State of Vermont
Office of the Secretary of State

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S. Lauren Hibbert, Director

April 13, 2022

To: Senator Hardy, Vice Chair, Senate Committee on Health and Welfare
From: S. Lauren Hibbert, Director, Office of Professional Regulation

Re: H.353 and S.242

Dear Senator Hardy,

Thank you for reaching out to me with several questions related to H.353 and S.242. After our conversation, I talked with Carrie Phillips, the Executive Officer for the Board of Pharmacy. I asked her to provide me with a brief description of the Task Force's work. I have attached her summary to this memo. As I said on the phone, the goal of the task force is to provide VDH and the legislature with concrete recommendations for statutory changes for the next session.

She also provided me with an infographic on white bagging. It is also attached to this memo. It is created by ASHP which is an association of healthcare system pharmacists (hospital pharmacists) so it is an advocacy tool, but I think it is helpful to explain what white-bagging is.

I also clarified and confirmed with Carrie the information I gave you about "specialty" drugs and pharmacies.

- The term "specialty drug" does not refer to a *class* of drugs, nor does it have any official definition, meaning it is not defined by the FDA nor its official compendium, USP.

- Until 2017, the term was not defined in NABP's Model Act, which now defines the term as, "a drug used to treat a chronic or specific disease or condition that requires frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver." It is not defined in Vermont statutes or rules.

- Commonly called specialty drugs are typically (if not always) very expensive, frequently have specific storage and handling requirements, and often are injectable drugs, many of which require aseptic preparation for administration by sterile intravenous infusion.

- The term "specialty pharmacy" is also in NABP's Model Act includes the term, "specialty pharmacy practice." However, the definition of a specialty pharmacy practice is *not substantively* different from standard pharmacy practice: "Specialty Pharmacy Practice means the provision of pharmacist care services, which involves drugs used to treat chronic or specific diseases and conditions that require frequent communication with other health care providers,

extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver. Drugs Dispensed by a Specialty Pharmacy may also require instruction and training on complex administration processes and/or handling and storage considerations." This is not atypical work for a pharmacy.

- From a regulatory standpoint, there is no distinctly different nor concerning part of, nor act involved with, dispensing of so-called specialty drugs compared to dispensing any drug, which would preclude any pharmacy from doing so, nor require any unique requirements.

- Only 4 of 50 Pharmacy Boards have a separate license category for "specialty pharmacy" and none require accreditation for a "specialty pharmacy."

- A pharmacy benefits manager (PBM) may require their pharmacies to receive "specialty pharmacy" accreditation. However, requiring an insured patient, for whom a specialty drug has been prescribed, to use only pharmacies owned by the PBM itself, or those holding an accreditation not otherwise required by pharmacy regulations, may interfere with a patient's right to choose from where they receive pharmacy care. This is the problem H.353 is trying to fix. These issues are shown with intravenously infused specialty drugs, needing aseptic preparation. When these drugs are dispensed from a pharmacy that is not responsible for the preparation for administration to the patient (i.e., an institutional/hospital or home infusion pharmacy) it disrupts the essential and federally required verification process of supply chain pedigree, product legitimacy and adherence to necessary handling conditions. This introduces the possibility of risks to drug quality and patient safety (i.e. this is white bagging).

Our office supports the passage of S. 242. We do have recommended edits – primarily so that H.353 and S.242's language work well together. These edits are a bit complicated and if it looks like the committee is moving in that direction after today's hearing I will quickly submit written testimony tomorrow. We could also testify on these edits but I understand time is limited.

Carrie and I will both watch the Committee today and are available if you need further help or clarification.

Lauren

April 12, 2022

To: Lauren Hibbert
From: Carrie Phillips
Re: Interdisicplinary Pharmacy Task Force

Why the Task Force was formed?

- The Office of Professional Regulation (OPR) receives numerous and routine inquiries from a variety of reference points about non-pharmacy locations and professionals purchasing, storing, dispensing and compounding of medications
- Statutory and other regulatory guidance, outside of those for pharmacy practice, is incomplete and ambiguous
- Vermont Board of Pharmacy asked OPR to convene an interdisciplinary task force (TF) with membership from all relevant professions to work together to learn the scope of such activities and develop solutions for clarity

Process

- The TF met four times
    - October 22, 2019 – introduction and discussion of dispensing
    - January 22, 2020 – discussion of compounding
    - March 24, 2021 – recap of dispensing and compounding discussions and review of pertinent information from Vermont and Federal laws as well as relevant organizations; discussion of next steps
        - Preparation of a survey to garner information on non-pharmacy dispensing and compounding to send to all relevant professionals
        - Discuss "white bagging"
    - December 15, 2021 -
        - White Bagging
            - A pharmacy-benefits management (PBM) practice that results drugs for infusion being prepared in clinics and offices.
                - In addition to risks related to quality of such compounded sterile products, numerous administrative issues arise for institutional pharmacies (hospital pharmacies)
            - This practice has been discussed at several Board of Pharmacy (BOP) meetings and ultimately needs be resolved via PBM regulations, alongside PBM payment issues
                - PBMs are regulated by the Department of Financial Regulation
        - Survey was prepared as a group to be sent out to licensees by OPR in late April 2022, a report of results and possible recommendations will be present to the Board of Pharmacy (likely at its May meeting) and TF members will be informed of the meeting's date

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WHITE BAGGING
Jeopardizes Patient Care

White bagging occurs when payers require a narrow network of plan-selected pharmacies to dispense clinician-administered drugs and bill a patient's prescription medication plan. White bagging is a risk prone process that should only be considered when determined by the provider to be necessary and appropriate to support patient care.

How Does White Bagging Work?

Provider makes diagnosis, develops medication treatment plan

PAYER-MANDATED WHITE BAGGING MODEL

Diagnosis and medication treatment plan entered into electronic health record (EHR)

Payer mandates provider must use an external specialty pharmacy

Provider must write an additional prescription order and send to the **payer-mandated pharmacy**

Bypasses EHR comprehensive safety checks

Health-system pharmacy has to coordinate medication delivery

Payer-mandated pharmacy receives prescription, dispenses drug and bills to patient, mails drug to health system

***POTENTIAL ISSUES:** misdirected mail, drug integrity, treatment plan changes, delayed delivery, patient scheduling*

Health-system pharmacy prepares **white-bagged** medication. Considers changes in patient's clinical status that may require updates to treatment plan

Treatment plan updated

Issues result in delayed treatment

No changes

HOSPITAL AND HEALTH-SYSTEM MODEL

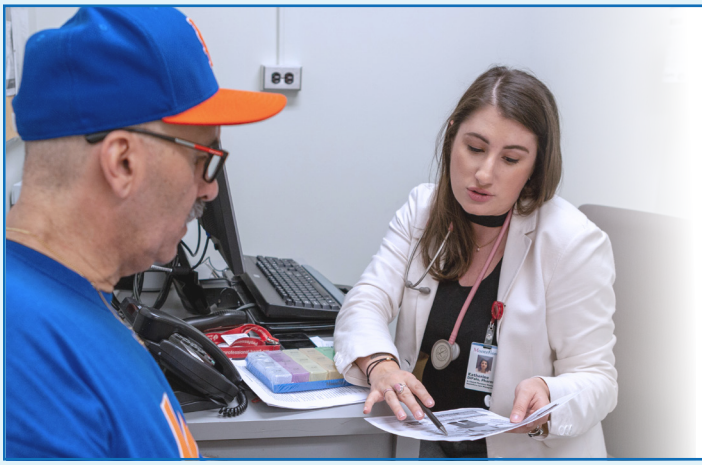
Diagnosis and medication treatment plan entered into EHR. **EHR provides comprehensive medication safety checks and information**

Health-system pharmacy receives medication order

Health-system pharmacy prepares medication the **day of clinic infusion** from its inventory. Considers changes in patient's clinical status that may require updates to treatment plan

Patient receives medication infusion after interprofessional consultation

What are the Consequences?



FOR PATIENTS

- Delayed care for urgent treatment changes
- Delayed treatments due to payer benefit requirements
- Difficulty in care coordination
- May be charged co-pays for drugs not received due to shipping errors, treatment changes, etc.
- Anxiety when payer unnecessarily requires use of an additional unfamiliar pharmacy provider

FOR THE HOSPITAL

- Negative impact on overall medication-use system
- Introduces multiple risk points
- Fragments established healthcare record for prescriptions
- Undermines EHR integrity

How to Protect Patients

White bagging threatens practices that healthcare organizations have established to keep patients safe and hinders the ability of pharmacists to ensure medication and supply chain integrity.

ASHP IS WORKING TO:

Advocate that the Food and Drug Administration enforce safety requirements in the **Drug Supply Chain Security Act** undermined by white bagging

Encourage state policymakers to **prohibit insurers and pharmacy benefit managers from mandating white bagging** or from steering patients away from health systems that refuse to accept potentially dangerous white-bagged drugs

For more information and resources, visit
ashp.org/whitebagging

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