

TO: Senate Committee on Insurance, Licensing & Forestry

FROM: Chris Spahr, MD, Chief Quality Safety Officer, Children's Wisconsin

DATE: Thursday, January 20, 2022

RE: Support for SB 753, prohibiting mandatory insurance "white bagging" for clinician administered drugs

I want to thank Chairwoman Felzkowski and members of the committee for the opportunity to share Children's Wisconsin's (Children's) perspectives on SB 753. My name is Dr. Chris Spahr and in my role as a physician and as Children's Chief Quality Safety Officer, I take our commitment to high quality patient care to heart each day and it's what brings me here to be with all of you today to express Children's support for SB 753.

Many of you are familiar with Children's Wisconsin. With our top pediatric hospital care, primary care offices, Children's Community Health Plan, various community health programs, child welfare services and more, families across Wisconsin and across the country have come to expect the best and safest care for their children when they think of us and we're proud of that. From well-child visits, to broken bones to complex medical issues cared for by the more than 70 specialty areas at Children's, we know that kids aren't just little adults and they require unique and special care, including experts in areas like patient safety, quality and pediatric medication management.

Over the last few years, health insurance companies have begun implementing a practice, known as "white bagging" which requires that certain medications that need to be administered by a clinician in a health care setting have to be obtained from a specialty pharmacy, often owned by the insurer. In theory, medications are ordered from the specialty pharmacy, which dispenses to the health care provider, who then administers the medication to the patient. In practice though, white bagging has caused a multitude of issues for patient families and the providers who care for them – from medication procurement to drug delivery to patient safety and care. In my role, I focus on reducing risk, promoting safety and working to ensure the best health outcomes for kids.

Medication errors are one of the most common incidences of medical error. The health care system takes these errors seriously and has implemented quality improvement initiatives and safety checks to reduce these types of errors in order to reduce patient harms and improve care delivery. Examples include designing ordering systems to check that the dose is appropriate for a patient's weight, scanning a patient's wristband and the medication to ensure its being delivered to the right patient, and programming pumps that administer intravenous (IV) medications to deliver the right dose at the right rate. These and many other improvements ultimately produce the highest levels of safety when they are linked through one continuous process in our system – from ordering of the medication through delivery and monitoring the patient. White bagging bypasses many of these safeguards and processes that health care institutions set up to protect patients, reduce waste and inefficiency, and allow for the safe provision of health care. I'd like to outline a few examples of these challenges to help demonstrate why passage of SB 753 would help reduce safety risks and disruptions to care for Wisconsin patients.

Currently, the patients most impacted by insurer mandated white bagging at Children's are patients in our specialty care clinics diagnosed with cerebral palsy who are being administered botulinum toxin, most commonly referred to by the brand name Botox. Botox is beneficial for patients with cerebral palsy who experience tight muscles that affect their range of motion, functionality and daily living. Botox helps loosen their muscles so that daily tasks like dressing, diaper changing and placing in car seats are more comfortable for the child and more manageable for the caregiver. These patients receive their medications from a clinician as often as 90 days between injections with some kids being able to go longer in between injections based on their individual needs.

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When an insurer mandates white bagging, obtaining the appropriate authorizations for the medications becomes a time-consuming and complicated endeavor. Mandatory white bagging requires increased provider time and patient family engagement even before the drug is able to be shipped. Our clinicians spend hours of time per patient sharing information with the specialty pharmacy who often have inconsistent ordering processes and occasionally have stringent restrictions on discussing patient details which makes it challenging to confirm the correct patient.

Currently, Children's staff have to call the insurer each time (typically every 90 days) prior to the new shipment for the specialty pharmacy to re-verify benefits which takes about three days. Once benefits verification happens and the family gives verbal consent, the drug can be shipped, but not until any balances owed by the patient family to the specialty pharmacy are paid. The drug will not ship until all of these issues are resolved, these steps are complete and any co-pays are collected. Each step often requires direct outreach by Children's staff to the specialty pharmacy or insurer and the patient family. On average this takes 2-3 hours of staff time per patient per shipment to complete this process and resolve any issues even before the drug can be shipped to us. White bagging requires a certain lead time to get the order in and the medication delivered in time for the patient's appointment. For those needing medications more urgently, the time required to complete the white bagging process is frustrating and confusing for families – especially when Children's has most of the medications needed in stock in our own pharmacy.

Children's experiences with the delivery of medications through the white bagging process have resulted in disappointing delays in kids' care. White bagged medications are frequently delivered to the wrong location, which raises questions about chain of custody, confidentiality, and appropriate storage of the medications, not to mention safety concerns if someone was to find the medication and use for other unintended purposes. Patients often make appointments weeks to months in advance, preparing by scheduling time away from work and school. If the drugs don't arrive to us in time due to delivery challenges, this results in delaying much-needed therapies for these patients that is simply out of both their and our control. For example, we have encountered situations where the delivery service does not deliver the medication on the appointed day, retains the medication, and subsequently, appropriate storage conditions were not maintained for an extended duration. We need to ensure that the medications are maintained at the right temperature, and under the custody of trained professionals before administering them. This situation is also repeated when medications are delivered to the wrong site, sometimes to the provider's office which may not have adequate storage or meet refrigeration requirements. Additionally, one of the most common specialty pharmacies won't address the medications to our pharmacy which increases the chance of improper delivery. All of these situations have led to further increasing costs of providing care due to therapy delays or additional costs for the insurer to replace and resend medications that we could've used if they were delivered properly. Issues with delivery and the increased need for provider and patient engagement in this process creates an undue hardship on families who already made schedule accommodations; this certainly isn't optimal for families already stressed by complex medical conditions.

We have heard that some insurers indicate that they have an alternative process to white bagging when an issue arises that would result in delayed administration of the medication; this alternative would instead allow the clinician to administer medication that the hospital has on hand without recourse to the patient or provider. We are not aware of any exceptions in our contracts or that have been conveyed to us in another way. Even if alternative processes did exist, these situations would become extremely difficult to manage from a pharmacy operations and safety perspective. The concept of handing off and communicating information from one team to another is a set up for miscommunication and poor outcomes. Hands off are at the root cause of many safety events in healthcare. Our goal is to minimize the number of handoffs and improve communications when they need to occur. This is extremely difficult to do in the white bagging process because of the different information systems, communication mechanisms (or lack thereof), multiple pharmacies and, in some cases, stringent policies on discussing patient information.

When certain white bagged medications arrive to us, they are in a form that requires reconstituting or compounding – essentially making the drug usable for a particular patient. This is an important and costly step in the process that requires specialized facilities and trained staff to ensure the safety of patients. Additionally, white bagged medications come with burdensome storage requirements we must follow which include ensuring that each medication is stored by individual patient and for their use only. This requires additional storage space which is exacerbated when appointments are cancelled or changed or patients are unable to complete their treatment regimens. White bagging also poses challenges to providing high quality care during the patient's appointment. For example, if a patient usually takes a

certain dose of their medication but their condition, via testing and other checks at the time of appointment, requires a different dosage of medication, the insurer pharmacy has only filled their usual dose. When white bagging is mandated, a required dose adjustment like this would often result in a delay in care as we would have to process a new order, await the shipment of the remainder of the dose, and have the patient return for another appointment in order to proceed with therapy. Due to the long lead time for shipment, we could not even consider delivering one dose in two separate administrations as it would result in suboptimal care. If not for white bagging, we could simply adjust the dose at the time of the appointment to have our pharmacy prepare and deliver what is needed, providing better health outcomes for the patient and reducing appointment scheduling burdens.

White bagging policies also state that these medications can't be used for other patients — if the patient doesn't use their dose, cancels their appointment or changes treatment regimen, the drugs we've ordered for them must be destroyed. Additionally, white bagging doesn't allow for many of the clinical, safety and quality checks that are built into health system pharmacy workflows. This is especially important in pediatrics as many drugs are formulated with adults in mind. Our pharmacy staff are specially trained in kids' anatomy, illnesses, metabolisms and how all of these could impact how a medication may interact with a patient. The specialty pharmacies that insurers require we order from do not have this training or access to medical records, which has resulted in medication dosing errors that can be dangerous to the patient and potentially further delay care when they're discovered. Recently, a medication was sent for a patient with the instruction to inject 10 mg weekly for four weeks, but the patient should have been receiving 2.5 mg weekly. This particular medication has the potential for anaphylactic reaction so must be carefully administered to gauge the patient's reaction and maintain their health and safety. Very fortunately, our Children's pharmacist caught the specialty pharmacy's dosing error.

Overall, the white bagging process and its requirements are incompatible with how health system pharmacies order, store and dispense medications for patients, creating a separate and often confusing and frustrating system for staff and patient families alike. Because of the varied shipping and ordering services used, it makes tracking these issues and concerns a real challenge. SB 753 would prohibit this practice which we believe would improve access to these critically needed specialty medications in a more timely, efficient and safe manner. Of course, while white bagging has an impact on Children's Wisconsin's ability to provide safe, high quality care for kids, more important are the voices of the patients and their families who experience these challenges and the impact they have on their children's healthcare.

I'd like to share a brief statement from the family of 8-year-old Landon Claeys from Grafton who could not be with us today. We are Megan and Mike and we live in Grafton with our sons, Robbie and Landon. We'd like to share more about our 8-year-old son Landon has cerebral palsy due to brain damage sustained at birth. Landon's cerebral palsy affects his motor control, sensory processing and his reflexes. Landon's doctors at Children's Wisconsin have used Botox injections on a regular basis to help loosen Landon's muscles that get tight which make it harder for him to do daily activities and causes him significant pain. We regularly scheduled his injection appointments for every three months so we could better manage Landon's muscle pain and tightness and allow us to plan for time away from school and work.

A couple of years ago, our insurance company suddenly started a policy, called white bagging, which would change the process for how Landon would receive his medications. Rather than using the medicine already in stock at the hospital's pharmacy like we were used to, Landon's doctors would have to order the medication from a specialty pharmacy that would then ship the medicine to the clinic for the appointment. Because of insurance company approvals and shipping delays, we had to reschedule an appointment of Landon's – unfortunately, the new appointment would be a month later and a month of Landon experiencing pain and hardship. Also, depending on how Landon's condition is at the time of the appointment, Landon's doctors and nurses may need more doses of Botox injections. With this white bagging process, we'd have to come back for another appointment once the additional doses were ordered and delivered. Before white bagging, the hospital could just use their stock of Botox to meet Landon's needs and made scheduling and the whole process simpler for us. For kids and adults with complex or chronic health conditions, navigating the health care system is already complicated, stressful and sometimes frustrating. Eliminating this policy, and supporting SB 753, would help health care providers to better care for kids like Landon. Thank you.

Hospitals don't usually raise issues with our elected officials that we normally negotiate in the contracting process with insurers. What is different about this issue is that insurers are implementing these mandated policies outside of the

regular contract with sometimes not more than 60 days' notice. While right now mandatory white bagging policies have been limited to select insurers and specialty drugs, our experience indicates this practice will grow and impact more and more patients, as well as negatively impact quality health care delivery. That's why it is important for the Legislature to act swiftly in moving this legislation forward. In short, we have issues with insurers' inflexible, mandated white bagging requirements as they compromise patient safety, timely and adequate care, and disrupt the day-to-day lives of kids and families. Thank you for the opportunity to share Children's Wisconsin's perspectives on this legislation which will have a significant impact for the children and families across our state who depend on specialty medications. I'm happy to answer any questions you may have.

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Children's Wisconsin (Children's) serves children and families in every county across the state. We have inpatient hospitals in Milwaukee and the Fox Valley. We care for every part of a child's health, from critical care at one of our hospitals, to routine checkups in our primary care clinics. Children's also provides specialty care, urgent care, emergency care, dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.