

Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200, Horsham, PA 19044
www.ismp.org

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CONTACT: Renee Brehio, Media Relations, ISMP
704-831-8822, rbrehio@ismp.org

**ISMP Cautions Against Unregulated
Physician Dispensing of Oncology Medications**

Horsham, Pa---In response to a bill introduced in the Utah senate that would allow oncology physicians to directly provide patients with oral drugs used in cancer treatment, the Institute for Safe Medication Practices (ISMP) is sending a strong message that physician dispensing without the regulatory oversight applied to pharmacies could have serious consequences in terms of medication safety.

Proponents of Utah Senate Bill 161 (<http://le.utah.gov/~2012/bills/sbillint/sb0161s06.pdf>) introduced it as a way to ensure that cancer patients have better access to the increasing number of new oral chemotherapy drugs. Currently, oncologists can administer IV chemotherapy in the office or clinic—a practice ISMP endorses only if a pharmacist is involved in preparation and a second trained professional conducts an independent check before administration.

The bill would allow oncologists and medical personnel under their direction to also dispense oral chemotherapy and other associated medications, bypassing the usual pharmacy safety checks. Despite opposition from numerous professional organizations, the bill passed the Utah Senate and after revision was approved by the House. It is expected to be signed by the governor.

Although ISMP fully supports removal of barriers to patient access to medications, cost containment achieved by use of lower-cost but effective medications, and improving patient adherence to prescribed therapy, it does not support unchecked physician dispensing due to the increased risk of medication errors, particularly with high-alert medications such as chemotherapy. While physician dispensing is permitted in most states, it is often carefully regulated and restricted to samples or conditions of immediate need.

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ISMP is concerned that physician dispensing of oral chemotherapy could potentially:

- **Remove Crucial Pharmacy Checks and Balances.** Physicians may not have access to the software pharmacists use to screen for overdoses, sub-therapeutic doses, allergies, and interactions among all the medications a patient is taking.
- **Result in Inadequate Labeling and Education.** Regardless of where a prescription medication is dispensed, each product should have a label with the same essential drug information and precautions that pharmacies must provide, and the patient should be counseled in its use, including any potential side effects. In physicians' offices, patient education may be delegated to staff with insufficient knowledge of the drug.
- **Lower Chances of Third Party Reimbursement.** Physician office staff may not be proficient in conducting online adjudication of medications with third party payers, including challenging denials to facilitate coverage. Unlike pharmacists, physicians and office staff may have limited experience with this facet of the dispensing process, and may not have the software required for online adjudication. Physicians' office staff also may not be experienced in signing up for and accepting Medicare Part D insurance plans, particularly when dispensing medications like oral chemotherapy that are not covered under physician-administered IV medications.
- **Create Potential Conflict of Interest.** Physicians can potentially profit from medications they prescribe--despite the risk, ISMP believes the vast majority put the health and safety of their patients well above profit margins. The Utah bill specifically forbids oncologists from directly or indirectly marking up, charging a commission, or making a profit on the dispensed cancer drug. However, it does allow physicians to obtain payment for expenses and services related to providing the drug.

The US Office of the Inspector General of the Department of Health and Human Services and the National Association of Boards of Pharmacy emphasize the necessity of regulatory oversight and accountability in the drug distribution and dispensing process, in order to protect patient safety. Any state legislation that grants physicians dispensing privileges should be sure the requirements mimic existing language in the state's Pharmacy Practice Act. For an ISMP newsletter article with a more in-depth discussion of the bill, visit: www.ismp.org/Newsletters/acutecare/showarticle.asp?id=17.

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org