

# Keck Medicine of USC

Keck Medicine of USC  
Department of Pharmacy  
1500 San Pablo Street  
Los Angeles, CA 90033

December 15, 2020

California Board of Pharmacy  
Attention: Complaint Unit  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833

Dear Mr. Gregory Lippe, President of the Board, and Ms. Anne Sodergren, Executive Director of the Board:

It is with a sense of urgency and concern for patient safety that I am submitting this complaint letter on behalf of the pharmacy department at Keck Medicine of USC to the California Board of Pharmacy. The recent actions and policies of several health plans in California, including Anthem Blue Cross and Cigna, preclude the pharmacy from complying with state laws and regulations and endanger Californians served by the department of pharmacy at Keck Medicine of USC (refer to Appendix I for a listing of our hospital pharmacy licenses).

In the past several months health plans including Anthem Blue Cross and Cigna began restricting pharmacies from procuring certain injectable and infusion specialty medications administered in an outpatient hospital facility setting directly from wholesalers or manufacturers. Instead, these health plans are requiring the medication to be ordered from and dispensed by their designated specialty pharmacy that is external to our organization and often located outside of the state, where the medication is shipped directly to the providers' office.

In accordance with state and federal laws and best practices, the hospital pharmacy is responsible for procuring, storing, compounding and dispensing medications to be administered to hospital patients. In accordance with Section 4059.5 of the Business and Professions Code of the California Code of Regulations, drugs may only be ordered by an entity licensed by the Board of Pharmacy, or by licensed healthcare providers acting within their professional scope. According to federal regulations that set out the Conditions of Participation as a hospital enrolled in the Medicare program, a hospital's pharmaceutical service functions to procure, store, compound and dispense all medications, biologicals and devices within the hospital – including its outpatient locations (i.e., 42 CFR §482.25 and related Interpretive Guidelines from the Centers for Medicare and Medicaid Services). Accrediting agencies, such as The Joint Commission, and many professional associations expect the hospital pharmacy to control the process for procuring, storing and dispensing medications as a recognized medication safety measure (for example, Joint Commission Standards MM.02.01.01 (selection and procurement of

# Keck Medicine of USC

medications), MM.03.01.01 (safe storage of medications and MM.05.01.07 (safe preparation of medications)). Moreover, pharmacies are required to maintain drug supply chain security in compliance with the federal Drug Supply Chain Security Act (Title II of Pub. L. 113-54). When medications are not procured by the pharmacy department, the provenance (pedigree, storage and handling) of these products cannot be determined, creating a compliance risk for the hospital pharmacy and – even more importantly – a risk for patients receiving medications that are not safe nor effective for use.

Forcing providers to order medications from an external pharmacy carries many additional patient safety risks. For hospitals in particular, such processes have been associated with an increased risk of avoidable errors such as delivery delays, lost shipments, and dosage errors. A higher incidence of errors may arise where more complicated distribution schemes send medications to individual provider offices, rather than a centralized hospital pharmacy. In contrast to internally procured medications, there is no assurance that a needed drug will be available to the patient at the time of the patient's visit in a timely manner if the provider and patient are reliant on the health plan-mandated outside distribution channel. Such delays in care can interrupt or postpone life-saving therapies received by patients, and impact the risk of morbidity and mortality. In addition, forced use of external pharmacies hinders the ability of the hospital pharmacy to provide proper oversight and stewardship of medications, including the ability to respond to drug recalls in a timely manner. Because the medications were not procured by the pharmacy, the ability to rapidly identify and quarantine recalled products will be impaired, increasing safety concerns for patients. Waste of medications will also increase, because when the shipped medication cannot be used by the intended recipient, for any reason, the provider is prohibited from using the medicine for another patient.

Additionally, external pharmacies do not provide the same level of pharmaceutical surveillance and safeguards as the hospital pharmacy. Many of the impacted medications are specialty drugs that require close evaluation and monitoring immediately prior to and after the administration of the medication. Unlike the external pharmacies, the hospital pharmacy has the expertise and up-to-date patient records available (e.g. laboratory results, medications lists) to perform activities such as drug interaction checks, screen for contraindications, and medication reconciliation to prevent inadvertent or improper ordering or administration of a medication. Certain of the specialty medications are high-risk chemotherapy agents, errors with which may be detrimental to patients' health and could result in harm or death.

The impacted medications may be shipped by the external pharmacy in a ready-to-administer form (e.g. pre-filled syringes, vials) or in a form requiring further compounding by the hospital pharmacy. Although either option is fraught with safety risk and regulatory compliance issues, the latter has more damaging downstream effects. When compounding a medication shipped by an external pharmacy, the hospital pharmacy forced to use a medication with suspect provenance, putting itself at an increased risk of liability if there are issues with the medication that are out of its control. While there is also a financial burden to the hospital when placed in this position, as health plans do not reimburse the hospital's costs for the compounding process, it is the increased risk to the patient and the increased risk to the hospital pharmacy that are of greater concern to us. Hospitals need to manage these risks, and if in so doing restrict the use of specialty medications from outside sources, could curtail Californians' ability to access needed care. Accordingly, we view these policies as both unreasonable and unethical.

The hospital pharmacies at Keck Medicine of USC strive for excellence in patient care and patient safety is our top concern. The recent trends by health plans to redirect procurement of injectable and infused

# Keck Medicine of USC

specialty medications to external channels pose significant risk to patient safety and hinders access to care. We find the current situation highly worrisome. I am writing this letter on behalf of our organization to escalate this matter to the attention of the California Board of Pharmacy for evaluation of the public safety risk and swift action. I am available for any questions or inquiries you may have. Thank you for your attention to this serious matter.

Sincerely,

A handwritten signature in black ink, appearing to be 'KA', with a long horizontal flourish extending to the right.

Krist Azizian, PharmD, MHA  
Chief Pharmacy Officer  
Keck Medicine of USC



## Attachment A

Hospital Pharmacy License number(s):

- 1.) HSP 49863 - Keck Hospital Inpatient Pharmacy
  - a. Related LSCs: 100235, 100236, 100238, 100242
- 2.) HSP 49864 – USC Kenneth Norris Jr Cancer Hospital Inpatient Pharmacy
  - a. Related LSCs: 100190
- 3.) HSP 49862 – USC Kenneth Norris Jr Cancer Hospital Ambulatory Pharmacy
  - a. Related LSCs: 100198
- 4.) HSP 56018 – Keck Hospital of USC – Norris Healthcare Center Hospital Pharmacy
  - a. Related LSCs: n/a
- 5.) HSP 53556 - USC Verdugo Hills Hospital Inpatient Pharmacy
  - a. Related LSCs: 101410, 100847
- 6.) PHY 52515 – Keck Hospital of USC Orange County Pharmacy
  - a. Related LSCs: 100681
- 7.) PHY 56776 – Keck Hospital of USC – Huntington Beach Treatment Center
  - a. Related LSCs: 101168
- 8.) Keck Hospital of USC – Arcadia Treatment Center
  - a. Related LSCs: 101273

**From:** [Dewana Leishman](#)  
**To:** [Sodergren, Anne@DCA](#); [Damoth, Debbie@DCA](#)  
**Subject:** Comments for Enforcement and Compounding Committee Meeting of White Bagging  
**Date:** Wednesday, February 17, 2021 9:49:52 AM

---

[EXTERNAL]: [dewana.leishman@gmail.com](mailto:dewana.leishman@gmail.com)

**CAUTION:** THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!

**DO NOT:** click links or open attachments unless you know the content is safe.

**NEVER:** provide credentials on websites via a clicked link in an Email.

---

If Outpatient Infusion Center pharmacies that have a compounding license are forced to accept drugs from Specialty Pharmacies for compounding and infusing to their patients, this violates the Drug Supply Chain Security Act (DSCA) we are held to. Pharmacists cannot ensure proper storage conditions were met by the pharmacy drug is coming from.

Also, there is the question of legality for a licensed sterile compounding pharmacy to receive patient specific medications dispensed by another pharmacy to compound and administer.

Thank you,

Dr. Dewana Leishman, Pharm.D.  
Dominican Hospital Infusion Center  
Santa Cruz, CA

**From:** [Amir Khoyi](#)  
**To:** [Sodergren, Anne@DCA](#); [Damoth, Debbie@DCA](#)  
**Subject:** Legality of Brown/White-Bagging  
**Date:** Sunday, February 14, 2021 10:01:00 AM

---

[EXTERNAL]: [amirkhoyi@comcast.net](mailto:amirkhoyi@comcast.net)

**CAUTION:** THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!

**DO NOT:** click links or open attachments unless you know the content is safe.

**NEVER:** provide credentials on websites via a clicked link in an Email.

---

Hello,

I do have a comment regarding both Brown Bagging as well as White Bagging that does seem to go unchecked by the Board of Pharmacy inspectors. A good example for Brown Bagging is how patients take their injectable Testosterone (C-II) vials to medical offices which are then stored there for ongoing administrations. Such clinics retain no logs demonstrating any kind of inventory control for those controlled drugs demonstrating no accountability for their proper disposition in the event patients change physicians, pass away, etc.

As for White Bagging, the practice is not treated the same way by the BOP when comparing this method of drug distribution by specialty pharmacies versus regular retail pharmacies. By law when a local retail pharmacy delivers a medication (that has been dispensed to a specific patient) to a clinic, that clinic must obtain a Clinic Permit and ask for a BOP exemption in order to avoid what's called "Drug Depoting". However, when the same is performed by a specialty pharmacy no such rules ever get enforced.

This may be a good opportunity for the Board of Pharmacy to standardize the requirements and train its inspectors to apply them consistently during their inspections.

Warmest regards,  
Amir

**Dr. Amir Khoyi, Pharm.D.**  
El Dorado Hills, CA 95762

*Confidentially Notice: This email and its attachments may contain privileged and confidential information and/or protected health information intended solely for the recipient(s) named above. If you are not the recipient, or the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any review, dissemination, distribution, printing or copying of this email message and/or any attachments is strictly prohibited. If you have received this transmission in error, please notify the sender immediately and permanently delete this email and any attachments.*

### **Reference**

[https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018\\_Final-1.pdf](https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf)

---



Virus-free. [www.avast.com](http://www.avast.com)

## Statement on the Practice of White-bagging

Hilary S. Ward, Pharm.D., BCOP

February 10, 2021

I am a pharmacist at a critical access hospital in the Sierra Nevada mountains. Our hospital-based pharmacy has been serving our small infusion room since 2008. I oversee much of the compounding that occurs for the patients we serve in the infusion room. We were recently notified by a large, California-based insurance company that we would be required to begin white-bagging a list of 106 medications, many of which are infusional oncolytics or drugs for other chronic diseases that we routinely give. I am opposed to allowing white-bagging or allowing insurance companies to require us to white-bag in this practice setting for several reasons.

Primarily, we see a white-bagging process for an infusion room like ours as a risk to patient safety. The inherent process of white-bagging means that we will receive medications, potentially highly toxic chemotherapy medications, labeled with a dose the patient has received in the past or calculated based on biometric parameters that are not current, and not in a ready to use format. When the patient presents for treatment, the dose of the medication may change due to toxicity assessment or lab values that result that day. We will now have facility orders and labels that are in conflict with the dose dispensed by the Specialty Pharmacy (SP). Having two labels for the same patient with different doses represents a significant risk for a dosing error during the pharmacy compounding process. Additionally, the SP's claim that their pharmacists will be counseling patients on their medication and monitoring for toxicity. However, they do not have access to the patient's clinical information in our EHR, nor are they present on the day of treatment to answer patient questions or participate in toxicity assessments and dose modification decisions. This is problematic in two ways: 1. The white-bagged medication may be a component of a multi-drug regimen and the SP pharmacists will not be equipped to counsel the patient appropriately on the entirety of the plan or may potentially provide incorrect information, 2. This creates a complex process whereby a subset of patients are being treated differently than other patients which increases risk for error and inequity. Critically, the SP pharmacists are not at bedside managing infusion reactions and anaphylaxis events when they occur.

Secondarily, I do not believe the white-bagging process supports my responsibilities as the pharmacist overseeing compounding at a facility licensed by the California Board of Pharmacy (CA BOP) for Sterile Compounding. As soon as the SP dispenses a concentrated, bulk medication to us, this medication has left their "closed-system" of quality assurance and all the associated storage controls, compliance with recalls, and supply chain tracking that ensures the medications are not counterfeit. I am now expected to take this medication that I cannot verify and compound it for administration to the patient. CA BOP regulations 1735.2 specify that the pharmacist overseeing compounding of any item must be able to ensure that the components used in the compounded item have not been compromised in any way. I don't believe I can maintain compliance with California sterile compounding regulations in the context of a white-bagging process.

Lastly, a white-bagging process also represents a financial threat to facilities like the one I work at. The markup we add to these types of medications is meant to offset the extensive clinical pharmacy

services, compounding efforts put forth by myself and other pharmacy staff in caring for our patients, and the cost of building and maintaining a sterile compounding facility that the CA BOP will license and certify. When the SP receives the revenue for their minimal pharmacy input, our local, high quality pharmacy services are not sustainable in the long term. Our rural health system provides oncology care for a population that spans a large geographic area, with the nearest California-based oncology program over 60 miles distant. The potential loss of this program and service constitutes the most significant patient safety issue of all and will be a significant loss to the community as a whole.

The insurance companies have taken a process that was meant to improve patient access to certain medications that were typically available through SP only and have turned it into a tactic to take revenue away from the pharmacies providing the services to the patient. We have very few supply issues on medications through our normal wholesale distribution process which is a process we can rely upon for ensuring that we receive and compound only quality, in date, properly stored, legally obtained medications for our patients. There is no validity to the argument that white-bagging somehow prevents providers from choosing a more expensive treatment option without justification. In oncology, treatment options are set by national guidelines and insurance companies do a sufficient job of ensuring that they are followed, regardless of the cost of a medication, through their normal authorization process.

I do understand that white-bagging has benefits for certain practice types like physician-run clinics who also administer infusions; however, I recommend that the Board prohibit the practice of white-bagging for pharmacies that hold a Sterile Compounding License in the State of California for all the reasons I've discussed. White-bagging in this practice setting conveys far more risk than benefit to our type of facility and we should not be required by insurance companies to engage in this risk.

Thank you to the Board of Pharmacy for this opportunity to share my thoughts and opinions on this topic. Please feel free to reach out to me for further discussion as you work through this issue.





February 16, 2021

University of California Health supports restrictions to the use of “White Bagging” in health system patients. White bagging bypasses the safeguards designed into medication systems. It limits the ability of nurses, physicians, and pharmacists to assure the safe acquisition and administration of medications for which they are legally responsible. The receipt, storage, and use of externally supplied prescriptions, creates confusion and increases risk of medication errors with multiple drugs for multiple patients from multiple pharmacies, in the same clinic or infusion center.

Effective with the UC Health Interim Policy dated November 30, 2020, it is the policy of the University of California that the responsibility and accountability for purchasing, mixing, and administering injectable medications to patients who receive care at University of California hospital outpatient clinics, ambulatory clinics, and student health centers, resides solely with UC Health pharmacists, and the physicians, nurses, and physician assistants who administer the drugs. In order to be able to assure the legitimacy of the original drug source and the appropriateness of subsequent storage and handling of any drug to be administered to a patient, UC Health will not administer any drug to a patient that UC Health does not purchase directly from either the manufacturer or an accredited wholesaler.

That interim policy is intended to mitigate against the potential risks to patient safety, and the associated product liability risk to the University, associated with commercial health plan practices that attempt to require health care providers to accept medications procured from an external pharmacy, which bypasses the UC Health pharmacy and the checks and balances that exist to ensure that each UC Health patient receives the correct medication, that the drug has been stored appropriately, and that the medication is available to be administered to the patient at the time of the patient’s appointment.

Actions by the Board of Pharmacy to further regulate use of White Bagging in health systems, is supported by UC Health Pharmacy.

Submitted by Pharmacy Leadership at the following UC Health Facilities:

Chad Hatfield. Chief Pharmacy Officer, University of California Davis

Melanie Joe. Chief Pharmacy Officer, University of California Irvine

Jess de Jesus, Chief Pharmacy Officer, University of California Los Angeles

Charles Daniels, Chief Pharmacy Officer, University of California San Diego

Desi Kotis, Chief Pharmacy Executive, University of California San Francisco

John Grubbs, Chief Pharmacy Officer, UC Health



# Impact of “White Bagging” on Patient Care and the Medication Use System: A Children’s Hospital Perspective

Melissa Chase, PharmD, BCSCP  
Directory of Pharmacy

Drew Dieckmann, Pharm.D.  
PGY-1 Pharmacy Resident



# Valley Children's Healthcare impact statement to the CA Board of Pharmacy on White Bagging

White bagging creates added risks and negative outcomes for children through the disruptions forced on the medication use system in hospitals and healthcare systems that circumvent the best practices designed to optimize patient safety and timely care.



# Impact on Hospitals & Providers

- High Potential for Waste

- “Patient-specific” medications – *cannot use for any other patient*
- Inability to change dose in a timely manner → **wasted, unused medication**
  - Doses may change for a variety of reasons, especially in pediatrics (changes in weight)
  - What if an error occurs during compounding or administration? Will specialty pharmacy send a replacement dose? If yes when will it arrive? Who pays for the replacement? Delays in care for the patient vs. hospital pharmacy immediately replacing with their own supply of drug.

- Patient Safety Concerns

- Delays in critical therapy. Can lead to extended hospital stay or readmission due to delays in approvals, or shipping delays.
- Multiple entities involved in chain of custody (cannot guarantee storage conditions)
- Increased risk of medication errors and serious harm when not compounded appropriately
  - New England Compounding Center – October 2012
  - Fungal contaminated steroid injections resulted in over 700 infections and **64 deaths**

# Impact on Hospitals & Providers

- Liability and Regulatory Concerns

- Ordering provider legally responsible for any drug injected/infused into the patient
  - Several law suits stemming from NECC steroids included **physicians and the clinics**
- Inability to ensure appropriate monitoring of FDA-mandated REMS programs
- Track and Trace Requirements DSCSA is bypassed by specialty pharmacy delivering vs. wholesaler delivering to Hospital Pharmacy.
- Joint Commission Medication Management Standards require all drugs to be managed by Pharmacy.

- Lack of reimbursement

- Administering/Infusion clinic is not reimbursed
  - No reimbursement for the supportive services to coordinate approval and delivery of the medication
  - Valley Children's is often responsible for the preparation of complex and **hazardous** specialty medications with no reimbursement for these Pharmacy Services.





## Impact on Patients

Miscommunication, Delays, Hidden Costs, Lack of Alternatives

# Impact on Patients

- More people and processes involved in a single patient's care → opportunities for **miscommunication**
  - Coordinating care between patient, caregiver/family, primary care provider/medical specialist(s), clinic staff, insurance (medical benefits vs. pharmacy benefits), specialty pharmacy, receiving/preparing pharmacy, infusion clinic.
- Potential for **delays in therapy**
  - **PATIENT** is responsible for making sure medications are ordered in time from the specialty pharmacy.
  - Subject to delays due to failed/late delivery (shipping), dose changes, out of stock medications, issues with prior authorization status, inability to pay co-pay up front, etc.

# Impact on Patient

- Hidden costs for the patient
  - Multiple trips due to rescheduled appointments (often > 1 hr drive for Valley Children's patients)
  - More time off work/school, added daycare needs, many can't afford any added costs.
- Lack of alternatives
  - "Brown Bagging"
    - High potential risk for error – added liability on hospital (was med stored correctly, etc.)
  - Patient sent to another clinic that accepts "white bag" patients
    - May not have nurses trained in pediatrics to administer medications
    - Adds to the stress of the patient/caregiver
    - More people → more risk for miscommunication → **negative patient outcomes**
- **KIDS DON'T BELONG IN ADULT INFUSION CENTERS!**



# Meet Our Patient

# Meet Our Patient

“June” is a wonderful 18 y.o. who was diagnosed with Chron’s Disease with abscess.

This means she will require intermittent infusions in an outpatient clinic every 8 weeks





# Meet Our Patient – “June”

## 6 weeks after discharge

Disease worsens despite treatment, plan to start **Remicade**

## 9 weeks after discharge

Remicade approved for 1 month (2 doses)

## 12 weeks after discharge

Receives 2<sup>nd</sup> infusion

## 7 weeks after discharge

Presents to clinic for 1<sup>st</sup> infusion; denied by insurance → **reschedule**

## 10 weeks after discharge

Patient receives 1<sup>st</sup> infusion (21 days after initial appt)

## 22 weeks after discharge

PA approved by insurance but not specialty pharmacy → confusion over who will supply medication

## 14 weeks after discharge

2<sup>nd</sup> authorization sent to insurance for continuation of Remicade as “white bag” **per insurance mandate**

## 24 weeks after discharge

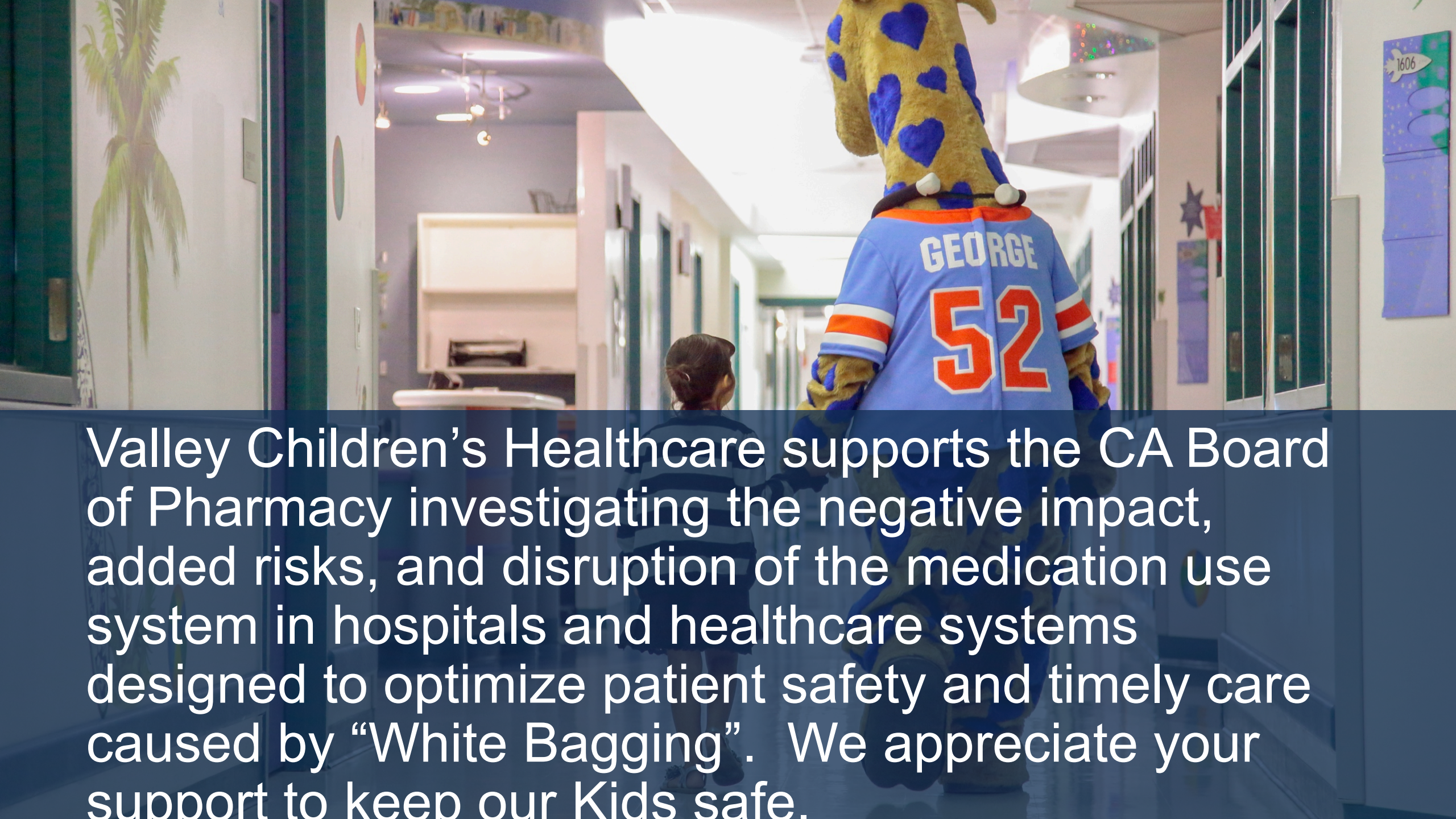
Scheduled for 4<sup>th</sup> infusion **(8 weeks late)**

## 23 weeks after discharge

Approval from insurance and specialty pharmacy, but **still must reschedule** to allow for medication to be delivered

## 16 weeks after discharge

Presents for 3<sup>rd</sup> infusion but medication not delivered → **reschedule 10 days later**



Valley Children's Healthcare supports the CA Board of Pharmacy investigating the negative impact, added risks, and disruption of the medication use system in hospitals and healthcare systems designed to optimize patient safety and timely care caused by "White Bagging". We appreciate your support to keep our Kids safe.



**From:** [John P Teague](#)  
**To:** [Sodergren, Anne@DCA](#)  
**Cc:** [John P Teague](#)  
**Subject:** White & Brown Bagging Clinical Experiences from the Front Lines  
**Date:** Tuesday, February 16, 2021 10:52:46 AM

---

[EXTERNAL]: [JTeague@pmhd.org](mailto:JTeague@pmhd.org)

**CAUTION:** THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!

**DO NOT:** click links or open attachments unless you know the content is safe.

**NEVER:** provide credentials on websites via a clicked link in an Email.

---

The definition of “white bagging and brown bagging”, cannot be found in our California Board of Pharmacy lawbook, nor are the terms common language in many pharmacists day-to-day operations. As pharmacists licensed by the California Board of Pharmacy, we are well versed in one hard pushed term “acquisition and disposition”. The number of times I’ve had senior pharmacists, and even board inspectors make a circle with there hand while citing the words “acquisition and disposition”, is just more than I can count. With acquisition and disposition it is very clear, we are accountable for ensuring medications are received from an appropriate source, that these medications are received intact and maintained to ensure stability and potency, further for dispositions that we ensure they are provided pursuant to appropriate orders etc. Acquisition and Disposition is our oversight and control, it’s where we ensure the medication controls are appropriately provided and care is resulted appropriately to our patients, it is our circle of life per se, and it also somewhat brings to mind the Federal laws overseeing Drug Supply Chain Security Act aka DSCSA and the various requirements that were kicked off in 2013 with a 10-year plan for implementation. With both “Acquisition and Disposition” and the Federal DSCSA they have some common ground and that is ensuring the medications provided to Californians and the American people are unadulterated, that they are legitimate medications which a pharmacist has overseen to ensure they are within manufactured stability and potency. As a licensed California Pharmacist overseeing the operations of a healthcare district that encompasses many offsite outpatient departments, including several infusion centers and specialty practice areas I have found the practice of “white and brown bagging” to go against not only our policies, procedures, and the direction that I’ve provided my staff over the years, but they also break the chain of “acquisition and disposition” as well as DSCSA. The pharmacist ability to control acquisition and disposition is removed from their practice, the medications maybe shipped to the patient, the physician office, or some other location where receipt is not by the pharmacist who is in charge of the preparation and disposition of the medication. Over the years, we have not allowed administration of patient own medications, unless there was a specific need and under which we had certain circumstances which were clearly defined, and strictly controlled by the department of pharmacy. We have never allowed a patient to use their own medication if it was part of our formulary as the liability is limitless when we treat patients with medications that could be potentially adulterated leading to harm to the patient, or the lack of stability and potency that may lead to lack of desired treatment and further progression of disease and confusion in clinical staff treating patients. There are also additional concerns including education on proper storage and

handling, is the medication a REMS drug, is it Hazardous, does it require compounding, the list could go on but I think it is clear to note that these processes are handled by an institution guided by formulary and pharmacy and therapeutics committee reviews that lead to education of staff; these normal processes are circumvented when the institutions department of pharmacy is circumvented.

With the growing involvement of Pharmaceutical Benefits Managers (PBM) into the practice of pharmacy we have continued to see this practice grow. A term was eventually coined "White/Brown Bagging", and articles were written and published within our journals, and we were forced to make a decision in how to care for patients that had no other option for care in our rural and remote area. Despite having the same medications on our shelves, or on our formulary and available to order, we've been forced to wait for these medications to come through the mail to either the patients home, the physicians office, or at times direct to our pharmacy, or even our hospitals mail room. We've begun to treat these medications as "Patient Own Medications", and it has created additional work not only for our staff but for those of the physician offices whom at times must ensure the security of these medications. I have had patients that have had delays in care due to treatment interruptions from these practices, others have experienced medication errors and other undue harm. I will list below some specific examples of just a few issues we have encountered.

One of our patients was previously being treated by our facility, had a delay in care and their regular treatment when the PBM refused to allow our pharmacy to continue to order the medication for their patient and the PBM required the medication to be shipped via "white or brown bag". The care of the patient was further delayed, as the PBM later notified patient of a high copay that the patient could not meet. The patient contacted our facility and the nurse and pharmacist coordinated and arranged for [REDACTED] to provide the medication for free due to patient need, but ultimately the patients treatment was delayed and would have further been delayed had the patient not proactively contacted our facility for assistance, and without our intervention in contacting the drug manufacturer for assistance.

Another elderly patient received a medication from our facility, she would regularly receive her injections from our treatment facility. Suddenly, her PBM required she administer this medication on her own and receive it only from their pharmacy through the mail. Due to her age and other factors she was unable to self-administer this medication and stopped her treatment due to her inability. The patient later contacted us to see if we could help and assist her in administering her medication.

Medication Error from [REDACTED] who utilized their pharmacy "[REDACTED] Pharmacy" to ship a medication to our Healthcare district, the medication ended up in the mail room or materials management department it was later delivered to the pharmacy. Upon receiving and opening the container, pharmacy staff found 3 vials of medication that were supposed to be stored under refrigeration but had been delivered to an unlicensed area and not received by a pharmacist. The vials totaled close to \$10,000 worth of medication and the temperature was out of range. The pharmacist received the package at our hospital pharmacy on 07/02/2020 and could not determine how long the package was left unattended, the packages had 3 dates written on 3 large boxes. It was noted upon being delivered to the pharmacy that the package was too large to fit in the refrigerator. The dates listed on the boxes were 05/05/2020,

06/03/2020, and 06/30/2020. There was a name on the packages that nobody recognized within the pharmacy or mail room, and there was no coordination with the pharmacy department that would have led us to be aware of a pending medication shipment. Our pharmacist called the pharmacy that had shipped the medication, and the pharmacist refused to assist our pharmacy department despite my pharmacist noting that this package was delivered without prior notice and without labeling identifying an appropriate address to “pharmacy” or “pharmacy department”, our pharmacist further explained to the shipping pharmacy that the name on the package was not an employee of the pharmacy or healthcare district; we later discovered the name on the package was that of the patient. Our pharmacist continued to pursue a resolution and contacted [REDACTED] who manufactured the medication, directly learning that the product had a 14-day unrefrigerated limit, but since we were unaware of when the cold temperature storage went out of range we were unable to use the medication for the patient, but luckily the [REDACTED] representative was able to assist us this time in replacing the medication and the pharmacist requested labeling shipment “Deliver to Pharmacy”. This Medication Error took much pharmacy involvement to resolve and was very troubling. There was a delay in patient care, a potential violation in HIPAA with the patient’s name on a box being shipped to an unauthorized location, and an obvious number of hurdles that most patients would be unable to navigate in order to find a resolution.

Lastly, I’ve personally experienced the trouble patients go through with “White/Brown bagging” where a medication error was caught. We had another patient that had been required to use a specific pharmacy who owns a specific PBM, the medication order was sent to that large retailer’s specialty pharmacy located in another county of our state. The medication was shipped to our physician’s office, luckily the physician office immediately brought the package to pharmacy as we had encountered “white/brown bagging” several times by this point and both departments were well versed in the handling process. Pharmacist found on inspection of the package, that 1 out of 3 vials of a \$7,000 per vial medication was expired. The physician office and pharmacy had difficulty contacting the pharmacy for resolution, and patient was unable to assist in the resolution but had already paid for this medication out of pocket and was upset. In order to assist I went to our pharmacy and reviewed the medication for any information to assist, finding little to no information on the package I used the medication label and searched for the pharmacy license on the board of pharmacy website. After discovering the address on the board of pharmacy website, I then had to google search online for the pharmacy’s contact information. After all this work I called the pharmacy which was a Specialty Pharmacy located in [REDACTED] It took me awhile to get through the phone systems IVR as these pharmacies are not well equipped to handle direct calls, I was then put on hold several times and eventually I was hung up on at least once. I called back and explained the situation of the Medication Error and emphasized that I needed to speak to a pharmacist, as by this point I was quite flustered by the effort I was needing to put forth to resolve this medication error I felt I needed the pharmacist and supervising pharmacist, and even noted my position as Director of Pharmacy. I explained to the pharmacy technician, that this medication was very important in the treatment of our patient. I never reached a pharmacist on my phone call, but rather was put on hold several times and transferred over the phone to another pharmacy located in the state of Florida, so now I’m speaking with a non-pharmacist owned by the same retail pharmacy in the state of Florida, how my call was transferred to Florida is really mind boggling. I expressed my issue and concern with the pharmacy technician and the need to speak



to a pharmacist, the technician told me “we are too busy” and “we are short staffed”. I was mortified by this response, as this was shortly following the New York Times article regarding Medication Errors, in which the article noted issues with this same pharmacy, especially that I being a pharmacist with years of experience whom was experiencing the same issues and having such extreme difficulty in helping my patient. I never received a call from a single pharmacist, I was further told that the medication was “not expired”, after being sent back over the phone to the [REDACTED] Pharmacy, and was forced to plead my case for my patient, with the pharmacy technician who should have been helping our mutual patient, but it sure seemed like only one of us had the patients best interest and care in mind. I spent close to 3-hours on the phone sent several emails including pictures to prove that the medication was expired. Eventually we were able to obtain the medication as a replacement from the specialty pharmacy, but the time and effort taken, and lack of pharmacist oversight was appalling.

I lastly, wanted to include a response from a nurse’s perspective. This response was given to me after I reached out to staff members for any particular insight they might have from the frontlines of specialty infusion and specialty pharmacy as they work in areas where they experience “white/brown bagging on a daily basis. “This process causes delay in treatment as well as many added man hours to the process. Most staff at these pharmacies are not properly trained and their management of authorizations has delayed treatment weeks and even months in many of our patients. This adds stress and anxiety to our already fragile demographics who are dealing with severe health concerns. Having to deal with multiple pharmacies depending on the patient’s plan is also an added challenge. We have also seen medication wasted as these pharmacies will auto refill the medication several weeks in advance leaving the patients with thousands of dollars in medications if the physician decides to stop the treatment. We see this typically with oral medications and have seen patients waste over \$10,000 dollars in a months’ worth of xtandi or sprycel.”

John P. Teague, Pharm.D., APh  
Director of Pharmacy  
Pioneers Memorial Healthcare District  
207 West Legion Rd.  
Brawley, CA 92227  
760-351-3367  
[jteague@pmhd.org](mailto:jteague@pmhd.org)



This message contains information that may be privileged or confidential and is the property of Pioneers Memorial Healthcare District. It is intended only for the person(s) to whom it is addressed. If you are not the intended recipient, you are not authorized to read, print, retain, copy, disseminate, distribute, or use this message or any part thereof. If you received this message in error, please notify the sender immediately

and delete all copies of this message.

“This message contains information that may be privileged or confidential and may contain confidential health information. This email is the property of Pioneers Memorial Healthcare District (PMHD). This email is intended to be reviewed only by the individual(s) or organization(s) named as addressee. If you have received this email in error please notify PMHD immediately - by return message to the sender - and destroy all copies of this message and any attachments. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of PMHD. Confidential health information is protected by state and federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 and related regulations.”



February 12, 2021

Attention: California State Board of Pharmacy  
Re: Hospital wide concern with "White Bagging" process

To whom it may concern:

I am writing on behalf of Lucile Packard Children's Hospital Stanford (LPCHS) regarding a potential change by multiple insurance companies with their infusion policies. These changes will no longer allow hospital-based infusion centers to provide and bill for their own medication infusions. These changes would allow an outside Specialty Pharmacy to send medications to Stanford for our patients, introducing multiple levels of patient risk in a process known as "White Bagging".

LPCHS already provides intravascular (IV) infusions for some of the country's highest risk, high complexity patients, and we adhere to the highest standards of safety. All IV medications for the inpatient units including ICU, oncology, GI, and transplant as well as ambulatory infusions, are prepared in a sterile IV room with hospital purchased medication supply that has been monitored for stability, sterility, proper handling. We maintain a history of prior reactions and have direct and close communication with all prescribers who are all part of our hospital system.

With White Bagging, our standards of quality assurance can be jeopardized as the outside vendor's storage, preparation, and handling of the medication cannot be verified. This poses a risk of contamination of the sterile environment as well as a lack of proper tracking for stability due to the use of a third party delivery system. In the event that a patient reacts to an infusion, or in the event of contamination, we must be able to track all sources of risk. This cannot be done properly if the medication is sourced from an outside facility.

LPCHS pharmacy policy ensures the safety for all of our infusion patients by requiring that on location medications are prepared by the hospital's pharmacy team. This policy prohibits the use of outside vendor medications from entering the hospital's sterile pharmacy environment. Our highest risk patients are not candidates for home infusion services as they require direct monitoring by a health care professional and access to a crash cart and intubation supplies if needed. These patients require their infusions to be given in a monitored hospital environment due to previous reactions, vascular access issues, or fragility. The proposed White Bagging policy forces patients to choose between remaining within the hospital system and paying for their medications out of pocket or jeopardizing their safety by finding another infusion center if one is available. Therefore, as an institution we have found the White Bagging proposed by insurance plans to be a direct safety risk, causing both patients and our hospital great distress.

Thank you for your attention to this matter.

Sincerely,



**Senior Vice President and Chief Government Relations Officer**



**Tzielan Lee, MD**

**Clinical Professor of Pediatrics**

**, Pediatric Rheumatology**

**Associate Chief Medical Information Officer (CMIO), Stanford Children's  
Health Associate Medical Director of Ambulatory Services, Stanford  
Children's Health**



**Shweta S. Namjoshi, MD MPH CNSC**

**Clinical Assistant Professor**

**Medical Director, Intestinal Rehabilitation & Nutrition Support**


**Medical Director, Children's Home Pharmacy**

**Division of Pediatric Gastroenterology, Hepatology, & Nutrition**

**Stanford University School of Medicine & the Lucile Packard Children's Hospital**

**750 Welch Road, Suite 116, Mail Code 5731**

**Office: 650-723-5070**



**Alka Goyal MD**

**Clinical Professor of Pediatrics**

**Division of Gastroenterology, Hepatology and Nutrition**

**Lucile Packard Children's Hospital**

**Stanford University School of Medicine**

**750 Welch Road Ste 116**

**Palo Alto, CA 94304**

**Tel: (650) 725-2531**

**Fax: (650) 498-5608**

**Email: [agoyal4@stanford.edu](mailto:agoyal4@stanford.edu)**



*John W. Day, MD*

John W. Day, MD, PhD  
Professor of Neurology and Pediatrics  
Director, Division of Neuromuscular Medicine  
Stanford Neuroscience Health Center, MC 5979  
213 Quarry Road  
Palo Alto, CA 94304  
Tel: (650) 725-7622  
Email: [jwday@stanford.edu](mailto:jwday@stanford.edu)

*Nasim Khavari*

Nasim Khavari (Feb 16, 2021 22:24 PST)

Nasim Khavari, MD MPH  
Associate Professor, Department of Pediatrics  
Associate Chief of Clinical Affairs, Pediatric Gastroenterology  
Stanford University School of Medicine and Stanford Children's Health  
[nkhavari@stanford.edu](mailto:nkhavari@stanford.edu)