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February 29, 2012

The Honorable Paul Ray, Chair, House Health and Human Services Committee  
The Honorable Evan J. Vickers, Vice Chair, House Health and Human Services Committee  
Utah House of Representatives  
350 North State, Suite 350  
P.O. Box 145030  
Salt Lake City, Utah 84114

**RE: SB 161 "Pharmacy Practice Act Revisions"**

Dear Chairman Ray and Vice Chairman Vickers:

On behalf of the American Society of Health-System Pharmacists (ASHP) I am writing to oppose SB 161 which does not contain sufficient provisions to safeguard patients receiving medications from oncologists or others under their supervision. For more than 60 years ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. ASHP members include pharmacists involved in the safe provision of chemotherapy in the outpatient setting, including ambulatory clinics and physician practice sites. Additionally, ASHP has offered comments to the American Society of Clinical Oncologists (ASCO) and the Oncology Nursing Society (ONS) in their development of standards for safe chemotherapy administration.

**Ensuring Patient Access While Guarding Patient Safety**

ASHP recognizes the appropriateness and pervasiveness of oncologist provision of cancer drug treatment regimens in an outpatient clinic and further recognizes the need to minimize barriers to medication access for seriously ill patients. However, patient safety must also be protected through appropriate regulatory accountability and oversight. Therefore, ASHP opposes the exemption from licensure in the Pharmacy Practice Act contained in SB 161. Oncologist provision of cancer drug treatment regimens in an outpatient clinic involves not only the administration of intravenous drugs, but also the dispensing of high-risk and toxic oral medications. Dispensing medications is appropriately regulated through the Pharmacy Practice Act.

**TOGETHER WE MAKE A GREAT TEAM**

Both the U.S. Office of the Inspector General of the Department of Health and Human Services (OIG) and the National Association of Boards of Pharmacy (NABP) emphasize the necessity of regulatory oversight and accountability in the drug distribution and dispensing process in order to protect patient safety.

In “Physician Drug Dispensing: An Overview of State Regulation,” OIG states: “Effective regulation of drug dispensing is important to protect the health and welfare of the public and to ensure accountability and adequate controls in the drug distribution system.”<sup>1</sup> Moreover, OIG specifies:

We think the States, at the very least, should adopt a basic threshold of regulatory requirements to govern dispensing by physicians. We suggest this threshold of regulation consist, at a minimum, of the following requirements:

1. The procedural requirements . . . such as labeling, record-keeping, storage, security, and supervision of the dispenser should be as applicable to dispensing physicians as they are to pharmacists.
2. A requirement for registration of dispensing physicians with a designated state agency . . . is needed so the states can identify those physicians who are actually dispensing for purposes of inspection and monitoring.<sup>2</sup>

Senate Bill 161 defines cancer drugs delivered through multiple administration routes – including the rapidly expanding number of oral cancer drug treatments.<sup>3</sup> The movement from administered therapies to dispensed, oral therapies makes the drug-labeling concerns discussed by OIG even more urgent. Moreover, ASHP guidelines on the necessity for patient counseling when dispensing medication complement OIG’s minimum threshold of regulation:

The human and economic consequences of inappropriate medication use have been the subject of professional, public, and congressional discourse for more than two decades. Lack of sufficient knowledge about their health problems and medications is one cause of patients’ non-adherence to their pharmacotherapeutic regimens and monitoring plans; without adequate knowledge, patients cannot be effective partners in managing their own care. The pharmacy profession has accepted responsibility for providing patient education and counseling in the context of pharmaceutical care to improve patient adherence and reduce medication-related problems.<sup>4</sup>

NABP states in their Model Practice Act:

Given that medications are an integral part of disease management, medication therapies and their delivery systems are becoming more complex, technological enhancements have improved the capabilities for patient monitoring, and entities motivated by economic gain are eroding standards of care, there is greater potential harm to the public and a greater need for patients’ medication use to be managed by a licensed pharmacist and State regulatory agencies to aggressively enforce standards of care.<sup>5</sup>

One goal of the Pharmacy Practice Act's regulation of medication and personnel is the prevention and detection of medication errors and adverse drug events. In its landmark 1999 report, "To Err Is Human: Building a Safer Health System," the Institute of Medicine (IOM) identified medication errors as the most common type of health-system error, contributing to several thousand deaths each year and costing \$2595–4685 per adverse drug event.<sup>6</sup> Pharmacists possess expertise in a drug's "therapeutic index," which is the ratio between the dosage of a drug that causes a lethal effect and the dosage that causes a therapeutic effect. The therapeutic index for chemotherapy medication is even less than that of other drugs. Because of their narrow therapeutic index, the opportunity for error with chemotherapy medication is even greater than with other drugs:

Individually and categorically, the therapeutic index for antineoplastic drugs is less than that for any other class of drugs. Adverse effects are an expected pharmacodynamic consequence attendant with antineoplastic use, and clinical toxicities may occur and persist at substantially lower dosages and schedules than are therapeutically used.<sup>7</sup>

**Current Landscape: States Permit – but Also Regulate – Physician Dispensing**

While it is often observed that physician dispensing is permitted in most states, it is frequently overlooked that it is carefully regulated in numerous states. **Montana** forbids physician dispensing, except under very restricted conditions.<sup>8</sup> With the exception of samples, **Virginia** requires dispensing physicians to be licensed by the Board of Pharmacy.<sup>9</sup> **North Carolina** requires registration with the Board of Pharmacy as a dispensing physician.<sup>10</sup> **Texas** severely restricts physician dispensing. In Texas, a physician may "provide, dispense, or distribute" a drug in an amount greater than "immediate need" only under two circumstances: (1) in a rural area (as defined by law) or (2) as a free sample.<sup>11</sup> **Maryland** and **Arkansas** allow physician dispensing, but only with a special permit.<sup>12</sup>

In closing, ASHP strongly opposes SB 161 and suggests that it be referred to an interim task force or study committee to fully examine the patient safety aspects of this issue and develop recommendations to the legislature. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8687, or by e-mail at [knoonan@ashp.org](mailto:knoonan@ashp.org).

Sincerely,



Karen A. Noonan  
Director, State Affairs and Grassroots Advocacy

CC: Sen. Curtis S. Bramble  
Rep. Rebecca Chavez-Houck, House Health and Human Services Committee  
Rep. Tim M. Cosgrove, House Health and Human Services Committee

Rep. Bradley M. Daw, House Health and Human Services Committee  
Rep. Daniel McCay, House Health and Human Services Committee  
Rep. Ronda Rudd Menlove, House Health and Human Services Committee  
Rep. Dean Sanpei, House Health and Human Services Committee  
Rep. Christine F. Watkins, House Health and Human Services Committee  
Shantel Mullin, President, Utah Society of Health-System Pharmacists  
Melissa Skelton Duke, Board Member, Liaison to Advocacy Committee, Utah Society of Health-System Pharmacists

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<sup>1</sup> “Physician Drug Dispensing: An Overview of State Regulation,” Office of Inspector General, Office of Analysis and Inspections, Department of Health and Human Services, May 1989, page 16.

<sup>2</sup> “Physician Drug Dispensing: An Overview of State Regulation,” Office of Inspector General, Office of Analysis and Inspections, Department of Health and Human Services, May 1989, page 17.

<sup>3</sup> SB 161 (5<sup>th</sup> Substitute): 58-17b-309. “cancer drug treatment regimen includes a chemotherapy drug administered intravenously, orally, rectally, or by dermal methods”

<sup>4</sup> Medication Therapy and Patient Care: Organization and Delivery of Services—Guidelines: “ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling,” page 249.

<sup>5</sup> National Association of Boards of Pharmacy (NABP) Model Act (<http://www.nabp.net/publications/model-act/>), Accessed 23 February 2012. Emphasis added.

<sup>6</sup> Kohn LT, Corrigan JM, Donaldson MS (Eds.). To err is human: building a safer health system. Washington, DC: National Academy Press; 1999. Bates DW, Spell N, Cullen DJ, et al. The cost of adverse drug events in hospitalized patients. *JAMA*. 1997; 277:307-11.

<sup>7</sup> ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents, page 223.

<sup>8</sup> NABP “Survey of Pharmacy Law,” 2012. Montana Code Annotated (MCA) 37-2-104.

<sup>9</sup> Virginia Board of Pharmacy, “Physicians Dispensing Drugs,” Guidance Document 110-29, Revised February 2011, [http://www.dhp.virginia.gov/Pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm) (Accessed 24 February 2012).

<sup>10</sup> According to the North Carolina Board of Pharmacy:  
A physician who dispenses prescription drugs, for a fee or other charge, must register with the Board each year. All dispensing physicians must comply in all respects with the laws and regulations that apply to pharmacists governing the distribution of drugs. These responsibilities include drug utilization review, patient counseling, appropriate packaging, labeling, and record keeping.  
[http://www.ncbop.org/dispphys\\_regreq.htm](http://www.ncbop.org/dispphys_regreq.htm) (Accessed 24 February 2012).

<sup>11</sup> Texas State Board of Medical Examiners, Authority of Physicians to Supply Drugs, 169.1-169.8.

<sup>12</sup> Arkansas Medical Practices Acts and Regulations, Regulation 12, “Pursuant to other provisions of Act 515 of 1983 any physician licensed to practice medicine in the state of Arkansas who is a “dispensing physician” as defined by Act 515 of 1983 shall comply with all provisions of the Act and shall register with the Arkansas State Medical Board on a form provided by it for that purpose.”

Code of Maryland Regulations (COMAR), Title 10, Department of Health and Mental Hygiene.