are not like other medications. They are hazardous to the patients who receive them and the personnel who handle them, if they are not handled properly. It requires significant investments and commitment in building infrastructure, process controls, and employee training to ensure that these medications are handled safely. Removing the oversight of the Division of Occupational and Professional Licensing by exempting oncology practices from the Utah Pharmacy Practice Act would remove a major measure of control that we have to ensure that these high-risk patients and oncology practice employees are protected.

ⁱ Jacobson J, Polovich M, Gilmore T, Schulmeister L, Esper P, LeFebvre K., et al. Revisions to the 2009 ASCO-ONS Standards for Safe Chemotherapy Administration: Expanding the Scope to Include Inpatient Settings. *Oncology Nursing Forum*. Vol 39, No. 1. Jan 2012.

ⁱⁱ American Society of Health-System Pharmacists. ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents. *Am J Hosp Pharm*. 1993;50:305-14.