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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

TELECONFERENCE ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING
INFORMATIONAL MEETING
MEETING MINUTES

DATE:	February 18, 2021
LOCATION:	Teleconference Public Committee Meeting Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor teleconference locations are provided.
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member Chair Jig Patel, Licensee Member Vice-Chair Ricardo Sanchez, Public Member Greg Lippe, Public Member Debbie Veale, Licensee Member Albert Wong, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Lyle Matthews, Assistant Executive Officer Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel Debbie Damoth, Administration Manager

I. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 1:05 p.m. Dr. Serpa advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's executive order. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments.

A roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Albert Wong, and Maria Serpa. A quorum was established.

II. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were offered.

III. Presentations and Discussions on "White Bagging"

Dr. Serpa advised the Committee it would hear presentations from various stakeholders on the practice of white bagging. She noted the meeting was publicized and identified stakeholders contacted to participate with the goal of receiving various perspectives on this practice to ensure education on the matter is comprehensive. Dr. Serpa thanked all of the presenters for their time as well as all of the stakeholders that provided written comments. She noted written comments received are posted on the Board's website.

Dr. Serpa provided background on the practice of white bagging. She noted much of the information provided is included in the information published by the National Association of Boards of Pharmacy (NABP) report on the practice. A link to this report was included on the agenda and in the announcements regarding the meeting. Dr. Serpa noted that "white bagging" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital or clinic for administration. It is often used in oncology practices to obtain costly injectable and infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.

Dr. Serpa advised members that the focus of the meeting was on white bagging but noted another practice called "brown bagging" which refers to the dispensing of a medication for a pharmacy directly to a patient, who then transports the medication to the physician's office.

Dr. Serpa noted the practice of white bagging has become more frequent as payors more robustly require the practice to reduce medication costs. The NABP report details out some benefits to the practice of white bagging, including the potential for a greater opportunity for pharmacists to use their expertise to improve patient outcomes as well as the opportunity for physicians to reduce costs associated with purchasing and stocking expensive medications. From the payer perspective, benefits include cost savings through negotiated dispensing rates and increased transparency.

Dr. Serpa added safety concerns have also been identified including the special handling that is required for many of these medications which can pose

safety, operational and unexpected financial burdens. Additional challenges may arise as specialty pharmacies may not have access to patient medical records as well as unpaid expenses resulting from coordination, storage and handling of patients' medications until the drug is administered. She noted the practice could present some challenges in instances where a change in dosage or strength of transition to a different class of medication is common. Additionally, the potential for delays in patient care resulting from troubling acquiring or receiving the appropriate medication can occur.

Dr. Serpa noted as included the NABP's report, it may be incumbent on the Board to determine who is accountable for verifying the authenticity and integrity of the drugs before administration as well as who would be responsible when a delay in therapy occurs. These may be questions we need to answer but suggested only considering these and other issues that may be identified today after the education portion has been completed.

California Department of Managed Health Care

Sarah Ream, Chief Counsel, Department of Managed Health Care (DMHC), addressed the committee to share DMHC's mission, role and responsibilities as the regulator of licensed health care plans in California under the Knox-Keene Health Care Service Plan Act of 1975 including full-service and specialized plans; commercial and Medi-Cal Managed Care Plans; and Medicare Advantage Plans (limited regulation). DMHC operates a Help Center to assist health care consumers receive services they are entitled to receive. Ms. Ream advised the DMHC does not regulate health insures licensed by CA Department of Insurance or self-insured employers; does not regulate providers including hospitals and pharmacies; does not require plans to contract with particular providers; or does not set provider reimbursement rates.

Ms. Ream reported most full-service plans cover medically necessary prescription drugs with cost-sharing allowed up to $250 for a 30-day supply in most instances. The DMHC receives and reports prescription drug coverage on information regarding health care costs associated with prescription drugs. Ms. Ream provide from 2017 to 2019, prescription drug costs paid by plans increased by $1 billion and accounted for 12.8 percent of total health plan premiums in 2019. She added the DMHC tracks costs and expenditures on prescription drugs.

Ms. Ream advised DMHC does not have the authority to prohibit white bagging or brown bagging provided the practice does not harm or impact enrollees' ability to receive medically necessary care.

California Association of Health Plans

Charles Bacchi, President and Chief Executive Officer, California Association of Health Plans(CAHP), provided his organization is a statewide trade association that represents 45 full-service health care plans who provide coverage to more than 26 million Californians. Mr. Bacchi advised most of CAHP's members provide coverage through the individual and group markets as well as partnering with the state for health care programs. CAHP also contracts with Medi-Care. Coverage is provided through the HMO model, PPO model, commercial health plans, public health plans (including county organized health systems and local initiatives), regional plans and fully integrated health care systems.

Mr. Bacchi added CAHP focuses on the affordability of health care coverage as health care costs increase and are an issue for everyone. He noted employers who hire CAHP to provide coverage to their employees including labor trusts and government payers are pressuring health care costs to be lowered and made more affordable for their budgets.

Mr. Bacchi advised majority of health care expenses goes for services such as hospital/doctor visits, prescription drugs, lab tests, x-rays, and medical supplies/equipment. He stated health care plans are regulated and must comply with transparency requirements for how premiums are set. Mr. Bacchi noted inpatient drug costs are substantial and plans have to cover the cost of medication and administration. Drugs that are administered to the patient by a provider at a site other than the patient's home such as clinics, hospitals, infusion sites or physicians' offices can cost significantly more which can be due to other charges or significant mark up for the cost of the drugs being acquired by the facility. Mark ups beyond the acquisition cost are sources of revenue for the facility and can be purchased at a lower cost while still being administered in a safe and efficacious manner.

Mr. Bacchi provided as health plan benefits have evolved, some have moved the drug portion of these inpatient costs to the drug portion of the plan which allows the plans to negotiate directly with the specialty pharmacies to acquire the drugs at the actual cost plus a minor dispensing fee resulting in a substantial reduction of costs (e.g., thousands of dollars per dose or per treatment) known as white bagging. Plans and insurers believe this has been done and can be done safely while not being a new practice. This model should have the same safety profile as a drug shipped by a wholesaler or distributor just purchased at a different point and price.

Mr. Bacchi advised there are known efforts by pharmacy boards and stakeholders across the nation to either limit or prevent the practice of white bagging. He stated it was important to note for the Board in considering any action that would limit or prevent the use of white bagging that it will not change the coverage for the drug as that is determined by the insurance policy that the plan purchased on behalf of enrollees. The costs for these medications will be increased to payers and will result in increased premiums as well as likelihood to increase costs to patients through premiums, enrollee cost sharing, or out-of-pocket costs. He added while many DMHC regulated products have relatively modest caps on out-of-pocket costs, there are other non-DMHC regulated products on the market that do have high co-pays or cost sharings so if the cost of the drug is marked up, the enrollee will have to pay more out of pocket to access the treatment. In some non-DMHC regulated plans, this could happen in self-insured models that could require the enrollee to pay up front for the prescription and seek reimbursement from the plan if the plan does not have a contract with the provider who is providing the service. When this happens, the higher drug costs can impact medication compliance due to lack of resources.

Mr. Bacchi stated this is a contract issue between plans and providers. Contracts can be developed that allow or do not allow this process with a perspective to provide the most effective way to deliver medications to enrollees to relieve the health care system from the burden of higher health care costs and protect enrollees' safety. He noted taking action that would impact this practice in California could have negative impacts and should be considered in deliberations.

Member Lippe inquired if the issue is the facility is adding a markup and white bagging wouldn't be needed if there was no markup. Mr. Bacchi responded if the price differential was the same, there would be less incentive for this to happen. As part of a strategy to lower health care costs, health plans are looking for ways to drive volume through their purchasing and negotiating a lower price.

California Medical Association

Yvonne Choong, Vice President, Center for Health Policy, California Medical Association (CMA) advised the committee that CMA represents more than 50,000 California physician and student members. She stated white bagging practice impacts many physician practices including oncology and rheumatology practices. Ms. Choong noted CMA has serious concerns regarding policies that require physicians to obtain medications administered in the office through specified pharmacies designated by the health care plan or

other entity. She reported mandatory white bagging negatively impacts patient care by creating delays in treatment that can impact patient safety; increasing out-of-pocket costs for patients; and possibly accelerating physician practice closures and consolidation by increasing costs if physicians have to pay for unreimbursed medications.

Ms. Choong provided background on how physician administered medications are managed outside of a white bagging requirement. Generally, physicians purchase the medication from a vendor and bills the payer for the medication with appropriate storage on site and available for all patients regardless of payer type. She stated immediate availability of medications allow the physicians to provide the appropriate treatment for patients and make medical decisions at the point of care based on the individual patient's health care needs. She noted white bagging changes this process by requiring the physician to order these medications in advance of patient treatment from specified pharmacies.

Ms. Choong added CMA's biggest concern is the impact on patient safety. She noted some medications are sensitive to temperature and light fluctuations as well as require special handling and storage to maintain efficacy. White bagging has the potential for serious adverse impacts on patient safety and delays in care. By removing control of the sourcing, storage, preparation and handling of specialty medications, physicians become at risk for exposing patients to potentially serious harm and increasing administrative burdens and liability risks to their practices. When medication for each individual patient needs to come from specialty pharmacies and is not part of the physician's on hand medication inventory, patient care is subject to delays in treatment that can be caused by delivery errors (e.g., incorrect medication is delivered, medication shipped to the wrong address, medication out of stock, etc.). Patients requiring these medications often have serious and debilitating chronic conditions (e.g., cancer, multiple sclerosis, etc.) where delays in treatment can be catastrophic to their care. Due to severity of conditions and complexity of treatment, drugs and doses must often be modified at the point of care based on patient specific conditions (e.g., weight, renal function, bone marrow function, lab test results, etc.). The inability to make changes at the point of care can result in treatment delays but this doesn't happen when medication supplies are managed by the physician's office.

Ms. Choong provided an example of a patient who was receiving treatment and had to spend hours on the phone with pharmacy representatives and complete online forms/questionnaires to ensure the already well-established treatment plan could be continued through the specialty pharmacy. Despite this additional work, the patient's treatment plan was delayed by two weeks. When a new treatment was prescribed by the patient's oncologist, the

physician followed the requisite procedure but patient care was delayed by a week. Some of the drugs had to be mixed but the specialty pharmacy was not able to supply these drugs or the pump required to infuse the medication.

Ms. Choong stated there are instances when the patient requires multiple drugs but the specialty pharmacy cannot fill all of the required drugs so that they have to be ordered from multiple vendors. If shipping of drugs is not coordinated, patient care is delayed.

Ms. Choong noted white bagging requirements can lead to increased medication waste, patient inconvenience and lost treatment time if the medication does not arrive in time for the scheduled appointment. While patient safety is the most concerning issue, there are other issues such as out-of-pocket costs for patients if patient co-pay assistance isn't provided by the specialty pharmacy. Additionally, this could lead to physician practices closing. If the physician is unaware of the requirement to use a specialty pharmacy, reimbursement to the physician may be denied if the physician used the wrong pharmacy and the cost must be absorbed by the physician. She noted in addition to increases costs due to COVID-19, implementing white bagging requirements accelerates the financial stress for independent and medium sized practices. CMA's concern is that a new wave of consolidation could be seen that could broadly increase health care costs and decrease patient access to care.

Thomas Semrad, MD, MAS, FACP, Medical Director of Clinical Research, Gene Upshaw Memorial Tahoe Forest Cancer Center, provided to the committee summary information on how white bagging has impacted his practice and care provided in his area. Dr. Semrad is a medical oncologist at a critical access hospital in Truckee, California, to provide treatment to cancer patients in the remote region. The closest infusion center is over 60 miles away.

Dr. Semrad advised his practice is known for high quality of care and being able to treat patients on the day of their scheduled appointment due to the distance many patients have to travel. He noted in the mountainous area of Truckee, delivery issues are frequently a problem due to weather. When a dose change is required, it is managed by having the appropriate stock on hand. The requirement of an insurance plan to use a specialty pharmacy providing a specific dose for a specific patient generates a huge cost and staff issue.

Dr. Semrad noted that drugs must be properly handled and stored. Pharmacists are asked to certify a product that has been pre-leveled for a patient from an outside source and wonders if that is acceptable. Additional and separate storage requirements, practice requirements, management protocols and preparation protocols are required for items involved in white bagging process.

He stated the concept of minimizing variation to minimize error is part of a quality assurance program but preparing the same drug from different settings does not minimize error. This results in additional liabilities to staff and safety risk to the patient.

Dr. Semrad noted delivery delays for oncological treatment could result in a patient's cancer worsening if there are delays and identified additional issues to include psychological well-being of the patient if treatment is delayed.

Dr. Semrad added white bagging is not providing the same type of care for every patient. Distributive justice isn't being achieved when patients subject to an insurance specific white bagging policy are treated under a different and arguably riskier protocol than those with different insurance.

California Hospital Association

BJ Bartleson, RN, MS, NEA-BC, Vice President, Nursing & Clinical Services, California Hospital Association (CHA), advised the committee CHA takes care of policy and advocacy for over 400 hospitals in California. CHA shares the concerns of white bagging related to affordability, patient safety, financial stress, operational burden and distributive justice.

Ms. Bartleson advised current policy used frequently by hospitals is called the "buy and bill" method where providers buy and store drugs for general use and bill payers for the doses used when the drug is administered to the patient. She stated white bagging; however, requires payers to reimburse third-party pharmacies which then distribute the medications to outpatient medical providers.

Ms. Bartleson provided a brief history of the introduction of white bagging from different payers as brought to the attention of CHA ranging from July – October 2020. She noted notification to the hospitals was inconsistent and delayed; in some cases, members notified CHA.

Ms. Bartleson advised patient safety and treatment delays include medication integrity, medication adjustment/timely delivery of medication, and preparation/labeling. She stated these guardrails are critical for patient safety. She noted impacts on hospital operations include strain on hospital systems, increased administrative burden, lack of compensation for unused medications, management of inventory of drugs for each patient, and threats to 340B Drug Pricing Programs for hospitals.

Ms. Bartleson provided a background on CHA's advocacy on the white bagging issue from June 2020 – January 2021.

Ms. Bartleson provided a comparison of the Board of Pharmacy regulations and conflict with white bagging procedures. She noted a few items to determine what possible solutions might exist. Specifically, she noted a conflict with Business and Professions Code section (BPC) 4024 with the definition of dispense that requires the furnishing of drugs or devices directly to a patient. When white bagging processes are used, the medications are marked as dispensed by the payer-designated pharmacy but not furnished directly to the patient. She continued BPC 4059 provides an exception for furnishing dangerous drug or devices by a manufacturer, wholesaler or pharmacy to each other but with white bagging medications are not sold between the designated payer specialty pharmacy and receiving health-system pharmacy. She noted BPC 4119.5 allows for the transfer or repackaging of dangerous drugs of a reasonable supply from one pharmacy to another. However, white bagging medications are patient specific and not considered reasonable supply. Ms. Bartleson referenced conflict with federal regulations, Drug Supply Chain Security Act (DSCSA), and CA Health and Safety Code.

Ms. Bartleson referred to the Massachusetts Health Policy Commission of 2017 and 2018 NABP Survey/Study as other advocacy efforts as documents to be used as reference documents. She highlighted the NABP Survey/Study that referenced while 28-31 percent of drugs nationally are supplied through white/brown bagging processes yet few states define the concept. The NABP Survey/Study also identified legitimate patient protection issues when a specialty drug is distributed to an entity other than the patient.

Ms. Bartleson noted Massachusetts and Ohio are focused on dispensing/redispensing prohibiting a pharmacist shall not redispense any medication that has been dispensed and has left the physical premise. New Jersey and Georgia are focused on other issues such as diverting patients and pharmacy benefit managers.

Ms. Bartleson reviewed recent advocacy from the American Hospital Association (AHA) to CMS in February 2021 noting white bagging practice should only be allowed where the provider and health plan agree through standard negotiations that it is in the best interest of the patient. Providers should be permitted to decline any such arrangements based on quality of care concerns.

Ms. Bartleson posed options for white bagging posing questions about consumer protection and in relation to current regulations with Board of Pharmacy assisting with comparing the process to the regulations.

California Children's Hospital Association

Grace Magedman, PharmD, DPLA, Executive Director of Pharmacy Services, Children's Hospital of Orange County (CHOC), and Shabnam Gaskari, PharmD, BCPPS, Executive Director and Chief Pharmacy Officer, Lucile Packard Children's Hospital Stanford, provided information on the risks and failure points that white bagging introduces from a pediatric perspective.

Dr. Gaskari reviewed the different models (e.g., buy and bill, white bagging, brown bagging and clear bagging) highlighting the process and the insurance benefit billed. She reviewed a historical perspective of white bagging as well as the process. Dr. Gaskari noted the introduction of an external pharmacy to the treatment plan adds an additional entity that can lead to greater risk.

Dr. Gaskari reviewed the problems with white bagging at different stages in the medication management process. At the prescribing stage, the risk/failure point is that pediatric patients can experience weight changes during the growth process that requires a change in dose or therapy. If the patient arrives for an infusion and the dose is no longer appropriate due to changes, the patient is unable to receive the infusion and there is a delay in therapy.

Dr. Gaskari provided at the distribution stage, the risk or failure point is the inability to verify the authenticity or integrity of the drug due to lack of supply chain oversight. She noted recall management is difficult when the pharmacist is not involved in the purchasing. The DSCSA is disrupted from this process when the pharmacist isn't buying the drug or supplying the drug. She further noted redispensing introduces the risk of contamination. Dr. Gaskari added some of the infusions are a lifetime chance for a patient like with gene therapy where there is one chance to get purity. If the drug is not stored and handled properly, the one lifetime chance could be lost.

Dr. Magedman added additional risks exist because external pharmacies do not have access to the patient's medical records and do not have the ability to provide comprehensive medication management especially during prescription verification. There is often a lack of pediatric expertise in specialty chronic conditions (e.g., metabolic deficiencies and oncology) which can lead to error. She had numerous stories where therapy was significantly delayed due to logistics (e.g., delayed deliveries, lost shipments, lack of coordination between drug receipt and scheduling, dispensed drugs expiring prior to scheduled appointment/procedure, etc.). These delays negatively impact patients and their families.

Dr. Magedman stated staff cannot be asked to compound drugs where authenticity and integrity can't be assessed. She noted possible incompatibilities with safety protections such as closed system transfer devices which require workarounds to accommodate. Dr. Magedman stated it is not acceptable to eliminate these protections for staff and patients.

Dr. Magedman advised at the administration point, when there are administration related reactions, chain of custody must be maintained to ensure contamination or adulteration was not a contributing factor. Pediatric patients require a special skill set of care such as IV placement in small veins or pediatric emergency response. She added when a patient is transferred to another facility because of payer restrictions and that facility is not equipped to serve pediatric patients, the patient's care and outcomes could be compromised.

Dr. Magedman advised at the point of patient education and monitoring, the providers take on the responsibility of medication education and administration. She stated external pharmacies can't monitor as effectively as health system pharmacies for adverse effects, adherence and patient outcome. Additionally, health system pharmacies have direct access to providers to communicate more effectively and efficiently. External pharmacies cannot perform any required safety monitoring or clearance prior to dose administration of certain specialty medications. She offered it is a risky practice to dispense without the ability to validate the medication for safe administration.

Dr. Magedman provided an example of a patient who was receiving a white bagged supplement implant for their precocious puberty. The patient was in the procedure and under anesthesia when the physician opened the delivered medication to find that the medication kit was defective. It wasn't acceptable to not complete the procedures so the institution had to provide their own product they fortunately had in inventory.

Dr. Magedman provided another example of a patient who experienced delays from a specialty pharmacy located 2,600 miles away from the patient. The patient experienced multiple rescheduled treatments and infusions that were eight weeks late. Patients and families experience disease progression, additional anxiety and lack of information about the coordination of their care.

Dr. Gaskari provided an example of a patient who was developmentally delayed with veins that were difficult to access. The patient was required to be transferred to another facility due to payer restrictions. The patient became so stressed that the facility was not able to access the veins for treatment and the patient had to be transferred to the emergency room.

Dr. Gaskari provided another example where the patient and parents were at the facility for a procedure but the facility had not received the medication from the specialty pharmacy. The patient's mother had to coordinate with the specialty pharmacy on the day of the procedure. She stated this is another worry for the patient and families who shouldn't have to be worried about receiving patient medication.

Dr. Magedman expressed concern that "brown bagging" may be viewed as a solution if white bagging is eliminated. She emphasized this is not an acceptable solution because it results in medications being left on porches, in hot cars or in food refrigerators where temperature can't be regulated. She stated "clear bagging" is not a solution.

Ms. Veale asked if dosing changes made so close to the scheduled infusion is common. Dr. Gaskari explained patients taking medications for irritable bowel symptoms experience weight changes due to nutrition. For patients who get infusions every month, the medication is dispensed three to four weeks in advance. At the doctor's visit prior to the infusion, if the weight has changed, a new drug or change of dose may be required. Ms. Veale inquired if it was common that medications are shipped three to four weeks before a procedure. Dr. Magedman added that depends on the specialty pharmacy and payer but typically the specialty pharmacy is not aware of when the procedure is scheduled. She noted medication could come a few weeks or days before the procedure or it may not come at all.

Ms. Veale inquired if there was little communication between the physician's office and the pharmacy. Dr. Magedman explained communication plays a part but there is also the prior authorization process that differs from payer to payer. She noted there is lack of communication during the authorization process to know if it has been denied or not. Health system pharmacists are better able to bridge the communication gap and advocate for the patient.

Ms. Veale asked if the prior authorization would still be required when specialty pharmacies are not being used. Dr. Gaskari provided pharmacists are better equipped to explain why the patient needs the drug therapy.

Ms. Veale inquired why there is a higher chance of fraud or contamination if coming from a remote pharmacy. Dr. Magedman clarified she said adulteration rather than fraud. She noted the ability of the pharmacists to detect contamination or assess for authenticity and integrity is around the DSCSA where the pharmacist is required to receive transaction history which can't be done when it comes from another pharmacy.

Ms. Veale inquired if the drug pedigree would have to transfer with the drug from pharmacy to pharmacy. Ms. Sodergren indicated the issue may be when the drug is considered to be dispensed and would have to be further researched.

The committee took a break from 2:44 p.m. to 2:50 p.m. Roll call was taken. Committee members present included: Gregory Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale and Maria Serpa. A quorum was established. Albert Wong joined the meeting at 2:53 p.m.

Rita Shane, PharmD, FASHP, FCSHP, Vice President and Chief Pharmacy Officer, Professor of Medicine, Cedars Sinai Medical Center

Rita Shane, PharmD, FASHP, FCSHP, Vice President and Chief Pharmacy Officer, Professor of Medicine, Cedars Sinai Medical Center, reported the issue of drug cost has been an issue for many years and white bagging is a reaction to the high cost of drugs and exponential increase of drug costs. She expressed concern that white bagging is a band-aid approach to the high drug costs noting it is an unknown process to patients who are now caught in the middle.

Dr. Shane reported the integrity of the drug is something pharmacists are responsible for and storage requirements do matter. Even though drugs are coming from another pharmacy, it is unknown how the drugs were sourced or stored appropriately prior to being received for infusion.

Dr. Shane advised the redispenseing issue has been address in Massachusetts and Ohio. In New Jersey and Georgia, the issue is framed around removing the patients' freedom of choice. Patients are supposed to have choice and patients are not aware of the process and how it could be affecting their care.

Dr. Shane reported safety concerns from multiple entities. Specifically, the American Society of Clinical Oncology (ASCO) recommends against brown or white bagging. The National Comprehensive Cancer Network (NCCN) Specialty Pharmacy Task Force recommends standardization of communication methods with the health care team.

Dr. Shane advised there are 57 checks when working with chemotherapy developed over 30 years ago as a result of Boston Globe reporter Betsy Lehman dying of an overdose of chemotherapy. Since that time, efforts have been made in systems and providers to ensure safety of chemotherapy. The death of Ms. Lehman and another patient at the University of Chicago underscore the importance of all of the checks put into place to ensure safety of

chemotherapy. Having the drugs available is important so all 57 checks can be performed. Having patient specific-chemotherapy for patients disrupts and fragments care. Dr. Shane noted dose changes are required for many types of patients (e.g., chemotherapy, inflammatory bowel disease, rheumatology, and transplant) who have chronic diseases that are debilitating. If not treated appropriately, the patients will end up back in the hospital resulting in increased health care costs or a delay in therapy resulting in disease progression and or death.

Dr. Shane stated there is data to support that delay in chemotherapy does result in disease progression. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) recommends standardizing processes to prevent error-prone aspects of the medication use process.

Dr. Shane provided patient safety challenges not previously discussed by colleagues. She stated there have been more delays than drugs coming in advance. She noted patients have visits the day of or day before they are scheduled for their medications. Changes in weight, labs, or bio markers could change the amount of drugs needed. Transplant patients may need a drug immediately or risk rejection of the newly transported organ, emphasizing there are many patient-specific factors that necessitate just-in-time drug inventory. For patients at discharge, the patient may not be able to be discharged from the hospital without receiving the drug from the specialty pharmacy.

Dr. Shane addressed how orders are built into electronic health records. Systems are spending time and resources making sure they have electronic health records that build out complex drug therapies. Drugs used for chronic disease typically affect the immune system. Patients must be evaluated and checks put into place (e.g., labs, recent infections, recent drugs that could be a contraindication) before these drugs are given. The courses of therapy including number and frequency of drugs are all integrated in the electronic health record. When a specialty pharmacy is used, questions arises about if a physician must call in the order? The systems were built to prevent deaths from incomplete or inaccurate orders. Providers who are critical to the care of the patients shouldn't have to call in the orders or have to remember to call in the next order. Depending on the disease there is a different frequency required for administration of drugs.

Dr. Shane provided master formulas are required by law for compounding. If different strengths of drugs are received, a new master formula is required which will further delay treatment.

Dr. Shane referenced the Louisiana Board of Pharmacy (8/27/2020) Legislative Action Letter that cited patients previously approved to receive medication

benefit were now being denied and forced to receive medication under the prescription benefit outside their healthcare organization resulting in severely delayed and abandoned pursuit of treatment. According to the letter, the payers are not assisting with helping patients when issues arise.

Dr. Shane provided examples of impacted patients. A patient who had multiple sclerosis since 2015 needed additional induction with periodic treatment. Treatment from the specialty pharmacy was significantly delayed and the patient had to make arrangements to get treatment elsewhere. A patient with hepatocellular cancer had a prior authorization denied and patient was administered for disease progression. High cost drugs should not impact patients when they are the most vulnerable.

Ms. Veale inquired if a prior authorization was necessary for the second patient regardless of the pharmacy. Dr. Shane indicated with white bagging additional prior authorizations are built in. Ms. Veale stated it seemed like communication with a pharmacy outside of the facility was the issue. Dr. Shane provided for complex care and pediatric patients, it is a team approach with the physician entering the treatment plan with the pharmacist and nurse workflow. She stated adding another pharmacy makes the pharmacy function as a wholesaler. The only purpose is to reduce the cost of health care to the insurance at the expense of the patient.

Ms. Sodergren inquired about chemotherapy patients taking multiple medications and if a single specialty pharmacy would provide all the medications or if multiple specialty pharmacies involved. Dr. Shane provided some medications had to be bought and some came from a specialty pharmacy.

Ms. Veale asked if Dr. Shane's organization is accepting white bagging. Dr. Shane indicated her organization is not and are helping the patients get redirected to other entities for treatment.

California Society of Health-System Pharmacists

Steven Thompson, Director of Pharmacy, Torrance Memorial Medical Center, and former president of the California Society of Health-System Pharmacist (CHSP) addressed the committee on behalf of CSHP.

Dr. Thompson advised CSHP has similar views on white bagging as other presenters and noted an increasing trend of white bagging. He noted many

states are addressing this issue such as Louisiana, Ohio, Texas and Massachusetts as well as associations such as AHA addressing the issue with CMS.

Dr. Thompson advised members that Torrance Memorial does not allow white bagging for many reasons. He noted concerns violating the DSCSA. He added delays in delivery due to weather or traffic. Dr. Thompson noted challenges in entering medications into the electronic health record. He noted the inability to take advantage of the vetting of medication order sets through multiple departments making sure supportive orders (e.g., labs, dietary, medications, etc.) are included with the medication orders to ensure safety for the patient. He indicated the inability to use barcode scanning on medication that provides for additional levels of safety for the patient. Dr. Thompson also stated many times dosage changes are needed after precursory appointments and indicated external pharmacies do not have access to patient history or medical profiles. He added when a hospital doesn't allow white bagging, it drives the patient out of the system and then the system doesn't have a complete medical history. He stated it also impacts costs of drugs but the real focus is that the patient is put in the middle of the process and makes it difficult to take care of the patient.

Keck Medical Center of USC

Krist Azizian, Chief Pharmacy Officer and Chief Regional Oncology Officer, Keck Medicine USC, presented to the Committee on the reasons white bagging is an issue now indicated that as a result of cost of care, payers are rolling out cost of care initiatives and policy changes. He noted vertical integration has occurred within the payers, PBM and specialty pharmacies. There is also a transition from the medical benefits to the pharmacy benefits where the specialty pharmacy buys and bills for the drug and the hospital or provider only bills for the administration. This adds another layer and is confusing to the patients and providers. Coordination is shifted to the providers and health systems. Providers should be taking care of patients and not focused on administrative coordination efforts. There is also impact to patient care and safety.

Dr. Azizian noted for the pharmacist and pharmacy teams there are major conflicts with regulatory requirements. He stated there were about eight regulatory/statutory and Joint Commission requirements that white bagging has a conflict with around procurement, storage and preparation of the medication. Shipment loss and delays will result in postponement of life saving therapies and increased waste. When examinations or laboratory results are required on the day of or day prior to infusion, the provider may need to change dose based on weight, delay or cancel dose or change regimen and the medication is wasted.

Dr. Azizian stated external pharmacies do not have the same capabilities to provide the same level of medication surveillance and safeguards, nor access to clinical information for the patient. Dr. Azizian noted DSCSA requires action on recalled products indicating without the appropriate pedigree information makes it difficult to act on recalled products.

Dr. Azizian provided examples of patient impact due to payer mandated white bagging including a patient with brain cancer and melanoma who had a one-week gap in treatment, a patient with colon and liver cancer who had a physician change treatment from infusion to oral therapy to avoid gaps in care. Further, Dr. Azizian highlighted a patient with neuroendocrine tumor had a two-month gap in treatment due to the patient's inability to afford their share of cost as a result of the conversion from medical benefit to pharmacy benefit due to payer mandate. A patient with liposarcoma was pending hospital discharge after a chemotherapy treatment was unable to receive medication from a mandated specialty pharmacy causing delays in discharge. In this case, the prescription was sent two-three weeks prior to discharge.

Dr. Azizian stated USC has a strict policy prohibiting white or brown bagging as they are not able to meet federal and state regulatory requirements. Letters are sent to patients with an option to file a complaint with DMHC. Coordination is required to educate providers because of the unilateral decision by payers.

Dr. Azizian requested the Board to advocate for patients, evaluate the public safety risk and take action. He suggested reviewing and revising regulations to prohibit unilateral mandated white bagging policies and to prohibit unilateral exclusion of health-system owned specialty pharmacies from payer network. If outside of the Board's jurisdiction, advocate and collaborate stakeholders for patients and provide guidance to profession on how to handle white bagging.

Ms. Veale asked for an explanation of what happens when medication coverage is switched from the medical benefit to the pharmacy benefit portion of insurance. Dr. Azizian explained the patient may have a high share of cost or be in a doughnut hole. In the example provided, the patient couldn't afford their share of cost and they were unsuccessful in finding price reduction plans so the patient decided to wait to continue treatment until the beginning of the new year when insurance could be changed. When the medical benefit is being used, the pharmacy on the facility site can be accessed but when the pharmacy benefit is being used, the specialty pharmacy has to be used with a different co-pay structure.

Ms. Veale inquired if Board regulations would allow redispenseing. Ms. Sodergren stated time would be needed to work with counsel. She noted Ohio is

prohibiting the redispenseing of a previously dispensed medication whereas Massachusetts is taking a different approach.

PIH Health

Diane McGowan, PharmD, BCSCP, Director of Pharmacy, PIH Health Whittier – Hospital, addressed the committee as a hospital run infusion center with drugs purchased through the hospital pharmacy.

Dr. McGowan advised there was no notification of the change in policies as white bagging just started occurring. She noted in addition to other regulation conflicts with white bagging, CCR 1735.3 (b) and (c) requires the pharmacy maintain records for the proper acquisition, storage and destruction of chemical drug products used in compounding. When received from a secondary source, they are unable to achieve the regulation.

Dr. McGowan commented standardization of delivery has been challenging as specialty pharmacies do not seem to know what to do. Some are calling patients asking if medications are needed, instructing the patients to pick up the medications, sending medication directly to the physician's office or delivering the medication to a desk at the front of the hospital. USP 800 requires many steps to receive hazardous drugs that are not being followed (e.g., wear chemotherapy rated gloves, drugs sealed in impermeable bags, receive in neutral air flow zones with a chemotherapy spill kit ready). Chain of custody of drugs are not reliable.

Dr. McGowan stated it has impacted the standard of care for patients. The lack of standardization allows for possible errors in the compounding process if the drugs are received in different concentration amounts. She reported eight patients who experienced delayed care because the drugs did not come in time.

Dr. McGowan noted with a small chemotherapy negative pressure room, there is not enough room to store each patients' medication. She commented with the electronic health record, these are added as a nonformulary drug which does not include checks for dose range, allergy, duplicate drug and the ability to have standardized order sets are lost as well as bar coding upon administration.

Dr. McGowan stated this is a variation from the prescription in violation of CCR section 1716. The physicians are writing an order for an IV administrable drug to be given to a patient over a certain amount of time. The specialty pharmacies

are deviating from the prescription when provided as vials to another pharmacy.

Dr. McGowan reported white bagging is not accepted at PIH Health Whittier – Hospital due to patient safety concerns; it is impacting the members. Some patients received their last dose while others decided to not receive their last dose. She requested the Board support current regulations that make white bagging illegal.

Chairperson Serpa advised the Committee public comment submitted can be found on the Board's website for public review.

The Committee took a break from 3:49 p.m. to 3:55 p.m. Roll call was taken. Members present included Greg Lippe, Jignesh Patel, Debbie Veale, Albert Wong and Maria Serpa. A quorum was established. Dr. Wong confirmed attendance after the last roll call.

Public Comment

Vu Phan, oncologist physician, highlighted a patient who had no issues with the new procedure but experienced a three-week delay in their treatment plan. Dr. Phan contrasted that experience to another patient who only received half of the medication and the practice had to supplement the medication with the risk of not being reimbursed. Dr. Phan provided a third patient who experienced a three-week delay and was so frustrated she paid for her own medication. A fourth patient couldn't afford the medication because it was run through the pharmacy benefit and not the medical benefit. Dr. Phan stated white bagging should be criminalized.

Becky Natali commented many HMOs are doing white bagging to reduce costs. Ms. Natali stated white bagging presents logistical issues, safety risks and delays in therapy due to the bifurcated system. She provided examples of patients arriving for treatment but the medication has not arrived. She stated it shouldn't be a pharmacy benefit because the patient cannot administer the medication that requires compounding and the provider is required to hold the medications. White bagging results in a lot of pharmaceutical waste and allows for fraud where the medication can end up in different channels.

Melissa Chase, Director of Pharmacy, Valley Children's Hospital, commented she has similar experiences with white bagging. Due to the limited access in the central valley of California, Valley Children's Hospital allows white bagging and has had to deal with the abrupt changes in policy. Ms. Chase provide written comment about a patient with Crohn's disease who had prior authorizations denied for Remicade but was able to get it approved through buy and bill for

two doses. After the second dose and weeks of delay, the second prior authorization was approved but the insurance required it be white bagged. Additional weeks went by as the specialty pharmacy was working on getting similar authorization. The specialty pharmacy was over 2,600 miles away from the hospital. The patient was able to receive great care initially but the implementation of the required white bagging by the insurance significantly delayed subsequent treatment.

Warren Fong, oncologist physician, representing the Medical Oncology Association of Southern California, commented the number of medication errors increase with the more people involved in the process. Dr. Fong stated the risk of contamination increases with time. He added another problem is centralization of prescription preparation increases the impact of error. He recalled the New England Compounding Center affected 14,000 doses in 23 states where 800 people became ill and over 100 people died. This does not happen then things are done locally. In Mississippi, a compounding pharmacist reduced the dose of Taxol to increase profit affecting thousands of people. Dr. Fong added when chemotherapy is provided, typically, it is provided with pre-medications and/or several chemotherapy drugs. If one medication is missing, the treatment can't be provided. He added oncology practices are in financial trouble and are closing because of this process. When chemotherapy is received, specialized equipment and nurses are needed that represent uncompensated costs when medications are received through the white bagging process. He added while this saves the insurance costs through vertical integration, the costs incurred by the providers is not represented.

Chad Morton provided a comment through the chat feature. Counsel Smiley provided it was allowable to read the comment to the record because of his audio issues. Dr. Serpa read his comment into the record, "How do we accommodate compassionate use medications that often times don't come directly from the manufacturer but from a vendor pharmacy?" Dr. Serpa indicated the question was not related to white bagging and encouraged him to contact via telephone to clarify his question.

Mark Johnston, CVS, commented white bagging has been in existence for decades and is not a new issue. He stated pharmacies, prescribers and hospitals have worked together without regulations to increase communication, modify policy and change operations to make white bagging work for the benefit of patients. He stated the accounts today are initial reactions to third-party changes. Medications from specialty pharmacies are considered dispensed. He stated CVS Specialty shipping pack out is much more scientific than the package utilized by the manufacturer shipping to wholesaler or the wholesaler shipping to the hospital or clinic. He stated cost, profitability and/or third-party billing is not within the jurisdiction of the Board. White bagging begins with

pharmaceutical manufacturering contract which is not within the Board's statutory authority. He stated the definition of the word dispensed is being twisted. He encouraged the Board and attorneys to assess board law relevance indicating President Lippe verified if hospitals accepted the same reimbursement, specialty pharmacy would not be needed. Third-party billing does cause delays but all parties try to prevent delays from happening. Removing costs from the discussion, he believes it can be resolved with increased communication and modification of inflexible operations.

Mr. Lippe clarified he asked a question if the facilities didn't mark up the drugs, would that take away the need for white bagging? He stated he wasn't endorsing any point of view for or against white bagging.

Sam Martinez commented on the Board's website the says it promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care. He stated we all agree this is not the highest quality of care with white bagging.

Dawn Holcombe, Medical Oncology Association of Southern California, stated members include hospitals and health care systems of all sizes as well as private medical groups and practices who provide cancer services. She noted additional information will be submitted for the record. Ms. Holcombe noted white bagging is not common place upon the county and if forced is in violation of California law – Health and Safety Code, Article 5, Standards 1367.22 (c) which requires plans purchase services in a manner providing continuity of care and demonstrate medical decision are made by qualified medical providers unhindered by fiscal or administrative management. White bagging puts both the providers and patients at risk and endangers patients. It creates added waste and violates California patient steering laws – Health and Safety Code, Division 1, Administration of Public Health 135 to 1179.102, part 1.9, Medical Referral Services 334-445.

Chad Morton commented a similar process exists for compassionate drug where patients are able to get essentially get free drugs from a manufacturer and it is sent to an infusion pharmacy as well. The process is used when a patient can't afford their medication and only available to private pay insurance patients and not Medicare or Medi-Cal patients.

Dr. Serpa thanked everyone for participation in the meeting today. She stated there certainly are issues with patient access to specialty medication and safety. She continued the issues between payers and providers are complex and noted considerations for opportunities available for the Board to address. She reported the committee will be providing a summary of this informational meeting as part

of the Board's April 29-30, 2021 meeting. She noted following the meeting, any addition activity by the Board will be announced.

IV. Adjournment

Chairperson Serpa adjourned the meeting at 4:26 p.m.