Testimony
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S.242 An act relating to prescription drugs dispensed by a health insurer designated pharmacy for administration to a patient in a health care setting

Good morning, my name is Wes McMillian and I'm the Director of Pharmacy at the UVM Medical Center and a member of the Board of Directors of the Vermont Society of Health-System Pharmacists. I am here today to offer support of S.242 because it will improve the safety, quality, timeliness, efficiency, and patient-centeredness of administration of medication infusions to Vermonters when they are clinically indicated.

In our current health care model, the provider makes a diagnosis and creates a medication treatment plan in a shared decision with the patient. The medication can then be ordered and administered in the hospital or provider clinic, or the payer may mandate a practice we refer to as "white bagging" or "brown bagging."

"Brown bagging" is defined as a medication that is either picked up by a patient from a payer-designated pharmacy or delivered to a patient's home directly from the payer-designated pharmacy, which then is transported by the patient to the hospital or provider clinic for compounding, if needed, and administration to the patient.

"White bagging" is defined as a medication that is delivered directly from the payer-designated pharmacy to a hospital or provider clinic for compounding, if needed, and administration to the patient.

Issues with white and brown bagging:

1. For infused medications, the provider will enter a treatment plan into the patients Electronic Health Record. This guides treatment over a period of time. With payer mandated white/brown bagging, the provider has to order the medication in a separate e-prescribing function. There is a potential for transcription errors when completing a separate prescription. As an example, the provider may enter a 500 mg dose every month in the treatment protocol, but accidentally order 400 mg in the e-prescription. If 400 mg is a normal dose, the payer-designated pharmacy will dispense only 400 mg and the full dose will not be available during the infusion visit.
2. The offsite specialty pharmacy dispensing pharmacist may not have all of the pertinent patient demographic and clinical data to make an informed decision, which could lead to a medication error.
3. There are inherent delays in medication delivery from specialty pharmacies, which may lead to delays in medication administration.

4. Further, delays in administration may cause disease flares that require acute care treatment – we have had patients within the Network require hospitalization or have their disease worsen as a result of a medication delay.
5. The pedigree of the medication is unknown since patient-specific medications are excluded from the federal Drug Supply Chain Security Act (DSCSA) regulation. The chain of custody of the medication cannot be assured.
6. Some providers will not purchase products from specific suppliers due to a history of FDA warning letters relating to poor quality. What is received from an outside pharmacy has to be used regardless of the supplier.
7. The medication could be delivered from the pharmacy to the provider office, hospital/clinic mailroom, or the hospital pharmacy (rare). As an example, I have personally received a non-descript manila envelope with patient specific medication in my office mailbox.
8. The storage and transport conditions of the medication are largely unknown since federal and state law do not require temperature-monitoring devices for medications once they leave the pharmacy. The liability falls onto the receiving provider. As a pharmacist, I have absolutely no idea if the medication delivered from an external pharmacy is not tainted and is safe to compound.
9. Multiple medication inventories need to be maintained by the provider. One inventory for medications prescribed and administered in-house, that is patient agnostic, and another to accommodate white bagging. It is not easy to discern who is receiving therapy from which inventory.
10. If the provider discontinues the medication regimen after the medication has been dispensed/delivered, the medication must be wasted. The medication cannot be redispensed or used to treat another patient. The patient and payer must pay for the medication in advance of the administration. The patient and payer will not recoup the expense. Many infusion drugs are thousands of dollars per dose. Infliximab, also known as Remicade, a commonly used drug for treatment of gastrointestinal and rheumatological diseases is $2,000-$4,000 per dose.
11. If, upon physical exam and clinical review, the provider needs to change a medication regimen, a new prescription will need to be sent to the pharmacy and the patient's therapy will be delayed. Same day treatment is virtually impossible.
12. Lastly, the receiving pharmacy or provider clinic will have to redispense an already dispensed medication if the medication requires compounding. Redispensing is not included in federal or state statute or guidance and is a regulatory gray zone for pharmacists and physicians.

S.242 will meet the needs of patients served in hospitals, infusion clinics, and rural provider offices and ensure safe, effective, and quality patient care.

1. This bill will not eliminate white or brown bagging. However, the medication supply chain integrity, chain of custody, pedigree and medication storage requirements (e.g. cold chain) will be ensured. Patient and medication safety will be ensured.
2. This bill will allow the Vermont Board of Pharmacy to create rules to govern the practice of white and brown bagging.
3. This bill will allow flexibility for rural providers and patients to choose what is best for them in a shared-decision regarding where their medication originates. The patient can decide whether they would like to use their prescription benefit and have the medication delivered to their

provider or use the provider's clinic supply. This bill also allows providers to leverage specialty pharmacies to access expensive medications that may be too expensive to procure themselves.

4. This bill will minimize therapy delays and improve patients' access to same day treatment.

I truly appreciate the Committee's time and the ability to provide testimony in support of S.242.