Medication Safety Committee Meeting

August 26, 2020

Conference Call

Dial:

800-882-3610

Passcode: 4206832#

Meeting Book - Medication Safety Committee Meeting

Medication Safety Committee Meeting Agenda - August 26, 2020

11:00 AM I. CALL TO ORDER/INTRODUCTIONS
O'Brien

11:05 am II. BUSINESS

A. Roundtable - Questions for you to consider with your comments
Bartleson

1. What COVID-19 issues are problematic/better?
2. Remdesivir distribution?
3. Critical Care Drug shortages?
4. PPE Issues?
5. Other

B. Remdesivir Update — Page 4
Bartleson

C. SNS Drug List — Page 8
Bartleson

D. ISMP and ENFit — Page 9
Bartleson

E. Whitebagging Update — Page 25
Bartleson

F. Legislation / Regulations
Bartleson

1. CHA ADDS Regulatory Comment Letter — Page 52
2. AB 1710 (Woods) — Page 54

12:00 pm III. EX OFFICIO REPORTS

A. CDPH Update
Woo

B. CSHP Update
DeMartini

C. Board of Pharmacy Update
Sodergren

1. List of Waivers — Page 57

2. Link to Waivers on Board of Pharmacy Website

IV. INFORMATION

V. NEXT MEETING

A. November 11, 2020

1:00 pm VI. ADJOURNMENT

California Health and Human Services
Remdesivir Distribution Fact Sheet

June 30, 2020

Remdesivir is the only antiviral effective against COVID-19 in a clinical trial. This intravenous investigational drug inhibits viral RNA polymerase. The supply of remdesivir is limited. Clinical trial data have shown equivalent outcomes with 5 days of treatment compared with 10 days of treatment[i] and better outcomes in people who started treatment before requiring mechanical ventilation[ii]. Treating for 5 days and treating people with severe illness early before they require mechanical ventilation could maximize the public health benefit of remdesivir.

Additional clinical trial data:

- NIH's Adaptive COVID-19 Treatment Trial (1,059 participants) reported a 32% faster time to recovery (11 days vs. 15 days) for participants who received remdesivir compared with those who received placebo ($p<0.001$). Results also suggested a survival benefit, with a mortality rate of 7.1% for the group receiving remdesivir versus 11.9% for the placebo group ($p=0.059$). In a subgroup analysis, participants with hypoxemia who required oxygen therapy but not mechanical ventilation (or high-flow oxygen or noninvasive ventilation) had the most benefit.
- A Gilead remdesivir clinical trial (397 participants) reported equivalent rates of clinical improvement among participants with severe COVID-19 illness (oxygen saturation $\leq$ 94% or receiving supplemental oxygen) but not requiring mechanical ventilation who were randomized to a 5-day or 10-day treatment course. Another Gilead remdesivir clinical trial (584 participants) reported improved clinical outcomes in patients with moderate COVID-19 illness (hospitalized but not requiring oxygen) who received a 5-day treatment course compared with standard care.
- Study conducted in China (236 participants) showed no difference in time to recovery except a trend toward faster recovery in participants treated early (within 10 days of symptoms onset) [iii].
- The benefit of remdesivir and optimal duration of treatment in people with severe COVID-19 illness who require mechanical ventilation is still being evaluated. In Gilead's trial, among participants who progressed to require mechanical ventilation on day 5, the mortality rate was 40% in the 5-day group compared with 17% in the 10-day group.

FDA issued an emergency use authorization (EUA) on May 1, 2020

The fact sheet for health care providers reviews the full conditions of use[iv], and should be reviewed prior to administration of the medication.

The EUA allows treatment of COVID-19 in adults and children hospitalized with severe disease (defined as a low blood oxygen level (oxygen saturation ≤ 94%), needing oxygen therapy, or requiring mechanical ventilation or extracorporeal membrane oxygenation (ECMO).

EUA conditions of use include that:

- Empiric treatment of hospitalized patients with suspected COVID-19 can be considered pending laboratory confirmation of COVID-19 infection.
- Remdesivir is administered by intravenous infusion of 200 mg on Day 1 followed by 100 mg/day.
- A 5 day treatment course is recommended for adults and pediatric patients not requiring invasive mechanical ventilation or ECMO. Treatment may be extended up to 10 days if not showing clinical improvement.
- A 10 day treatment course is recommended for adult and pediatric patients requiring invasive mechanical ventilation or ECMO.
- All patients must have an estimated glomerular filtration rate (eGFR) determined and hepatic laboratory testing performed before dosing.
- Health care providers are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths considered to be potentially attributable to remdesivir.
- Health care providers must communicate information consistent with the "Fact Sheet for Patients and Parents/Caregivers"[v] (and provide a copy) prior to the patient receiving remdesivir.
- Hepatic laboratory testing should be performed daily while receiving remdesivir. Remdesivir should be discontinued in patients who develop an ALT ≥ 5 times the upper limit of normal or an ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR. Grade 3 or 4 hepatic laboratory abnormalities were reported in approximately 5% of participants receiving remdesivir in Gilead's clinical trial.

Allocation of remdesivir for EUA use

Access to remdesivir is currently being coordinated by the U.S. government and being distributed by AmerisourceBergen. Allotments of donated remdesivir are being sent to the state of California every two weeks until the full inventory of donated remdesivir has been allocated during the week of June 29th. Each allotment is then allocated to hospitals in California via the counties' Medical and Health Operational Area Coordinator (MHOAC) based on the current census of hospitalized patients with confirmed COVID-19.

Beginning in July (after the donated supply of remdesivir has been allocated), hospitals will be charged no more than the Wholesale Acquisition Price (WAC) for remdesivir. Gilead has announced that the Wholesale Acquisition Price (WAC) is $520 per vial adding up to $3,120 for a five-day treatment course[vi]. The federal government with input from state governments will continue to direct the allocation of remdesivir supply from July to September. Hospitals will receive the product shipped directly from AmerisourceBergen instead of from the MHOACs. Details on the distribution process are posted on the California Department of Public Health's website.

As the supply of remdesivir is limited, facilities should consider an ethical framework for distribution and refer to CHHS's Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19. Considerations for allocation include:

- A clinical prioritization team to make allocation decisions that is distinct from the clinicians providing direct care is recommended to protect the integrity of the patient-provider relationship and to ensure that decisions are fair and consistent.
- Withholding or reserving remdesivir for future use is not recommended, particularly if there are current patients presenting with severe illness.
- If patients receiving remdesivir are transferred to another hospital, their remaining doses of remdesivir should transfer with them.
- Children and pregnant mothers are still eligible to receive remdesivir through compassionate use from Gilead (instead of the donated supply).
- Patients who have already received remdesivir should not be eligible to receive additional doses from this donated allocation.

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[i] Goldman JD, Lye DCB, Hui DS, et al. Remdesivir for 5 or 10 days in patients with severe Covid-19. N Engl J Med. DOI: 10.1056/NEJMoa2015301.

[ii] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the treatment of Covid-19 — preliminary report. N Engl J Med. DOI: 10.1056/NEJMoa2007764.

[iii] Wang Y, Zhang D, Du G, et al. Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial. Lancet. Published online April 29, 2020. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext

[iv] FDA Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734™). Accessed May 8, 2020. https://www.fda.gov/media/137566/download

[v] FDA Fact Sheet for Patients and Parents/Caregivers. Accessed May 8, 2020. https://www.fda.gov/media/137565/download

[vi] Open Letter from Gilead, June 29, 2020. Accessed June 29, 2020. https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29

Remdesivir Payment Summary

Reimbursement will depend on the payor. For Medicare, reimbursement is part of the DRG claims. Most commercial insurance, there are no differences with reimbursement as to other prescriptions. For Medi-Cal, because Remdesivir is an FDA approved drug, it will be reimbursable. If you are a 340B provider, there are limitations with the reimbursement. If reimbursed in the outpatient setting, reimbursement is limited to acquisition cost, plus a dispensing (FFS delivery system). Until January 1, 2021, for Medi-Cal managed care, it depends on the reimbursements negotiated between the plans and the hospitals. Post January 1, 2021, the reimbursement is AAC+dispensing. Inpatient claims it's part of the DRG claim, or subject to negotiations with plans.

Proposed Pharmaceuticals to be stored in the Strategic National Stockpile (SNS)	
Medication	**Norepinephrine**
Hydromorphone	**Dobutamine**
Ciprofloxacin	**Dopamine**
Rocuronium	**Vancomycin**
Doxycycline	**Atropine**
Levofloxacin	**Cisatracurium**
Cefepime	**Dexmedetomidine**
Enoxaparin	**Fentanyl**
UF Heparin	**Midazolam**
Ondansetron	**Morphine**
Meropenem	**Propofol**
Tazobactam (Zosyn)	**Dexamethasone**
Piperacillin (Zosyn)	

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ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Last week, ISMP celebrated our 22nd Annual **CHEERS AWARDS**, which recognize organizations, groups, and individuals who have demonstrated an extraordinary commitment to advancing patient safety. This year's winners were honored at a dinner held at Stoney's Rockin' Country in Las Vegas, NV, on December 10, 2019. Please join us in congratulating this impressive group of leaders who have played their cards well to create innovative projects, programs, educational efforts, and research to prevent medication errors and improve the safety of patient care.

CHEERS AWARDS Winners

For more than 28 years, the **Anticoagulation (AC) Forum** (www.ismp.org/ext/330) has been educating healthcare professionals and advocating for clinical best practices in the field of anticoagulation therapy. Founded in 1991, the AC Forum has a membership of 12,000 pharmacists, physicians, and nurses, representing more than 3,000 anticoagulation practice sites that support more than 1 million patients annually. The AC Forum's flagship program, the Anticoagulation Centers of Excellence, provides access to tools, guidelines, assessments, current literature, patient and family educational materials, and many other resources to improve patient outcomes through application of evidence-based best practices.

The AC Forum recently released a US Food and Drug Administration (FDA)-funded report, *Core Elements of Anticoagulation Stewardship Programs*, similar to successful stewardship campaigns involving antibiotics. The anticoagulation stewardship guide outlines ways to improve the safety and quality of patient care and reduce adverse drug events associated with anticoagulants. The guide defines 7 core elements for implementing anticoagulation stewardship programs, starting with securing administrative leadership commitment and ending with advancing education, comprehension, and competency. It also includes a checklist for evaluating current practices and a gap analysis that identifies weaknesses in oversight modalities (i.e., regulations and quality measures) for hospitals and skilled nursing facilities. The guide is available for download via the AC Forum's website. There is no cost to join the AC Forum and all resources are free of charge.

Boston Children's Hospital (www.ismp.org/ext/331) has developed a unique tiered system to respond to external medication recalls that may cause harm to patients. Staff found that pediatric patients taking certain outpatient medications at home often were not contacted when major recalls occurred and, in some cases, could be disproportionately harmed. For example, when blood pressure medications were found in leukotriene receptor antagonist containers, a single dose of the antihypertensive would be unlikely to harm most adults but could injure a child. Therefore, in 2018, the hospital pharmacy staff created an external medication recall management system to notify pediatric patients and their caregivers when significant recalls occur.

Since then, 251 recalls have been logged into the system, some involving multiple medications. Five of the recalls required an immediate response due to risk of significant

continued on page 2 — CHEERS >

SAFETY briefs

Legacy feeding tubes, administration sets, and transition adapters going away. The Global Enteral Device Supplier Association (GEDSA) has announced that member manufacturers will begin phasing out the manufacturing of legacy feeding tubes starting July 1, 2020. Also, on January 1, 2021, there will be an industry-wide discontinuation of transition adapters, including those sold singly or now attached to ENFit feeding sets (**Figures 1** and **2**), as these will no longer be needed. These moves will essentially force the adoption of ENFit, a global standard that was established to reduce the risk of enteral feeding set and syringe misconnections with vascular lines or other

continued on page 2 — SAFETY briefs >

Figure 1. ENFit feeding set used for enteral feedings. Note the white transition adapter that fits legacy feeding tubes. The adapter, removed in this photo, now accompanies feeding sets but will not after 2021.

Figure 2. Transition adapter on ENFit administration set fits legacy gastrojejunostomy feeding tube. These and other legacy feeding tubes will no longer be manufactured after July 1, 2020, and will be replaced by tubing with ENFit connectors.

> CHEERS — continued from page 1

patient harm. Notifications have included direct patient or caregiver contact, calling retail pharmacies, messaging by mail and email, and communication via patient portals and external webpages. The communication with retail pharmacies about the recalls has had the additional benefit of helping alert outpatient pharmacy customers who were not patients of Boston Children's Hospital. Since most of the recalls have involved medications that were not on the hospital formulary and were not dispensed to hospitalized patients, the outpatient pediatric population may not have known about the significant recall without this notification program.

Special Recognition

The **Arizona Safe Medication Collaborative Team** received special recognition during the 2019 **Cheers Awards** for its timely and persistent statewide advocacy for adult IV push medication safety. In just 10 months, the team has been able to pull together key stakeholders in Arizona to advocate for the adoption of best practices, including those reflected in the *ISMP Safe Practice Guidelines for Adult IV Push Medications* (www.ismp.org/node/97).

Surveys have been conducted with clinical nurse faculty and bedside nurses to determine what clinicians are being taught and variations in IV push practices, and an IV push competency checklist has been developed to assist with verifying skills and reinforcing knowledge. The team also contacted *Micromedex* and the *Davis's Drug Guide* and secured their agreement to update their references using the ISMP guidelines. This dedicated group of advocates is currently working with the Arizona State Board of Nursing Scope of Practice Committee to obtain an official advisory opinion to adopt the ISMP guidelines. The team has been invited to draft the opinion, which was recently presented to the Board. Their grassroots effort has made significant progress in addressing a difficult and longstanding medication safety issue and can serve as a catalyst for change in other states as well.

GEORGE DI DOMIZIO AWARD Winner

The **George Di Domizio Award** was established in 2012 in memory of a late ISMP trustee who advocated for greater cooperation between the medical industry and the broader healthcare community to promote safer drug products. This year's **George Di Domizio Award** was presented to **Dennis Tribble, PharmD, FASHP**.

Dr. Tribble has shown extraordinary leadership in developing innovative technology for safe medication preparation and delivery. He has more than 30 years of experience in the field, first in hospital pharmacy management and then with the medication management automation industry. He holds more than 30 patents in healthcare automation, including the development of the first IV robotic device and the first IV workflow software. He was an early proponent of barcoding to improve the accuracy of pharmacy compounding and bedside medication administration. Dr. Tribble has served as an advisor for the *ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations*. He is known not only for his expertise in pharmacy automation, but also for his openness, objectivity, and honesty in responding to safety-related issues.

Dr. Tribble is a founding member of the Healthcare Information and Management Systems Society Pharmacy Informatics Task Force and past chair of the American Society of Health-System Pharmacists Section of Pharmacy Informatics and Technology. He has also worked with the nonprofit Emily Jerry Foundation on increasing awareness of the need for technological solutions to reduce the risk of medication errors. He is currently Director of Medical Affairs for the Medication Management Systems at BD.

continued on page 3 — CHEERS >

> SAFETY briefs cont'd from page 1

clinical tubing connections (e.g., irrigation lines, neuraxial access sites). Provider organizations that have yet to convert to ENFit are urged to develop plans to do so as soon as possible. Also, it is important to ensure that this information is communicated to the broader healthcare community in your organization, including purchasers and clinical personnel, such as pharmacists, nurses, interventional radiologists, and physicians who insert gastrointestinal tubes. For additional information, be sure to communicate with your enteral feeding supplier and regularly access the GEDSA Stay Connected website (www.gedsa.org).

HIGH-ALERT **ADC vendors to provide important new safety enhancement.** Many medication information technology-related errors happen when just the first few letter characters of a drug name are used to select the intended medication from screen listings. For example, readers will recall that our first newsletter in 2019 (www.ismp.org/node/1326) described a tragic error involving a woman with a brain hematoma who was sent to radiology from a neurological step-down unit for a positron emission tomography (PET) scan. The woman requested medication to help ease her anxiety, which led to an order for **VERSED** (midazolam). A nurse was called to radiology to bring the drug and administer it to the patient. To obtain "Versed" (a brand no longer marketed) from the step-down unit's automated dispensing cabinet (ADC), the nurse typed just the first 2 letter characters, "V-E," of the drug name. However, the drug did not appear on the ADC screen because the cabinet was set to retrieve drugs by the generic name—midazolam. The nurse then set the ADC to override and again typed "V-E" into the search field, this time retrieving vecuronium instead of what she thought was Versed. The nurse went to radiology and injected the vecuronium intravenously, not realizing she was administering a paralyzing agent. The unmonitored, unventilated patient stopped breathing, was unable to call for help, and died.

Typing at least 5 letter characters (instead of 2 or 3) most often limits similar names from appearing together on the same

continued on page 3 — SAFETY briefs >

The next newsletter will be published in 2020 on January 16. See you next year!

> CHEERS — continued from page 2

LIFETIME ACHIEVEMENT AWARD Winner

The ISMP **LIFETIME ACHIEVEMENT AWARD**, given in memory of ISMP's late Trustee David Vogel, PharmD, honors individuals who have made ongoing contributions to patient safety throughout their career. This year's **LIFETIME ACHIEVEMENT AWARD** was presented to **Rita Shane, PharmD, FASHP, FCSHP**.

Dr. Shane has dedicated her more than 40 years of professional work to making medication use safer for patients by taking an evidence-based approach to developing innovative practices. She is currently Chief Pharmacy Officer and Professor of Medicine at Cedars-Sinai Medical Center in Los Angeles, California, and Assistant Dean of Clinical Pharmacy Services at the University of California-San Francisco School of Pharmacy.

In 2018, she co-authored legislation requiring hospital pharmacists in California to obtain medication lists for high-risk patients when they are admitted and again when they are discharged. Dr. Shane has collaborated on research that led to the approval of "tech-check-tech" by the California State Board of Pharmacy for technician-filled medication cassettes in hospitals. She introduced the concept of high-alert patients and, recently, laid bare the risks to patients caused by payer-driven biosimilar requirements (www.ismp.org/node/1524). She was also one of the investigators in a multicenter study of medication errors that were prevented by emergency department pharmacists.

Dr. Shane has won numerous professional awards, including three awards from the American Society of Health-System Pharmacists—the Harvey A.K. Whitney Award, Leadership Award, and Honorary Membership Award. She has been listed among the "50 Experts Leading the Field of Patient Safety" by *Becker's Hospital Review,* published more than 100 papers, and given more than 200 presentations nationally and internationally.

CHEERS AWARDS Keynote Presentation

The keynote speaker for the 22nd Annual **CHEERS AWARDS** was **Marcus Schabacker, MD, PhD**, Chief Executive Officer and President of the ECRI Institute (www.ecri.org). Dr. Schabacker spoke about some of the biggest challenges facing the healthcare industry, such as the move of care delivery from the hospital to the home, aging populations and the rise of chronic diseases, significant shortages of healthcare professionals, and the persistence of medical errors. To address these problems, he expanded on the potential for emerging technology and a digital health ecosystem to help support clinicians and provide safe, secure, private, and validated healthcare that is accessible to everyone. Noting that consumers are already using digital health tools—from mobile technology to remote monitoring—he emphasized the need to overcome current digital health challenges such as poor-quality data, the negative impact on provider productivity, and potential security and privacy breaches of protected patient data. He stressed the growing need for independent, fact-based, and transparent evaluation of new technologies to ensure the quality of care and patient safety. Dr. Schabacker also addressed ISMP's new affiliation with ECRI, pointing out ways that joining forces will make both organizations even stronger and better able to serve their common missions.

Thanks for Another Wonderful Year!

We would like to thank the organizations and individuals who attended and/or supported this year's **CHEERS AWARDS** dinner. It was a fun evening, and the entertainment included old Las Vegas music and casino tables that lured all to try their hands at poker, blackjack, and roulette. Luckily, at this event, everyone was a winner for patient safety. Visit www.ismp.org/cheers-awards for a list of contributors and winners, and www.ismp.org/support for ways you can help ISMP continue the fight against preventable medication errors. We look forward to another great year of working together to improve medication safety in 2020.

> SAFETY briefs cont'd from page 2

screen. In January 2019, we called upon vendors to consider software changes to allow a configurable option for the required number of letters to narrow the choices, ideally to one drug or drug category. At the time, both Omnicell and BD/Pyxis agreed to investigate incorporating that into their software. This recommendation is also in two of our guideline publications (***Guidelines for the Safe Use of Automated Dispensing Cabinets***, page 9, statement 4.4 [www.ismp.org/ext/328] and ***ISMP Guidelines for Safe Electronic Communication of Medication Information***, page 4, statement 19 [www.ismp.org/ext/329]).

The good news is that Omnicell announced last week that new search functionality for the XT ADC is being implemented in support of our guidelines calling for a 5-character search. Thus, a unique drug name will likely appear on the screen. Also, in communication with BD/Pyxis, we have learned that they, too, will make enhancements during their next software release. ISMP thanks and congratulates both companies for their response.

HIGH-ALERT

Use methotrexate oral solution only with great caution. You may not be aware that there is a methotrexate oral solution (**XATMEP**) that is meant for pediatric use. The drug is indicated for the treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen. The product is also approved for use in pediatric patients with polyarticular juvenile idiopathic arthritis who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents. Each mL of the solution contains 2.5 mg of methotrexate. Given that parents sometimes measure liquid doses incorrectly, especially when using teaspoons that vary in volume and dosing cups that may have a nonmetric scale, it is frightening to dispense a 120 mL bottle of methotrexate (2.5 mg/mL) for home use.

All oral liquids should be dispensed with an appropriate dosing device, such as an oral syringe that measures in metric units only, so parents can measure liquid medications accurately. It would be nice if the

continued on page 4 — SAFETY briefs >

FDA Advise-ERR Taking Crysvita with active vitamin D analogs is contraindicated

CRYSVITA (burosumab-twza) injection, approved by the US Food and Drug Administration (FDA) in April 2018, is a fibroblast growth factor 23 (FGF23) blocking antibody used to treat X-linked hypophosphatemia (XLH) in patients 6 months and older. XLH is caused by excess FGF23, which suppresses renal tubular phosphate reabsorption and renal production of 1,25-dihydroxyvitamin D. Before Crysvita, treatment with oral phosphates and active vitamin D was the standard of care for XLH.

Crysvita is contraindicated with concomitant use of oral phosphates and/or active vitamin D analogs (**Table 1**). Concomitant use will increase phosphate concentrations greater than with Crysvita alone, which may result in hyperphosphatemia that can induce nephrocalcinosis. Cholecalciferol (D_3) and ergocalciferol (D_2), used for nutritional vitamin D deficiency, are not contraindicated with Crysvita. In fact, supplementation with cholecalciferol or ergocalciferol is recommended to maintain normal 25-hydroxyvitamin D levels.

Table 1. Active Vitamin D Analogs Contraindicated with Crysvita

Active Vitamin D Analogs
calcitriol (**ROCALTROL**)
paricalcitol (**ZEMPLAR**)
doxercalciferol (**HECTOROL**)
calcifediol (**RAYALDEE**)

FDA has received 70 reports of concomitant use of Crysvita and a vitamin D product. Of the 58 reports that specify the product involved, 57% describe cholecalciferol or ergocalciferol, which are not contraindicated, and 43% describe a true contraindication with an active vitamin D analog, mainly calcitriol. Thus, more than half of the reports indicate a lack of understanding of which vitamin D products are contraindicated.

In September 2019, FDA updated the Crysvita prescribing information to specify the active vitamin D analogs to discontinue 1 week prior to initiation (**Table 1**). A drug interaction section was also added describing possible hyperphosphatemia, which can induce nephrocalcinosis as a result of increased phosphate concentrations from concomitant use of Crysvita with oral phosphates and/or active vitamin D analogs.

To help prevent the concomitant use of Crysvita and oral phosphates and/or active vitamin D analogs:

For Prescribers, Pharmacists, and Nurses

- Educate practitioners about active vitamin D analogs (calcitriol, paricalcitol, doxercalciferol, calcifediol) and their contraindication for use with Crysvita.
- Prior to prescribing, dispensing, and administering Crysvita, determine whether patients are taking oral phosphates and/or active vitamin D analogs. Review the patients' medication regimen in the medical record and with the patient, and conduct a thorough medication reconciliation.
- Ensure that patients have discontinued oral phosphates or active vitamin D analogs for 1 week before starting Crysvita, and that they do not restart these products while taking Crysvita. (Crysvita is administered every 2 or 4 weeks; oral phosphates and active vitamin D analogs should be avoided throughout this time and until fasting serum phosphorus has been reassessed.)
- Work with information technology (IT) to create order entry system alerts for concomitant use of Crysvita and oral phosphates or active vitamin D analogs.
- Educate patients about the importance of not taking oral phosphates or active vitamin D analogs while receiving Crysvita injections (even between injections).

For Insurers

- Create alerts to warn against the concomitant use of Crysvita and oral phosphates or active vitamin D analogs (calcitriol, paricalcitol, doxercalciferol, calcifediol) when claims are submitted for both drugs.

ISMP thanks Celeste Karpow, PharmD, MPH, FISMP, and Briana Rider, PharmD, CPPS, FISMP, from the FDA Division of Medication Error Prevention and Analysis, for contributing this article.

> SAFETY briefs cont'd from page 3

manufacturer provided an oral syringe. Also, it is critically important to educate parents about dose measurement using the teach-back method to demonstrate how they will measure each dose accurately. If parents are given a prescription for oral methotrexate liquid to be filled at a community pharmacy, product labeling recommends telling them to ask their pharmacist for a proper measuring device and demonstration. However, from a patient safety standpoint, this drug is best provided to parents in compounded, prefilled oral syringes containing the exact dose. Because community pharmacies are rarely set up to fill and dispense pharmacy-prepared syringes of oral methotrexate (four syringes per month when dosed weekly), this may fall upon the hospital pharmacy or would need to be arranged through an outsourcer. When educating parents or caregivers, healthcare practitioners should emphasize that the recommended dose should be taken one time *weekly* (for either labeled indication, ALL and polyarticular juvenile idiopathic arthritis) and that daily use of the recommended dose has led to fatal toxicity.

Given that this is a chemotherapeutic agent and a hazardous drug, there are concerns with manipulating the drug and discarding unused drug and used syringes. This is a subject beyond the scope of this safety brief but nevertheless a concern, especially with parents handling the drug in the home.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Special Recognition... Our 2019 Acute Care *ISMP Medication Safety Alert!* Advisory Board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2019 nears an end, we want to thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

- **Ivyruth Andreica**, PharmD, BSN, FISMP, Ivenix, Inc., North Andover, MA
- **Michelle Bell**, RN, BSN, FISMP, CPPS, Patient Safety Authority, Harrisburg, PA
- **Kelly Besco**, PharmD, FISMP, CPPS, OhioHealth, Columbus, OH
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- **Linda Cohen**, RN, MPH, MSN, CDE, BC-ADM, SUNY Downstate Medical Center, Brooklyn, NY
- **Bob Feroli**, PharmD, FASHP, Armstrong Institute, Johns Hopkins, Baltimore, MD
- **Michael Ganio**, PharmD, MS, FASHP, American Society of Health-System Pharmacists, Bethesda, MD
- **John Gosbee**, MD, MS, Red Forest Consulting & University of Michigan, Ann Arbor, MI
- **Peggi Guenter**, PhD, RN, FAAN, FASPEN, American Society for Parenteral and Enteral Nutrition (ASPEN), Silver Spring, MD
- **Roy Guharoy**, PharmD, MBA, FCCP, FASHP, Baptist Health, Montgomery, AL
- **Beverly Holcombe**, PharmD, BCNSP, FASHP, FASPEN, American Society for Parenteral and Enteral Nutrition (ASPEN), Silver Spring, MD
- **Caren Hughes**, PharmD, BCOP, Mayo Clinic, Jacksonville, FL
- **Jane Jeffrie Seley**, DNP, MSN, MPH, GNP, BC-ADM, CDE, CDTC, FAAN, FAADE, New York-Presbyterian Hospital/Weill Cornell Medicine, New York, NY
- **Russell Jenkins**, MD, Medical Director ISMP, Emeritus, Gilbert, AZ
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- **Steve Meisel**, PharmD, CPPS, M Health Fairview, Minneapolis, MN
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- **Rachel Meyers,** PharmD, BCPS, BCPPS, FPPA, Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey, and Saint Barnabas Medical Center, Livingston, NJ
- **Raymond Muller**, RPh, MS, FASHP, Memorial Sloan-Kettering Cancer Center, New York, NY
- **Edward Murray**, PharmD, MBA, BCPS, HCA Healthcare, Inc., Nashville, TN
- **Shawn Osborne**, PharmD, MBA, University Hospitals Health System, Cleveland, OH
- **María José Otero**, PhD, PharmD, ISMP-Spain, Salamanca, Spain
- **Thomas Paparella**, DO, Lawn Avenue Medical Associates, Grand View Health, Sellersville, PA
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- **James Rinehart**, RPh, MS, FASHP, Winovation Associates LLC, Indianapolis, IN
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- **Elizabeth Wade**, PharmD, BCPS, FASHP, Concord Hospital, Concord, NH
- **Mandy Wollitz**, PharmD, BCPS, FISMP, AdventHealth Orlando, Orlando, FL

Happy Holidays

from the staff and trustees at the Institute for Safe Medication Practices. We wish you joy, health, and happiness this holiday season!

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 11, 2019

TO: Certification and Licensing Committee Members

FROM: BJ Bartleson, RN, MS, NEA-BC, Vice President Nursing & Clinical Services

SUBJECT: ENFit Tubing Connectors

SUMMARY

CHA received a query on hospital ENFit compliance that was generated from a story in Plastics News on hospital compliance. We replied from a survey you assisted with a year ago and in response we submitted an additional survey to you to get a glimpse of progress. Below are the survey results. It would appear we are slightly more compliant.

August,2019	**Tubing Connector Survey**	
Compliant	**If not, why**	**Comments**
no	process incomplete due to supplies	
no	Vendors contacted over the past 2 years did not have enough product to support a conversion	we are planning to begin implementation on 10/1/19
No	COH is not 100% compliance with the ENFit requirement. During the initial discussion with our vendors, they did not have the full scope of products. Therefore, we did not want to be the first one to convert over and cause issues for our staff and patients. We are working with our vendor partners to determine their product line health status to start our conversation effort again	
no	Manufacturers' delays in product conversion.	
yes		
yes		

No	B.D. does not make an ENFit G and J tube	when all enteral products are available without connectors we will transition.
yes		
yes		
yes		
yes		compliant since 2017
yes		
yes		
yes		
Yes (to the extent we can be, but not fully - a few outliers)	We have converted all of our feeding bags, tubing, and medication syringes to ENFit. There are some medications that we purchase from outsourcing pharmacy that have not yet been able to begin using ENFit devices.	There have been backorders and shortages of medication syringes from our current vendor-NeoMed. Additionally, there have been some published data to suggest that the dosing accuracy of the ENFit is highly variable. Additionally, not all oral meds are able to be drawn up by ENFit compatible devices (e.g., oral hazardous meds with stopper in bottle neck). Not all the administration adapters are suitable for use in neonatal patients based on feedback from nursing.

DISCUSSION QUESTIONS

1. What organizations have CHA been working with on this topic?
2. What are the regulatory requirements and what bill generated the specific dates? Have these dates been modified or extended?
3. Besides the inability to get the equipment, are there other patient care issues at play?
4. What if anything needs to be addressed?

Attachment: ENFit Rollout Hits Snag in United States, Plastics News, 9-3-18

BJB:br

Plastics News

February 14, 2018 01:00 AM

ENFit rollout hits snags in the United States

CATHERINE KAVANAUGH

Xeridium Medical Devices

A sweeping series of changes to ISO standards for feeding tube connectors are intended to reduce the possibilities of a deadly mixup, but some users of feeding tubes are rejecting the move.

Concerns about supply, dosing and blenderized diets is delaying the U.S. transition to a new standard for feeding tube connectors.

Concerns about supply, dosing and blenderized diets are delaying the U.S. transition to a new standard for feeding tube connectors.

The sweeping series of ISO 80369 standards were developed to prevent deadly medical mistakes. The standard would make small-bore connectors for tubes used for feeding, neuraxial, respiratory, intravenous, urethral and urinary devices incompatible. That means nutrients, medicines, gases and fluids won't be delivered to the wrong tubing system.

Adoption of the international standard is nearly complete in the United Kingdom and Netherlands and at the midpoint in Australia and New Zealand.

Delays and resistance

Small-bore connectors join medical components that have an inner diameter less than 8.5 mm to deliver fluids and gases. The connectors are made of plastics, including medical-grade ABS.

In addition to safety, advocates say the global standard will improve continuity of care regardless of a traveling patient's location and the health care facility's supplier.

However, the effort to implement the section of the standard that covers feeding tubes and gastric applications (ISO 80369-3) has met some delays and resistance in the United States.

Supply concerns linger about the only small-bore connectors on the market to meet the standard. Questions also have been raised about dosing accuracy. And, some patients are worried about losing legacy products with large inner diameters for homemade blenderized diets.

A nonprofit trade group of medical device manufacturers and suppliers was formed in 2013 to help the health care community make the transition to the new standards through an initiative called Stayed Connected. Based in Columbus, Ohio, the Global Enteral Device Supplier Association (GEDSA) urges compliance through adoption of connectors called ENFit, which is a GEDSA trademark that defines enteral connectors with a female-to-male orientation.

To prevent misconnections, the ENFit design reverses the traditional orientation of the small-bore connectors, which join components of feeding systems like syringes for drainage, hydration and medication as well as administration sets for either pump, gravity or bolus feeding.

The ENFit system has syringes and administration sets with female connectors that fit around the male connectors on the feeding tube. The connectors are distinctly designed for enteral use and are physically incompatible with other delivery systems.

The ENFit connectors currently are the only ones on the market that comply with the international standard, but adoption has been slow in the United States, which has 5,534 registered hospitals. Although the U.S. Food and Drug Administration recognizes the standard as a way to improve patient safety, compliance is encouraged, not required.

Currently, California is the only state to mandate the switch and set deadlines, although those dates have come and gone. The last one was July 1, 2016, according to Thomas Hancock, the out-going executive director of GEDSA.

"Despite the deadline, adoption has been limited to date. Perhaps the biggest concern cited for lack of adoption has been concern over limited supply in the U.S.," Hancock said in a phone interview.

Many health care systems have been waiting for manufacturers to build up complete inventories of ENFit components — administration sets, feeding tubes and syringes — in various sizes before changing over to the ENFit connectors. In the meantime, they are using transition connectors, which allow backward compatibility with existing inventory during the changeover phase.

"Some supply concerns stemmed from some of the bigger manufacturers that may not have had every syringe size or tube type hospitals needed," Hancock said. "We believe these concerns have been resolved and things should be moving forward."

Major health care systems, like the Mayo Clinic and Cleveland Clinic, and about 250 U.S. hospitals, have converted or will go live in the first quarter of 2018, Hancock said. And, in the state that is farthest along, the California Hospital Association says 22 percent of hospitals have completed the transition, 66 percent are beyond the halfway mark and 12 percent are in the early stages.

Manufacturers like Xeridiem Medical Devices, a GEDSA member based in Tuscon, Ariz., and part of Spectrum Plastics Group, say they have been ready for a U.S. transition but had been shipping product mostly outside the country until recently.

"Orders have picked up in the U.S. for products with ENFit connectors in Q1, so we're starting to see adoption in the U.S. take shape," Paul Melnychuck, senior director of business development and innovation, said in an email.

Not all enteral device manufacturers belong to GEDSA but the group has more than 30 members, including Baxter, Cook Medical, Boston Scientific, Halyard, Medtronic, NeoMed and Vesco Medical LLC, which Hancock helped start.

GEDSA members also use the trademark of NRFit for neuraxial tube systems.

'Important' concerns

Another major manufacturer, Becton, Dickinson and Co. (BD), said it is moving forward with the new design standards for neuroaxial products for spinals but has design concerns about the female ENFit syringe and low-dose tip (LDT) syringe.

A BD spokesman pointed to the Franklin Lakes, N.J.-based company's latest public statements about the decision, which went out to customers as letters in fall 2016.

"In the enteral space, after a design was settled on by ISO and industry began planning for launch, BD learned of important patient safety concerns about dose accuracy from the

clinical community — concerns that required a second look at the planned enteral connector design," one letter said.

The letters also say the ENFit designs for the two syringes don't perform as well as products already on the market, including its own, and could put vulnerable patients in harm's way, especially newborns.

BD told GEDSA that it is pursuing a male enteral syringe design that complies with the connector standard as well as defined dosage accuracy.

Hancock said he thinks BD's concerns were raised for competitive reasons. Some are related to a preliminary study based on prototype mockups that were later found to be "out of tolerance," he added. When fully validated, scaled production products were tested, Hancock said, performance concerns were completely resolved.

GEDSA's response to BD's concerns was posted on its website in a Nov. 8, 2016, letter. Regarding questions about small-volume dose accuracy, GEDSA says industry experts came up with an ENFit LTD syringe that performance tests show is "substantially equivalent" to other syringes. FDA has granted clearance for at least five manufacturers since testing was completed.

In response to another concern of U.S. clinicians, Hancock said GEDSA will publish a cleaning protocol supported by third-party testing for feeding tubes with ENFit connectors.

With the adoption rate of ENFit at 70-90 percent in many countries and no adverse events reported, Hancock said he is confident the system is "an ideal solution" for all patients, even those in neonatal intensive care units.

Seeking action

Other countries have not faced rollout issues and delays.

"Look deeper at the U.K.," Hancock said. "The reason why they are 95 percent converted is the national health system there got behind the change. They set deadlines and got manufacturers to agree, and if they didn't participate, they were out of a contract."

Hancock said he will suggest U.S. decisionmakers look at the new design standard as a quality issue that needs to be addressed with strong words of encouragement or even mandates and deadlines — at least for the majority of patients. Then, enforcement would likely follow.

GEDSA recommends that FDA set a deadline for health care systems to remove legacy tubes and transition connectors; the Joint Commission, which certifies 21,000 health care organizations, reissue its alert with stronger language that encourages adoption; and the Centers for Medicare & Medicaid Services (CMS) consider reimbursement for ENfit medical devices but not legacy tubes or transition connectors.

Although he does not think the latter recommendation is very likely, Hancock said GEDSA is pushing for the strongest language from CMS because of the tubing misconnection safety issue and problems that would persist with multiple enteral systems in the market.

The recommendations have drawn further ire from an opposition group called Tubies Against ENFit, who see them as attempts to create market demand for ENFit products while discriminating against patients that use legacy devices.

This group says tubies, as the patients call themselves, depend on the wide range of products sold now and oppose being forced to switch to the ENFit design.

Sanford Flach, one of the founders and a retired Navy master chief, has been tube-feeding about four years following radiation treatment for tongue and throat cancer. Like a growing number of tubies, he prefers blenderized meals, which tend to be thicker than commercial formulas.

Flach and others are concerned about the inner diameter of the ENFit connectors. These tubies point to ISO charts that show a 2.9-mm inner diameter (ID) while they currently use products with IDs up to 4.65 mm.

"This makes a big difference to those of us whose feeding tube is our lifeline," Flach said in a phone interview. "We have been attempting to stop ENFit for three years by helping the marketplace choose, but now that Hancock is taking action to make our legacy devices illegal and ineligible for Medicare reimbursement, the war is on, and we will take this to the Supreme Court if necessary to protect the rights and lives of innocent feeding tube users."

Trend to blend

Some 250,000 hospitalized patients and many more in long-term care and home settings — an estimated 500,000 children and adults in the United States — use feeding tubes. They can't take nutrition through their mouth because of stroke, cancer or injury, so it is delivered through silicone, PVC and polyurethane components into their stomach or small intestine.

Some patients have used home-blended food for decades, but the practice got popular around 2011 as startup companies like Liquid Hope came out with organic alternatives to

commercial formulas.

The latest estimates say 30-40 percent of tubies, or roughly 240,000 patients, are turning food from grocery stores and restaurants into a thin pancake-like batter for nutrition.

The trend emerged after the Joint Commission issued a 2006 alert about tubing misconnections caused by use of the classic luer connectors for a variety of medical applications. A call followed for industry-based standards and engineering designs for medical tubes and catheters that are organ-specific or need-specific and do not interconnect.

A group of manufacturers, clinicians and regulators began collaborating with the International Organization for Standardization in about 2009. They initiated the development of the standard known as ISO 80369, and many sections were published from 2010-16.

As manufacturers set out to meet the enteral standard and invested in tooling, homemade blending was surging for a variety of reasons. Some tubies say they get nausea or diarrhea from formula, that they're allergic to it or they want to limit sugars. Others simply enjoy sitting at the table and having what everyone else is, and maybe burping up a familiar taste.

David Rowland, a 78-year-old tubie in South Carolina, said he even meets friends for cappuccino and a blended sandwich. As he takes in the meal, he enjoys the smell and senses a warmth in his stomach.

"It's a nice feeling," he said.

Rowland had a chance to compare some ENFit sample products in 2014 against his feeding system, which consists of a 24 French-size tube with a large funnel connector for a catheter-tip syringe.

"I got a Subway sandwich, blended it with 20 inches of liquid and did it the legacy way, and it worked fine," Rowland said. "The next night I did it again with ENFit and I couldn't push it through. That's pushing. So you really can't gravity feed either. There's nothing unsafe about my funnel connector, yet ENFit seeks to change it."

Hancock said the Mayo Clinic and FDA studied gravity and bolus feeding of blenderized diets in 2016 and 2017. Scientists and engineers measured flow rates and looked at variables related to tube size, amount of water added, type of blender and amount of blending time. The study found "consistent" flow rates between blenderized food and commercial formula

for 20-minute feeds except for two subgroups. Feeding may take 31-39 minutes for 20 and 24 French-size tubes and 40-80 minutes for 14 French sizes.

Clogging issues were studied, too, and the results indicate both ENFit and legacy tubes clog, and the problem can be addressed with a high-end blender.

However, in response to concerns from tubies on blenderized diets, manufacturers are expected to offer their legacy products indefinitely.

"So far I haven't heard any manufacturer in the U.S. say they will discontinue their legacy tubes," Hancock said.

But tubies aren't appeased, because of concern about potential ENFit mandates and lost insurance reimbursement. Rowland describes the ENFit initiative as "good intentions gone wild at the expense of tube feeders." He's also a member of Tubies Against ENFit, which started an online drive in October seeking support to preserve connector choices. They have gathered more than 1,000 signatures and 260 comments in two months.

Dueling petitions

GEDSA has an online petition, too, to gather support for the new design standard from FDA, the Joint Commission and CMS. Almost 400 people had signed it as of late January.

A video gives accounts of people whose loved ones died from tubing misconnections, including the daughter of a woman whose nurse took the line from a blood pressure monitor and inserted into an IV port instead of the blood pressure cuff. Three bursts of air went into the patient's bloodstream and she died of an air embolism.

Another woman, Glenda Rodgers, tells how her daughter died while hospitalized in 2006 with nausea, vomiting and pain when she was 35 weeks pregnant. Her IV pole contained a bag with what appeared to be a melted milkshake.

"Every corner of the bag had 'not-for-IV use,' and it was hooked to her PICC line," Rogers says in the video, adding that the formula dripped into her daughter's bloodstream for six hours before the mix-up was discovered.

Some 116 cases of tubing misconnections had been identified up to 2010. The incidents caused 21 deaths, and 84 survivors suffered respiratory arrest, sepsis, renal impairment and neurological harm. However, the problem is believed to be wider with incidents going unreported or lumped into tracked categories like medication errors.

The GEDSA petition says the primary culprit is the common luer connector, which is compatible with multiple devices. Petition supporters are asking for national action to "drive conformity to a single, safer solution for all enteral accessories and to accelerate their adoption" with a mandated ENFit conversion deadline.

Flach said experts associated with Tubies Against ENFit have reviewed many of the case studies and dispute whether ENFit would have prevented some of the injuries and deaths.

Flach said he thinks ENFit was designed with the 2.9-mm bore as opposed to the upper parameter of 8 mm to benefit commercial formula makers by making it difficult or impossible for at-home tubies to continue using blenderized foods in their feeding tubes.

Hancock's response: "I am deeply offended by this accusation. Nothing could be farther from the truth. This initiative is about improving patient safety and has nothing to do with limiting patient preference."

"ENFit feeding systems are safe for all patient populations, performing as well as legacy devices for those who prefer blenderized diets. We were very surprised to learn how prevalent blended diets were and are pleased to confirm this growing segment of patients should not experience any compromise in performance with ENFit feeding systems," he said.

Hancock said GEDSA's focus has been to support communication efforts, try to synchronize launch timing and to work with stakeholders adopting ENFit. His term as executive director of GEDSA officially ended Jan. 5. The position has been filled by Mike Cusack, who most recently was director of business development, sales and marketing at Xeridiem.

Inline Play

August,2019	**Tubing Connector Survey**	
Compliant	**If not, why**	**Comments**
no	process incomplete due to supplies	
no	Vendors contacted over the past 2 years did not have enough product to support a conversion	we are planning to begin implementation on 10/1/19
No	COH is not 100% compliance with the ENFit requirement. During the initial discussion with our vendors, they did not have the full scope of products. Therefore, we did not want to be the first one to convert over and cause issues for our staff and patients. We are working with our vendor partners to determine their product line health status to start our conversation effort again	
no	manufacturers delays in product conversion.	
yes		
yes		
No	B.D. does not make an ENFit G and J tube	when all enteral products are available without connectors we will transition.
yes		
yes		
yes		
yes		compliant since 2017
yes		
yes		
yes		
Yes (to the extent we can be, but not fully - a few outliers)	We have converted all of our feeding bags, tubing, and medication syringes to ENFit. There are some medications that we purchase from outsourcing pharmacy that have not yet been able to begin using ENFit devices.	There have been backorders and shortages of medication syringes from our current vendor- NeoMed. Additionally, there have been some published data to suggest that the dosing accuracy of the ENFit is highly variable. Additionally, not all oral meds are able to be drawn up by ENFit compatible devices (eg, oral hazardous meds with stopper in bottle neck). Not all the administration adapters are suitable for use in neonatal patients based on feedback from nursing.

CA HMO Specialty Medications Requirement · Announcement

Published Date **5/8/20**
Expiration Date **10/7/20**

LOB Individual - Non-ACA, Individual - Off Exchange, Individual - On Exchange, Large Group, National Account, Small Group - Non-ACA, Small Group - Off Exchange, Small Group - On Exchange
State CA

1. System(s) – Solution Central
2. Functional Area(s) – Member Experience, Provider Experience, Broker Experience
3. Description – This document is to answer frequently asked questions (FAQ's) surrounding the Specialty Medications requirement for CA HMOs.

What's Happening?

- Anthem's contracted HMO medical groups are responsible for UM (including prior authorization) of specialty drugs administered in an outpatient setting, while Anthem is financially responsible for the cost of those drugs. Currently there are no restrictions on where the drugs can be obtained, and the groups can issue authorizations to any specialty drug provider without regard to cost.
- Effective July 1, 2020 all Independent Physician Associations (IPAs) and Participating Medical Groups (PMGs) where risk is carved out for specialty medications to Anthem for Commercial and Medicaid HMOs in CA must use CVS Specialty. For specialty drugs administered in a physician's office or outpatient hospital setting, Anthem will require IPAs and PMGs to use CVS Specialty where risk carved out to Anthem for Commercial and Medicaid HMOs effective 7/1/20.
- This requirement applies only to specialty medications that are covered under the member's medical benefit, not pharmacy benefit.
- Claims will be denied for specialty medications (where Anthem is at risk) if billed by an IPA, PMG, hospital, etc. If a physician or hospital obtains the drug from another pharmacy and then bills Anthem, the claim will be denied.

What does this mean to you?

Who is impacted?

- CA hospitals and physician offices that are part of IPAs or PMGs where Anthem is at risk for the cost of specialty medications.
- HMO medical groups, which will have to alert their UM departments of this change. (The HMO medical group will continue to be responsible for UM and prior authorization of specialty medications.)

Hospitals and physicians that may be accustomed to ordering from another pharmacy, or to directly buying from a pharmacy and then billing Anthem. The latter may experience a revenue loss as a result of this change that could be substantial

What's the impact?

- No more buy and bill – i.e. CA hospitals and physician offices that are part of an IPA or PMGs where Anthem is at risk for the cost of specialty medications will no longer be allowed to buy specialty medications and bill Anthem for the cost. CA PMGs and IPAs will continue to be responsible for UM and prior authorization of specialty medications.

How does it work?

- Providers will have a single point of contact to fill prescriptions.
- Once an approval is obtained, the ordering provider must contact CVS Specialty's dedicated Anthem line to order the specialty medication.

Phone Number: (877) 254-0015
Fax: (866) 336-8479

Hours of Operation (Eastern Time):
Monday – Friday: 8:00 a.m. – 10:30 p.m.
Saturday: 9:00 a.m. – 1:00 p.m.

- CVS Specialty can ship specialty drugs to a member's home, work, physician's office, or location of their choice, including more than 7,800 CVS/pharmacy locations across the country. Providers should continue to submit non-cap claims for the administration of the medication. Do not include charges for the medication itself.
- CVS Specialty holds national URAC and NCQA quality accreditations.

How are claims impacted?

Providers will no longer bill Anthem for specialty medications covered under the medical benefit. Providers should procure medications from CVS Specialty, then CVS Specialty will bill Anthem.

For commercial membership, if a provider submits a claim for these medications to Anthem, the claim will reject as "Vendor Cap". The R50110 processing code will be triggered with the EOB message "PMG/IPA Responsibility". The claim will then be routed to the PMG.

What is the impact to members?

There is no impact to HMO members. The requirement affects physicians and hospitals. Physicians and hospitals will order the medications directly from CVS Specialty to administer at the member's appointment.

When is the change occurring?
Dates of service on or after July 1, 2020.

Is this a benefit change?

This is not a change to benefits.

Why is this changing?

Currently, physicians and hospitals can buy through the manufacturer and bill Anthem (referred to as Buy and Bill). Providers are incurring costs up front and Anthem is paying higher rates when reimbursing them than what would have been incurred through CVS Specialty. Through this change, providers will no longer incur the upfront costs of supplying the medication and Anthem will reimburse CVS Specialty directly at lower rates.

What is the pricing based on?

Pricing is based on contracted rates between Anthem and CVS Specialty.

Will this require Anthem patients to come back for another visit if the provider doesn't have CVS Specialty supplied drugs on hand?

No. This requirement applies only to scheduled outpatient procedures and not to emergencies. If the appointment is rescheduled, the provider is expected to hold the medication until it can be administered to the member.

What is Anthem's communication strategy?

PMGs and IPAs impacted by this change were sent a letter on 4/1/20 to notify them of the new requirement. Members will not be notified.

Will this force providers to stock up on CVS Specialty supplied drugs for Anthem members?

No. As of July 1, 2020 physicians will no longer need to stock specialty medications for Anthem members. Physicians will order specialty medications from CVSS and CVSS will dispense no more than a 30 day supply each time. CVS Specialty will fill specialty medications for each member individually. CVS Specialty only allows a 30 day supply and are member specific.

Other important information

Beginning 7/1/2020, Providers will be required to contact CVS Specialty's dedicated Anthem line to order specialty medications for commercial and Medicaid HMO members. CVS Specialty can ship specialty drugs to a member's home, work, physician's office, or location of their choice, including more than 7,800 CVS/pharmacy locations across the country. Providers should continue to submit non-cap claims for the administration of the medication. Do not include charges for the medication itself.
IMPORTANT: approval of and payment for medications obtained through pharmacies other than CVS/Caremark, will be denied.

CVS SPECIALTY'S DEDICATED ANTHEM PROVIDER SERVICE:

Phone Number: 1 (877) 254-0015
Fax: 1(866) 336-8479

Hours of Operation (Eastern Time):
Monday – Friday: 8:00 a.m. – 10:30 p.m.
Saturday: 9:00 a.m. – 1:00 p.m.

If Providers have questions about this process or about specialty drugs/member benefits, call our Provider Services Department at 1-800-677-6669.

Providers are required to comply with Anthem's programs related to the management of pharmacy expenses. Pharmacy medications administered in the office or in an outpatient hospital setting, must be procured through CVS Specialty effective 7/1/2020. This applies to all specialty drugs covered under medical benefits for Commercial members, where Anthem has financial risk. The HMO medical group will continue to be responsible for UM and prior authorization of specialty medications.

Communication Links:

Additional claims detail will be added once developed closer to the 7/1/20 go-live date.

Ancillary Claim Filing Medical Specialty Pharmacy (MSP) Drug List

Provider Correspondence attached below.

Related links

CA HMO Pharmacy Provider Letter.docx

Anthem

P.O. Box 4330
Woodland Hills, CA 91365

April 1, 2020

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED

Dear

Anthem Blue Cross (Anthem) is pleased to offer CVS Specialty as our designated specialty pharmacy for specialty medications administered in the office or outpatient hospital setting. Through this relationship, providers can procure specialty drugs that are covered through a member's medical benefit for all Anthem members. CVS Specialty provides fulfillment and distribution services to meet the needs of our members and our care providers while alleviating the buy and bill process.

To comply with Anthem's programs related to the management of pharmacy expenses, providers will be required to obtain specialty pharmacy medications administered in the office or outpatient hospital setting through CVS Specialty for dates of service on or after July 1, 2020. This applies to all specialty drugs covered through the commercial HMO member's medical benefits where *Anthem has financial risk* for the cost of specialty medications. The member's medical group will continue to be responsible for UM and prior authorization of specialty medications.

For dates of services on or after July 1, 2020, providers will be required to contact CVS Specialty's dedicated Anthem line listed below to order medical specialty medications for commercial HMO members. CVS Specialty can ship specialty drugs to a member's home, work, physician's office, or location of their choice, including more than 7,800 CVS pharmacy locations across the country. Providers should continue to submit for administration of the medication, but not bill for the medication itself. CVS Specialty will bill us and we will pay them directly. **If specialty medications are obtained through other pharmacies, the claim will be denied.**

CVS Specialty Dedicated Anthem Provider Service
Phone Number: (877) 254-0015
Fax: (866) 336-8479
Hours of Operation: Mon.-Fri. 8:00 am – 10:30 pm Eastern
Sat 9:00 am – 1:00 pm Eastern

If you have any questions, please contact our Provider Service staff at 1-800-677-6669. Thank you for your continued participation in the Anthem networks and the services you provide to our members.

Sincerely,

John Pickett
Regional Vice President, Provider Solutions
Anthem Blue Cross

Rev 03/2020

REVIEW OF THIRD-PARTY SPECIALTY PHARMACY USE FOR CLINICIAN-ADMINISTERED DRUGS

Report to the Massachusetts Legislature

Section 130 of Chapter 47 of the Acts of 2017

JULY 2019

EXECUTIVE SUMMARY

In this report, required by Section 130 of Chapter 47 of the Acts of 2017, the Massachusetts Health Policy Commission (HPC) examines the prevalence and impact of health insurance payer policies that seek to reduce overall pharmaceutical spending by requiring alternative methods of distribution and payment for certain costly specialty drugs. The specific drugs subject to these policies are not those typically dispensed by a retail pharmacy directly to a patient, but instead are administered by a clinician to a patient through injection or infusion in the outpatient setting (e.g. chemotherapy injections). These clinician-administered drugs are typically high priced and represent a growing share of all pharmaceutical spending in Massachusetts and the U.S.

In the traditional acquisition and payment method for these drugs, known as "buy and bill," the provider purchases and store drugs for general use, and payers reimburse the providers for the cost of the drug as well as for the cost of administration to the patient. In the commercial market, the provider payment amounts for the both the drug and administration are established through payer-provider contracting, and therefore, like all other medical services, can be influenced by market leverage dynamics that advantage certain high-volume providers in negotiating higher prices.[1]

In contrast, under the new policies implemented by payers, payers contract with third-party specialty pharmacies to purchase the drugs, removing the provider from the drug acquisition process. The payer reimburses the third-party specialty pharmacy for the drug and pays the provider only for the drug's administration. Since the reimbursement for the drug is not subject to the payer-provider contracting dynamics inherent in the buy and bill method, the price of drugs through third-party specialty pharmacies is generally significantly lower. The three most common alternative distribution methods are referred to as "white bagging," "brown-bagging," and "home infusion." These terms and methods are defined and described more fully in this report (see **Sidebar: Definitions**), but generally refer to the following:

- **WHITE BAGGING:** The third-party specialty pharmacy dispenses the drug and sends the drug directly to the hospital pharmacy or physician's office. The hospital pharmacy or physician's office stores the drug, and a clinician administers the drug to the patient.
- **BROWN BAGGING:** The third-party specialty pharmacy dispenses the drug directly to the patient. The patient then transports the drug to the provider for administration.
- **HOME INFUSION:** Payers may contract with home care services for a clinician to administer a drug in the patient's home. Home infusion may be considered a subset of brown bagging because drugs and associated supplies for home infusion are typically shipped directly to the patient's home.

As such policies have become more widely adopted, providers have raised concerns about consequences of these policies, in particular with regard to patient safety and access. Additionally, these policies may impact the amount of patient cost-sharing required, although this can vary considerably based on the specific benefit design of the patient's health plan. These concerns and considerations are comprehensively evaluated in the report.

In conducting this study, the HPC consulted closely with the Department of Public Health (DPH) and the Division of Insurance (DOI), reviewed available literature, engaged with stakeholders through a public listening session and written testimony, analyzed data from the Center for Health Information and Analysis' Massachusetts All-Payer Claims Database (APCD), and conducted a survey of commercial payers. Preliminary findings and draft recommendations were presented publicly for discussion at multiple HPC meetings.

The HPC's analyses and recommendations are designed to support the Commonwealth's interests in controlling healthcare spending; preventing potential harm to patients, including impacts on cost, safety, and access to care; and avoiding other potentially negative consequences. This executive summary presents an overview of the report's findings and recommendations regarding white bagging, brown bagging, and home infusion.

KEY FINDINGS

Prevalence and payer policies

Use of white bagging has become increasingly widespread in the U.S., while brown bagging remains relatively uncommon. A 2015 national survey estimated that 9 percent of drugs administered in a hospital outpatient department were supplied through white bagging, and 1 percent were supplied through brown bagging. In the physician office setting, 26 percent of drugs were supplied through white bagging, and 2 percent were supplied through brown bagging.[2]

Massachusetts data suggest that at least a few thousand commercial patients receive drugs through white bagging each year and over 10,000 commercial patients receive drugs through home infusion. Among health plans surveyed (which did not include national payers), two payers require white bagging for select drugs, two payers require home infusion for select drugs, and no payers require brown bagging. Most payers allow the option of white bagging, brown bagging, or home infusion.

Exceptions policies

As these policies are implemented, providers and patients must navigate a wide range of requirements applicable to different drugs and exception rules that vary from payer to payer. Among payers that require white bagging or home infusion:

- Fallon and NHP[i] require home infusion for certain drugs; both only allow exceptions if medical necessity criteria are met;
- Tufts Health Plan (THP)[ii] does not allow exceptions to its policy requiring white bagging for certain drugs; providers must receive a patient's drugs from CVS Caremark;
- Blue Cross and Blue Shield of Massachusetts, Inc.'s (BCBSMA) white bagging policy requires certain drugs to be filled by a contracted network specialty pharmacy; however, BCBSMA offers a site neutral payment policy through the following mechanisms:
  - Any qualified facility may join the plan's specialty pharmacy network, for purposes of coverage only for the drugs requiring white bagging which allows providers to use a buy and bill payment method, with drug reimbursement set at the third-party specialty pharmacy rate.
  - Providers that do not have pharmacies that meet the plan's criteria may also gain an exception for the drugs requiring white bagging allowing them to buy, store and bill for the drug, with drug reimbursement also set at the third-party specialty pharmacy rate.

FINANCIAL IMPLICATIONS

Commercial

The HPC observed substantially lower commercial prices per unit for Botox, Xgeva and Remicade distributed with white bagging, based on BCBSMA prices in the APCD. In 2013, the per unit price for the drugs ranged from 15 percent to 38 percent lower with white bagging than with the traditional buy and bill method, not accounting for rebates. Price differences remained substantial in 2015, but decreased slightly, potentially reflecting the implementation of BCBSMA's site neutral payment policy in the fourth quarter of the year. The price differences observed in Massachusetts are generally consistent with national estimates.

Data suggest that average commercial patient cost-sharing in Massachusetts is relatively low with both the buy and bill method and white bagging. In 2015, the highest average cost-sharing under either coverage type was $42, the cost-sharing associated with 100 units of Botox through white bagging. While white bagging had higher cost-sharing than buy and bill more often, differences were relatively minimal (ranging from $12 higher for Botox with white bagging to $2 lower for Xgeva with white bagging). However, a small share of patients had very high cost-sharing with the buy and bill method, likely reflecting whether patients had already met their medical deductible. For both the buy and bill method and white bagging, total patient cost-sharing depends on the price of the drug and on the benefit design.

Medicare

The HPC analyzed 2018 Medicare prices and patient cost-sharing using the Part B fee schedule and Part D plan finder for Remicade, Sandostatin LAR, Gammagard Liquid, and Xgeva/Prolia. Prices for these drugs were higher with Part D than Part B, although these prices do not include rebates that a plan may receive under Part D. Compared to Part B, prices per unit with Part D ranged from 13 percent higher (Xgeva) to 79 percent higher (Sandostatin LAR).

Patient cost-sharing trends varied substantially by drug. For example, cost-sharing for Gammagard Liquid averaged 113 percent higher on average with Part D compared to Part B ($117 versus $55, respectively), while cost-sharing for Xgeva/Prolia averaged 27 percent lower with Part D compared to Part B ($315 versus $432, respectively). These results suggest that white bagging has the potential to result in much greater cost-sharing for some Medicare beneficiaries.

i Neighborhood Health Plan, Inc. (NHP) changed its name to AllWays Health Partners, Inc. as of January 9, 2019.

ii The HMO licensed as Tufts Associated Health Maintenance Organization, Inc. is doing business as Tufts Health Plan in Massachusetts.

Other financial implications

In addition to cost-sharing, if a drug is not available at the time of a patient's appointment, the patient could incur additional expenses such as for transportation, time away from work, and child care.

SAFETY AND ACCESS

Brown bagging

Providers who testified were virtually unanimous in raising safety and access concerns associated with brown bagging. Safety concerns stem from the challenge of ensuring drug integrity in a chain of custody that includes the patient, including requirements for drug handling, storage, and temperature control that may be compromised while the drug is in the custody of the patient, as well as difficulty maintaining accurate documentation related to the drug.

Home infusion

Some providers and patients raised safety concerns with home infusion, while other patients support having the option of home infusion. Some literature suggests that infusion can be safely performed in the home environment. Provider safety concerns generally focused on the lower level of expertise and resources available in a home setting compared to a clinic setting.

White bagging

Testimony regarding safety and access was mixed for white bagging. Some providers expressed concerns, but some also described safeguards that they employ to successfully manage use of white bagging in their practices.

Providers outlined safety and access concerns with white bagging, including:

- Drugs may not be streamlined with in-house pharmacy systems that provide safety controls and manage inventory;
- Drugs that arrive from third party specialty pharmacies can be incompatible with in-house equipment to deliver the infusion;
- Providers cannot control which specific formulation of the drug the patient receives, which can impact side effects;
- Providers lack leverage with specialty pharmacies and distributors to correct safety issues; and
- If the appropriate drug is not available at the time of the patient's appointment, the patient may experience a number of adverse results: wasted time; additional expenses for transportation, child care, and time away from work; and potentially missed doses or lower drug adherence.

However, other testimony detailed a number of best practices that payers and providers can deploy to safely integrate white bagging. In some circumstances, white bagging can improve access for patients, particularly for patients receiving care with small providers. The range of provider perspectives and actions suggests that white bagging can be used safely, but use of best practices to support patient safety and access is critical.

Other unintended consequences

In addition to questions of safety and access, white and brown bagging policies may result in other unintended consequences, including drug waste and additional provider expenses.

With respect to drug waste, since a drug obtained through white and brown bagging can only be administered to the patient for whom it was ordered, any excess of the drug in the vial must be discarded. For example, if a patient's dosage requires half a vial, the other half of the vial would be discarded, and the payer's cost and patient cost-sharing would still apply to the entire vial. If a patient was not able to receive the drug, the drug could not be used for other patients. However, some providers, particularly smaller practices, may find it advantageous to use white bagging to avoid stocking drugs that may not be used before their expiration.

White and brown bagging may also create uncompensated provider expenses, as well as increased administrative complexity in the health care system. With the buy and bill method, payment to the provider for the drug compensates providers for the costs of both acquiring and storing the drug. White bagging requires provider resources for intake and storage of the drug after receipt from the third-party specialty pharmacy, but providers are not compensated for these expenses. Furthermore, since payers in Massachusetts have different policies for white and brown bagging, providers report that compliance with the wide range of payer policies and exceptions consumes staff resources and increases administrative expenses. Greater alignment between payer policies could reduce administrative expenses associated with white and brown bagging and support more efficient health care spending in the Commonwealth.

RECOMMENDATIONS

Based on this analysis of the impact of white and brown bagging practices on health care costs, patient safety, and access to clinician-administered infused or injected prescription drugs, the HPC recommends the following:

1 **Payers should not require brown bagging for any drug.** Payers should not require direct dispensing to a patient of any specialty drug that must be administered by a clinician. There is strong clinical consensus that requiring patients to properly store and then transport a drug to their clinician for administration jeopardizes patient safety.

2 **Payers should offer home infusion as an optional benefit, not as a requirement.** Use of home infusion should be an individual decision by the provider and patient in cases where a provider and patient determine that drugs can be safely shipped, stored, and administered in the patient's home.

3 **Payers that require white bagging should use best practices in policies and ensure minimum safety standards and capabilities in the third-party specialty pharmacies with which they contract.** White bagging can be used safely in some cases, and may offer advantages for small providers, but for payers that require white bagging, use of best practices in payer policies is critical to the safe implementation of white bagging. Best practices for payer policies include a patient-specific expedited exception process, minimum safety standards for third-party specialty pharmacies, and criteria for selection of drugs appropriate for white bagging.

4 **Payers that require white bagging should offer site neutral payment for those drugs that are subject to white bagging requirements, allowing providers the option to use the buy and bill method with reimbursement for the drug set at the third-party specialty pharmacy rate.** The site neutral payment option would only need to apply to the drugs for which a payer required white bagging. This policy lowers drug prices, reduces provider administrative expenses associated with compliance with multiple different policies, and addresses concerns about safety and access.

5 **Lawmakers should take action to increase public transparency and public oversight for the full drug distribution chain.** Lawmakers should enable increased public transparency and public oversight for pharmaceutical manufacturers, medical device companies, pharmacy benefit managers, and rebates to payers, consistent with existing Commonwealth requirements on payers and providers.

6 **The Group Insurance Commission, the Massachusetts Health Connector, MassHealth, and all other state payers should consider requiring all plans with which they contract to adopt best practice provisions.** These provisions include not requiring brown bagging or home infusion, implementing safety standards, and providing a site neutral payment option.

BACKGROUND

INTRODUCTION

The supply and financing of prescription drugs that a clinician administers to a patient through injection or infusion in the outpatient medical care setting have become an area of increased policy attention. Clinician-administered drugs, also referred to as physician-administered drugs, are commonly used in oncology and rheumatology treatment, as well as for other complex conditions. Clinician-administered drugs are typically high-cost, and spending for clinician-administered drugs represented almost one-quarter of all commercial drug spending and 4 percent of total commercial health care spending in Massachusetts in 2015.[3] Spending for these drugs is also growing rapidly; commercial spending for these drugs grew 5.1 percent in 2015 and 9.5 percent in 2016.[iii]

Coverage and reimbursement for these drugs under traditional insurance policies have led to several challenges. Traditionally, providers buy and store these drugs for general use and then bill payers for the dose used when they administer a drug to a patient, commonly referred to as the "buy and bill" method. Under the buy and bill method, providers negotiate payment rates with payers, as they do for all other medical services, and rates typically vary.[iv] The buy and bill method creates incentives for inefficient pricing and increased use of clinician-administered drugs. First,

iii HPC analysis of Massachusetts All-Payer Claims Database

iv The HPC has found that, like other medical services, those providers with a high volume for these drugs (i.e. high market share) also receive substantially higher negotiated prices for these drugs. For example, see analysis of hospital price variation for oncology drugs in the HPC's 2018 Cost Trends Report.

outpatient providers[v] can generate potentially substantial revenues from the use of these drugs by obtaining them at deep discounts from manufacturers or wholesalers and then in turn billing insurers at rates that greatly exceed the acquisition cost for the drug (plus professional fees for drug administration). Second, this system provides little incentive for providers to choose more affordable drugs for patient treatment when available since they may receive higher reimbursement for higher cost drugs; in turn, drug manufacturers have inadequate incentives to affordably price these drugs.[4] Consequently, payers assert that the buy and bill system frequently results in higher prices and spending for drugs than if insurers paid an independent third-party pharmacy for the drugs, rather than the provider.

In response, some payers have moved away from this traditional method for clinician-administered drugs and instead use third-party specialty pharmacies for drug distribution. Payers reimburse third-party specialty pharmacies for the drugs, which these pharmacies distribute directly to patients ("brown bagging") or outpatient medical providers ("white bagging") in anticipation of treatment (see **Sidebar: Definitions**). Paying for drugs under these alternative distribution methods may result in lower drug prices. For example, one commenter cited typical costs for Vivitrol of $4,000 per month through buy and bill versus $1,000 per month through white bagging, with annual differences totaling an estimated $36,000 per patient.[vi] While these policies may lower drug spending, providers have identified other impacts. White and brown bagging may result in removing or diminishing drug revenue streams for providers. There may also be unintended consequences of these policies, especially regarding patient safety and access to care.

Section 130 of Chapter 47 of the Acts of 2017 requires the Health Policy Commission (HPC) to analyze payer policies that require certain categories of prescription drugs to be provided by third-party specialty pharmacies rather than by hospitals or physician offices and provide recommendations to the Legislature. In conducting this study, the HPC consulted closely with the Department of Public Health (DPH) and the Division of Insurance (DOI). Published sources provide some information on prevalence of white and brown bagging in the U.S. and comparison of prices for select drugs. However, literature provided little information regarding safety and access, and no Massachusetts-specific published sources could be identified. Particularly given the lack of available literature, the HPC used a multi-pronged approach to collect information. The HPC engaged with stakeholders through a public listening session on May 9, 2018 and sought written testimony, analyzed price data from the Center for Health Information and Analysis' Massachusetts All-Payer Claims Database (APCD), and conducted a survey of commercial payers focused on prevalence, drug selection, and policies related to safety and access.[vii] The HPC also supplemented this survey by searching publicly available plan documents. Preliminary findings and draft recommendations were presented publicly for discussion at multiple HPC meetings.

The HPC is an independent state agency established by Chapter 224 of the Acts of 2012, *An act improving the quality of health care and reducing costs through increased transparency, efficiency and innovation*. The mission of the HPC is to monitor the reform of the health care delivery and payment systems in Massachusetts and develop innovative health policy to reduce overall cost growth while improving the quality of patient care.

The HPC's analyses and recommendations are designed to support the Commonwealth's interests in:

- Controlling healthcare spending
- Preventing potential harm to patients, including impacts on cost, safety, and access to care
- Avoiding other potentially negative consequences

This report details the HPC's review of current payment practices regarding clinician-administered drugs, analysis of the impact of these practices, and policy recommendations.

v Most direct payer reimbursement for clinician-administered drugs covers drugs that are administered in an outpatient setting. Drugs that are administered in an inpatient setting are typically covered under the diagnosis related group (DRG) bundled payment.

vi Comments of David Twitchell, CPO, Boston Medical Center Health System. Health Policy Commission Listening Session on White Bagging and Brown Bagging. May 9, 2018.

vii The testimony and a recording of the listening session are available on the HPC's website at: https://www.mass.gov/info-details/hpc-special-events-and-public-sessions#public-listening-session---shifting-drug-distribution-channels:-may-9,-2018-

DEFINITIONS

Specialty pharmacy: Specialty pharmacies have the capability to store and dispense medications with special requirements, such as those associated with clinician-administered drugs. For example, a drug may require a temperature-controlled supply chain or "cold chain." Given that specialty drugs are typically high-cost and used in treatment for complex conditions, specialty pharmacies may also provide enhanced services to support patient outcomes, such as medication adherence programs and coordination with clinicians in a patient's care team.

Specialty pharmacies are defined by their services, not their location or affiliation. For example, they could be part of a hospital or clinic, or they could operate independently. Specialty pharmacies do not require licensure distinct from the traditional pharmacy license in Massachusetts.

Buy and bill: Buy and bill is the traditional method of acquisition and payment for clinician-administered drugs. Providers' pharmacies purchase and store drugs for general use, and payers reimburse the providers for the drug, as well as the administration costs, when it is administered to a specific patient.

Medicare covers these drugs under Part B (part of Medicare's medical benefit) and typically reimburses providers at a payment rate of average sales price (ASP) plus 6 percent. Under commercial plans, providers are reimbursed a rate that is negotiated between the provider and payer which, as with other services, can vary substantially between providers. Commercial payers may receive rebates from manufacturers.

Patient cost-sharing requirements (deductibles, copayments, and coinsurance) vary based on insurance type and benefit design. Patients may have a single copayment that covers both the drug and the administration, or they may have separate cost sharing requirements.

White bagging and **brown bagging:** White bagging and brown bagging are alternative means of supply and payment for clinician-administered drugs. Payers contract with third-party specialty pharmacies to purchase the drugs, removing the provider from the drug acquisition process. Instead of reimbursing the provider for the drug, the payer reimburses the third-party specialty pharmacy for the drug and pays the provider only for the drug's administration.

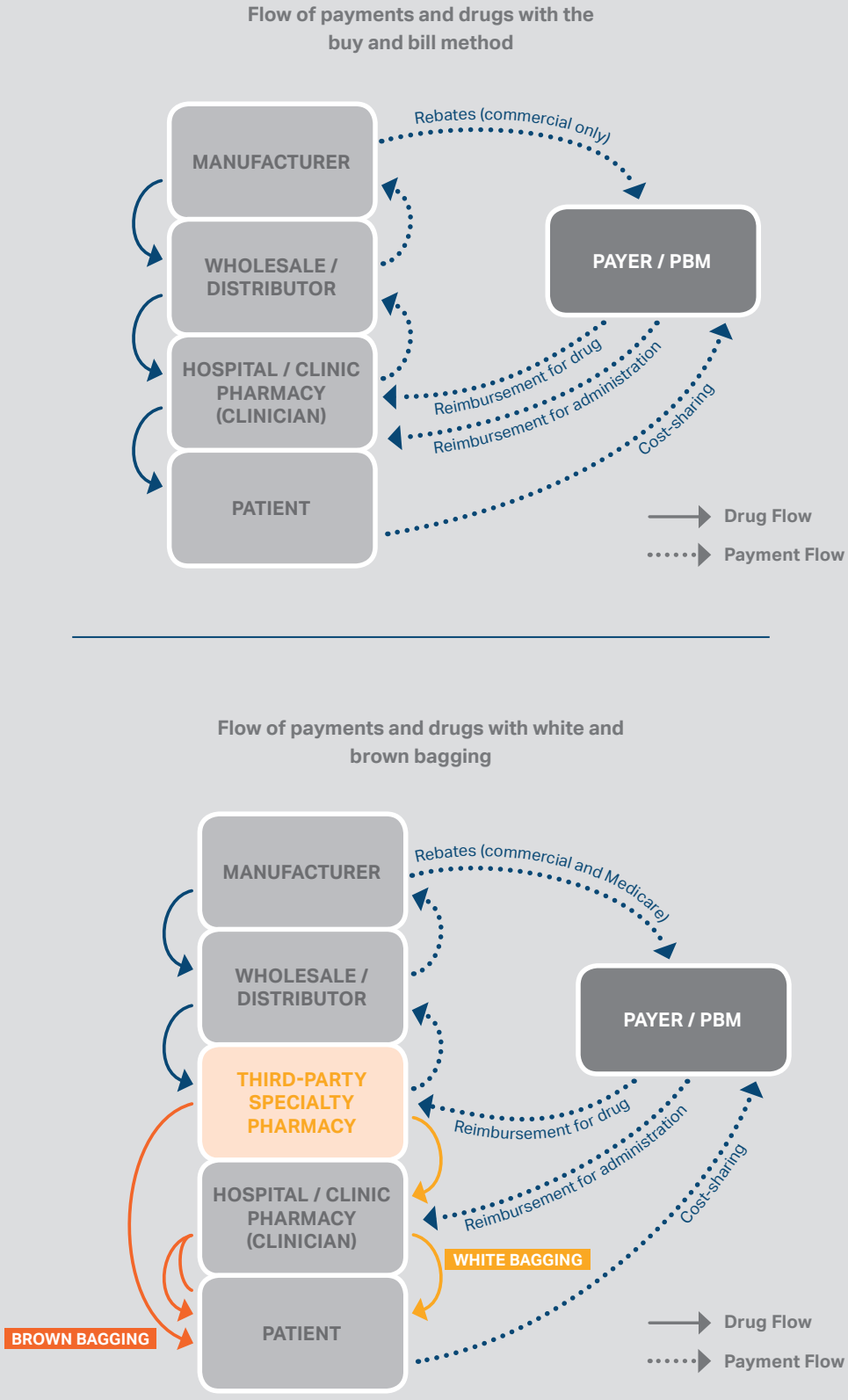
Medicare covers these drugs under Part D (Medicare's prescription drug benefit). Commercial payers also cover these drugs under their prescription drug benefit (the benefit that also covers traditional drugs that a patient would obtain at a pharmacy). With these channels, commercial payers and Medicare Part D generally negotiate drug prices at a national level through contracts with national pharmacy benefit managers (PBMs), which in turn contract with third-party specialty pharmacies. Payers may receive rebates from manufacturers in addition to any discounts at the point of sale. Only the reimbursement for the provider's administration of the drug is subject to rate negotiation between the payer and provider.

As with the buy and bill method, patient cost-sharing requirements (deductibles, copayments, and coinsurance) with white and brown bagging vary based on insurance type and benefit design.

- **White bagging:** The third-party specialty pharmacy dispenses the drug and sends the drug directly to the hospital pharmacy or physician's office. The hospital pharmacy or physician's office stores the drug, and a clinician administers the drug to the patient.
- **Brown bagging:** The third-party specialty pharmacy dispenses the drug directly to the patient. The patient then transports the drug to the provider for administration.
    - **Home infusion:** Payers may contract with home care services for a clinician to administer a drug in the patient's home. Home infusion may be considered a subset of brown bagging, because drugs and associated supplies for home infusion are typically shipped directly to the patient's home.

Exhibit 1 illustrates the flow of payments and drug for buy and bill versus white and brown bagging.

Exhibit 1: Flow of payments and drugs for the buy and bill method versus white and brown bagging



PREVALENCE AND PAYER POLICIES

The HPC analyzed the prevalence of current payer policies regarding clinician-administered drugs in Massachusetts, including white and brown bagging. These policies can inform considerations for patient safety and access to care, such as how payers select drugs, the capabilities of the specialty pharmacies used, and the exceptions processes. Payer policies also inform considerations for administrative waste. For example, a lack of alignment between payer policies can increase provider costs when providers have to adapt systems to comply with multiple policies.

PREVALENCE

The use of white bagging has become increasingly widespread in the U.S., while brown bagging remains relatively uncommon. A series of surveys of medical and pharmacy officers across the U.S. found that the proportion of clinician-administered drugs always covered by the medical benefit (i.e. through the buy and bill method) fell from 64.3 percent to 44.1 percent between 2015 and 2017.[5] Furthermore, the majority of respondents anticipated further increases in coverage via third-party specialty pharmacy. A 2014 survey of U.S. oncology practice managers found that about one-fourth of drug volume for in-practice use was supplied to practices by specialty pharmacies through white and brown bagging.[6]

Differences by site of care

Other data suggest that prevalence of white and brown bagging varies by setting. A Magellan survey of payers in 2015 found that nationally, 9 percent of drugs administered in a hospital outpatient department were supplied through white bagging, and 1 percent were supplied through brown bagging.[7] Prevalence of white bagging in particular was considerably larger in the physician office setting, with an estimated 26 percent of drugs in the physician office setting supplied through white bagging and 2 percent through brown bagging.

Research suggests several possible explanations for these differences. Some physician offices report that using a third-party specialty pharmacy is helpful in managing inventory and risk across small numbers of patients.[8,9] The financial incentive to use a buy and bill system is also likely less strong for physician groups than it is for hospitals. Compared to hospital outpatient departments, drug margins tend to be slimmer on average for physician groups due to higher drug acquisition costs[viii] and lower commercial reimbursement prices from payers.

Prevalence in Massachusetts

It is difficult to estimate with precision the prevalence of white and brown bagging in Massachusetts, but use appears relatively low overall. The HPC conducted a survey of six commercial payers in Massachusetts (which did not include national payers), representing approximately 72 percent of commercial member lives in the Commonwealth.[ix] Survey responses indicate that some Massachusetts payers require white bagging and most allow it, at least for some drugs. Most payers at least offer home infusion as an optional benefit, and some require its use for certain drugs. No payer that responded to the survey reported requiring brown bagging for drug administration in hospitals or physician offices. Data from the payer survey suggest that at least a few thousand commercial patients receive drugs through white bagging each year in Massachusetts, and over 10,000 commercial patients receive drugs through home infusion.[x]

PAYER POLICIES

The HPC analyzed payer policies on white and brown bagging, including payer policies related to safety and access, to better understand the current landscape in Massachusetts. Findings presented in this section are primarily based on the results of the HPC's payer survey. The HPC also searched publicly available plan documents, particularly for payers that did not respond or were not included in the survey.[xi]

The HPC found that providers and patients must navigate a wide range of applicable drugs, requirements, and

viii Physician groups may have higher drug acquisition costs particularly because physician groups are not typically eligible for the 340B drug pricing program that allows Medicare/Medicaid disproportionate share hospitals and other safety net providers to purchase outpatient drugs at a large discount.

ix HPC analysis of 2017 commercial enrollment from CHIA Enrollment Trends Databook, August 2018

x Estimates for white bagging for commercial members are based on the following data points: THP reported that approximately 2,500 members filled a medication through a white bag option in 2017. Fallon reported that approximately 315 members received a medication through white bagging in the first half of 2018. HPHC reported that approximately 1,180 members received a medication through white bagging in Q1 2018. BCBSMA reported that about 10 percent of its providers receive drugs through a specialty pharmacy. Estimates for home infusion for commercial members are based on the following data points: 2,500 THP members in 2017; 68 QHP (and 238 MassHealth) BMCHNP members in 2017; 70 NHP members as of August 2017; 115 Fallon members; 2,115 HPHC members in 2017; 6,000 BCBSMA members.

xi HPC distributed the survey to BCBSMA and the plans included in the Massachusetts Association of Health Plans. National payers were not included in the survey.

exception rules that vary between payers. Key results from the survey included:

- Two payers require white bagging for select drugs:
  - Blue Cross and Blue Shield of Massachusetts, Inc. (BCBSMA) requires white bagging for drugs including Remicade, immunoglobulin (which has many brand names), Botox and similar drugs, and Xgeva and similar drugs.[xii]
  - Tufts Health Plan (THP)[xiii] requires white bagging for Synagis and drugs in the viscosupplement class.
- In addition to any requirements, most payers allow the option of white bagging, brown bagging or home infusion for select drugs at the provider's discretion (Harvard Pilgrim Health Plan, Inc. (HPHC),[xiv] Boston Medical Center Health Plan, Inc. (BMCHP), BCBSMA, THP, Fallon).
  - THP noted that some providers had requested white bagging, stating, "Based on provider feedback and requests, Tufts Health Plan has made certain medical benefit drugs available under white bag option based on our specialty pharmacy availability."
- Two payers require home infusion for select drugs:
  - Fallon requires home infusion for 11 drugs.
  - Neighborhood Health Plan, Inc.[xv] (NHP) requires home infusion for 30 drugs.[xvi]
- No payer that required white bagging or home infusion provided specific detail on the criteria used to determine whether a drug was appropriate for these policies.

Payers that did not respond to the survey also appear to have policies regarding white and brown bagging. For example, published medical necessity criteria and plan documents indicate that UniCare GIC requires home infusion for a number of drugs.[10,11] One hospital noted that Cigna and Unicare GIC have particularly large numbers of drugs subject to white bagging.

Exceptions policies

The HPC also requested information from payers about any exceptions they make to their white and brown bagging requirements and found varying results. THP states that it does not allow exceptions to its policy requiring white bagging for certain drugs. Fallon and NHP, plans which require home infusion for certain drugs, both state that they only allow exceptions if medical necessity criteria are met.

BCBSMA's white bagging policy requires certain drugs to be filled by a contracted network specialty pharmacy. However, BCBSMA offers a site neutral payment policy to providers. The policy allows any qualified facility to join its specialty pharmacy network, for purposes of coverage only for the drugs requiring white bagging, which allows providers to use a buy and bill system with drug reimbursement levels set at the third-party specialty pharmacy rate. Providers that do not have pharmacies that meet BCBSMA's qualifications for its specialty pharmacy network may also gain an exception for the drugs requiring white bagging allowing them to buy, store and bill for the eligible drugs, with drug reimbursement also set at the third-party specialty pharmacy rate. BCBSMA states that approximately 90 percent of providers that administer applicable drugs use this modified, site-neutral method of buy and bill.

In contrast, THP contracts exclusively with CVS Caremark for its specialty pharmacy network. Therefore, even if a provider operates its own specialty pharmacy, it must coordinate to receive the patient's drugs from CVS Caremark to meet THP's requirements for white bagging for those drugs subject to its policy.

FINANCIAL IMPLICATIONS: IMPACT ON HEALTH CARE SPENDING AND PATIENT COST-SHARING

This section reviews data regarding the impact of white and brown bagging on health care spending, focusing on the difference in prices for drugs covered through buy and bill versus third-party specialty pharmacy (i.e. white and brown bagging) for commercial payers and Medicare.[xvii] This section

xii Drug list based on BCBSMA survey responses and plan documents, available at: https://www.bluecrossma.com/common/en_US/pdfs/New_SOB/55-1224_Medications_Covered_Under_Pharmacy_Benefit.pdf

xiii Tufts Associated Health Maintenance Organization, Inc. does business as Tufts Health Plan.

xiv HPHC noted that its list of drugs "approved for distribution via white bagging has not changed in 5 years and will not change due to changes in reimbursement structures making it no longer financially advantageous."

xv NHP changed its name to AllWays Health Partners, Inc. as of January 9, 2019.

xvi For NHP's commercial (HMO and PPO) and Health Connector members only

xvii For the commercial analyses using Massachusetts claims, average patient cost-sharing includes the patient's deductible, copayment or coinsurance for the drug based on actual use. The Medicare analysis relies on fee schedules and therefore estimates payments and patient cost-sharing, including the deductible, copayment or coinsurance and cost-sharing during the coverage gap.

also evaluates the financial impact for patients, comparing commercial and Medicare patient cost-sharing for drugs covered through buy and bill versus third-party specialty pharmacy. The HPC compared payer and patient spending only for the drug itself and not for the drug's administration or other services that may be associated with a visit.

FINANCIAL IMPLICATIONS: COMMERCIAL MARKET

Commercial drug prices

The HPC used the APCD to analyze a selection of drugs, based on a convenience sample from providers. Results presented here are for BCBSMA because, for the drugs selected, BCBSMA was the only payer with a robust sample size of claims in both the medical and pharmacy claim files in 2015, the latest year of APCD data available at the time of the analysis. The analysis categorized claims in the medical claims file as drugs covered through buy and bill; claims in the pharmacy claim file were categorized as drugs covered through white bagging.

For each drug, the analysis compared spending per unit with buy and bill versus white bagging, including payer spending and patient out of pocket spending. BCBSMA's white bagging policy became effective October 1, 2015, including its site neutral exception provision that allows qualified providers to continue to buy and bill under reimbursement rates equivalent to specialty pharmacy levels. Results for 2015 may reflect the implementation of BCBSMA's site neutral payment policy in the fourth quarter of the year. 2013 is also included in order to provide a comparison of a full year of prices before the introduction of the site neutral payment policy.

Drug prices were substantially lower with white bagging. In 2013, the per unit drug price – the unit by which the drug is billed – for the three drugs analyzed ranged from 15 percent lower to 38 percent lower through white bagging than through buy and bill (**Exhibit 2**).[xviii] These figures do not account for any rebates that the payer may have received under white bagging or buy and bill.

Price differences per unit in 2015 remained substantial between buy and bill and white bagging. The differences were smaller in 2015 than 2013, although these results may reflect the implementation of BCBSMA's site neutral payment policy in the fourth quarter of the year.

Exhibit 2: Commercial price and patient cost sharing per billing unit of drug in Massachusetts with the buy and bill method versus white bagging (Blue Cross Blue Shield of Massachusetts), 2013 and 2015

2013	Total price per unit		Difference	Patient cost-sharing per unit		Difference
	Buy and bill	White bagging		Buy and bill	White bagging	
Botox (100units)	$680	$481	-29%	$20	$31	$11
Xgeva (120mg)	$2,279	$1,416	-38%	$16	$30	$14
Remicade (100mg)	$942	$798	-15%	$4	$9	$5

2015	Total price per unit		Difference	Patient cost-sharing per unit		Difference
	Buy and bill	White bagging		Buy and bill	White bagging	
Botox (100units)	$702	$537	-24%	$30	$42	$12
Xgeva (120mg)	$2,043	$1,581	-23%	$23	$21	-$2
Remicade (100mg)	$1,106	$975	-12%	$9	$11	$2

Notes: Results are for Blue Cross Blue Shield of Massachusetts. Figures do not include rebates. Cost-sharing includes applicable deductible, copayment, and coinsurance. Results are not adjusted for inflation. Billing units are based on smallest pharmacy units; for buy and bill and white bagging, patient cost-sharing per unit is calculated as cost-sharing on a claim divided by the number of units for comparability (actual cost-sharing may not necessarily correspond to units dispensed or administered). Drug claims in the medical claims file are characterized as covered through the buy and bill method; drug claims in the pharmacy claim file are categorized as drugs covered through white bagging.

Sources: HPC analysis of the Center for Health Information and Analysis' Massachusetts All-Payer Claims Database, 2013 and 2015

xviii The number of units per claim for the drugs in this analysis typically ranged from 1 to 5.

The results that the HPC observed in Massachusetts are generally consistent with national estimates. A Magellan report used 2016 commercial claims to compare prices for clinician-administered drugs under the buy and bill method in different sites of care (physician office and hospital outpatient department) and under third-party specialty pharmacy (defined as "specialty pharmacy / home delivery" in the report).[12] From this report's list of top clinician-administered drugs by commercial spending, the HPC analyzed results for the drugs for which specialty pharmacy prices were available (**Exhibit 3**). Prices for these drugs in the hospital outpatient department were substantially higher than the specialty pharmacy prices. For example, the price per unit for Sandostatin LAR was 111 percent higher through buy and bill in a hospital outpatient department than through specialty pharmacy ($350 versus $166).

Buy and bill prices for drugs administered in a hospital outpatient department were also much higher than prices in the physician office setting. In many cases, buy and bill prices in the physician office setting were lower than specialty pharmacy prices. These differences in buy and bill prices by setting of care highlight how the impact of white and brown bagging policies may vary by provider type. In particular, physician offices and providers that receive relatively lower prices may experience relatively less financial impact than hospital outpatient departments from white and brown bagging or site neutral payment policies.

Cost-sharing for commercial patients

Assessing differences in patient cost-sharing is critical to understanding the financial impact of white and brown bagging. Data suggest that average commercial patient cost-sharing in Massachusetts is relatively low per unit with both the buy and bill method and white bagging. In 2015, the highest average per unit cost-sharing under either coverage type was $42, which was the cost-sharing associated with 100 units of Botox through white bagging (pharmacies typically dispense Botox in either 100 or 200 unit vials) (**Exhibit 2**). While white bagging resulted in higher patient cost-sharing than buy and bill did for most of the drugs in the study sample, differences were relatively

Exhibit 3: Price differences by setting and coverage in the U.S. for select commercial drugs, 2016

	Cost per unit					Distribution of use		
Drug	Home/ SP	Office	Comparison to SP (%)	HOPD	Comparison to SP (%)	Home/ SP	Office	HOPD
Remicade (10 mg)	$120	$90	-25%	$227	89%	8%	52%	40%
Gammagard Liquid (500 mg)	$65	$54	-17%	$82	26%	49%	27%	24%
Xgeva/ Prolia (1 mg)	$19	$17	-11%	$33	74%	5%	68%	27%
Botox (1 unit)	$6	$6	0%	$12	100%	20%	68%	12%
Sandostatin LAR (1 mg)	$166	$183	10%	$350	111%	5%	46%	49%
Entyvio (300 mg)	$18	$19	6%	$37	106%	13%	34%	53%
Stelara (1 mg)	$228	$177	-22%	$306	34%	24%	68%	8%
Orencia (10 mg)	$41	$42	2%	$105	156%	6%	66%	28%
Gamunex-C (500 mg)	$65	$57	-12%	$107	65%	36%	22%	42%
Rituxan (100 mg)	$914	$878	-4%	$1,482	62%	1%	48%	51%
Tysabri (1 mg)	$19	$19	0%	$37	95%	8%	47%	45%
Soliris (10 mg)	$226	$227	0%	$416	84%	16%	36%	48%
Xolair (5 mg)	$32	$32	0%	$87	172%	32%	62%	6%

Notes: SP = specialty pharmacy. Prices do not include rebates. Billing units are based on lowest medical reimbursement units, and units in this exhibit differ from those used in Exhibit 2 for some drugs. Based on the report's list of top 25 drugs by commercial spending, the table displays drugs for which specialty pharmacy prices were available.

Sources: HPC analysis of data from Magellan Rx Management. Medical Pharmacy Trend Report: 2017 Eighth Edition.

minimal. For example, differences in average cost-sharing per unit in 2015 ranged from $12 higher for Botox with white bagging to $2 lower for Xgeva with white bagging.

While these results suggest that cost-sharing was relatively low on average, the buy and bill method can result in very high costs for a small fraction of patients who may not have met their medical deductible. **Exhibit 4** compares the distribution of patient cost-sharing per 100 mg of Remicade under buy and bill versus white bagging. Cost-sharing under buy and bill was more polarized: the vast majority of patients (91 percent) had no cost-sharing, but 3 percent had cost-sharing between $100 and $500 and a relatively small number of patients had cost-sharing of more than $500. This result likely reflects whether patients had already met their medical deductible. In contrast, for drugs covered with white bagging, almost all patients had relatively low cost-sharing ($20 or less), although amounts were typically higher than $0. About 2 percent of claims had more than $20 in cost-sharing.

Exhibit 4: Distribution of patient cost-sharing per unit of Remicade (100mg) with the buy and bill method versus white bagging (Blue Cross Blue Shield of Massachusetts), 2015

Cost-sharing	Distribution	
	Buy and bill	White bagging
$0	91%	4%
<$0 – $10	3%	55%
<$10 – $20	1%	38%
<$20 – $30	*<1%*	2%
<$30 – $40	*<1%*	*<1%*
<$40 – $50	*<1%*	*<1%*
<$50 – $100	1%	*<1%*
<$100 – $500	3%	*<1%*
More than $500	*<1%*	*<1%*

Notes: Results are for Blue Cross Blue Shield of Massachusetts. Cost-sharing includes applicable deductible, copayment, and coinsurance. Billing units are based on smallest pharmacy units; for buy and bill and white bagging, patient cost-sharing per unit is calculated as cost-sharing on a claim divided by the number of units (actual cost-sharing may not necessarily correspond to units dispensed or administered). Drug claims in the medical claims file are characterized as covered through buy and bill; drug claims in the pharmacy claim file are categorized as drugs covered through white bagging.

Sources: HPC analysis of Center for Health Information and Analysis' Massachusetts All-Payer Claims Database, 2015

Limitations of analysis and considerations in the commercial market

BCBSMA results may not be generalizable to all commercial payers in the Commonwealth, and it is important to account for plan design in evaluating the impact of white and brown bagging on patients, in particular high deductibles in the medical benefit or specialty tier co-insurance in the pharmacy benefit. For both the buy and bill method and white bagging, total patient cost-sharing depends on the price of the drug and on the benefit design.

Furthermore, this analysis may not fully reflect the total change in patient spending when coverage shifts from buy and bill (coverage under the medical benefit) to third-party specialty pharmacy (coverage under the pharmacy benefit). In many commercial plans in Massachusetts, patients have a single copayment for the drug and administration under the medical benefit after meeting their deductible.[xix] When clinician-administered drugs are covered under the pharmacy benefit, patients could have separate copayments for the drug and the drug's administration, potentially increasing their overall cost-sharing responsibility. However, while details of benefit design significantly impact patient cost-sharing, this analysis suggests that patient cost-sharing in the commercial market does not differ substantially between the buy and bill method versus white and brown bagging in Massachusetts.

MEDICARE PRICES AND COST-SHARING

The HPC also analyzed prices and patient cost-sharing for Medicare beneficiaries in Massachusetts. White and brown bagging policies can affect Medicare beneficiaries who are enrolled in either Medicare Advantage or Original Medicare, as either could elect to shift coverage of some clinician-administered drugs from Part B (part of the medical benefit) to Part D (the prescription drug benefit). The HPC estimated differences in prices and patient cost sharing for Medicare beneficiaries in Massachusetts using Medicare's fee schedule for Part B drugs and prices and patient cost-sharing from the CMS' Part D Plan Finder tool. The selection of drugs for the analysis is based on a convenience sample from providers. Because cost sharing under Medicare Part D can vary throughout the year depending on how much of the drug benefit a patient has used, the analysis assumed that patients use one unit of a drug each month and averaged patient cost-sharing per billing unit of a drug over 12 months.

xix Estimate based on scan of sample of publically available Massachusetts payer plan documents for 2018 benefits.

Exhibit 5: Medicare drug price and cost-sharing per unit in Massachusetts for Part B versus Part D coverage, 2018

Drug			Total drug cost			Patient cost sharing			% cost sharing	
Brand Name	Generic Name	Part D unit	Part B	Part D	Difference	Part B	Part D	Difference	Part D	Part B
Remicade	Infliximab	1 vial, 100 mg	$871	$1,234	42%	$190	$260	37%	21%	22%
Sandostatin LAR	Octreotide Acetate, mi-Spheres	1 kit, 10mg	$1,836	$3,290	79%	$383	$363	-5%	11%	21%
Gammagard Liquid	Immun Glob G(Igg)/ Gly/Iga Ov50	1 vial, 2.5mg/25ml	$199	$352	77%	$55	$117	113%	33%	28%
Prolia / Xgeva	Denosumab	1 vial, 1.7ml	$2,080	$2,342	13%	$432	$315	-27%	13%	21%

Notes: Billing units are based on the lowest Part D units, and Part B payment and cost sharing per unit are converted to the lowest unit available under Part D. Results for Part D plans use zip code 02109 and are sourced from the plan with the second lowest premium, Aetna Medicare Rx Select. The Part D calculation uses one unit per month for 12 months, then divides by 12, to account for different prices in the initial phase, coverage gap, and catastrophic coverage. Part B and Part D figures include respective deductibles in the calculation, but not premiums. The deductible for this Part D plan is $405. The Part B deductible is $183 in 2018.

Sources: Medicare OPPS fee schedule 2018, Addendum B (Part B). Part D Plan Finder (Part D).

Results indicate that prices are generally higher with Part D than Part B, although these prices do not include rebates that a plan may receive under Part D.[xx] Compared to Part B, price per unit with Part D ranged from 13 percent higher (Xgeva) to 79 percent higher (Sandostatin LAR) (**Exhibit 5**). Patient cost-sharing trends varied substantially by drug. While patient cost-sharing per unit for Gammagard was more than twice as high with Part D than Part B ($117 versus $55), cost-sharing for Xgeva was 27 percent lower with Part D than Part B ($315 versus $432).

Considerations

This analysis presents cost-sharing on average, but cost-sharing amounts can vary widely for Medicare beneficiaries.[xxi] While Original Medicare beneficiaries have a standard 20 percent co-insurance for all Part B services including medical drugs, cost sharing under Part D varies based on a drug's tier placement in the formulary and the patient's phase of coverage (deductible, initial coverage, coverage gap, or catastrophic coverage). Furthermore, many patients have supplemental insurance to cover Part B cost-sharing, further complicating comparison of patient cost-sharing with white and brown bagging in Medicare. However, the variation in the data presented here suggests that shifting clinician-administered drugs to the pharmacy benefit has the potential to result in much greater cost-sharing for some Medicare beneficiaries. These results underscore the need for beneficiary protections if Medicare plans to shift drugs from the medical benefit to the pharmacy benefit, as well as the need for transparency such that beneficiaries can factor this information into their plan selections.

State-level policy regarding white and brown bagging could apply to Massachusetts Medicare beneficiaries through regulation of providers, pharmacies, or Medicare Advantage or stand-alone Part D plans that are licensed in the Commonwealth.

OTHER FINANCIAL IMPLICATIONS

In addition to increased cost-sharing, patients may face other costs as a result of poor implementation of third-party specialty pharmacy policies. If a drug is not available at the time of a patient's appointment, the patient could incur additional expenses such as for transportation, time away from work and child care. These considerations are discussed further in the section on patient access to care.

PATIENT SAFETY AND ACCESS TO CARE

SAFETY

Provider testimony raised safety concerns associated with white and brown bagging, but many providers reported that they have taken steps to address these concerns. White bagging, brown bagging and home infusion each present different challenges for patient safety. This section summarizes provider concerns, provider approaches, and principles for safety based on stakeholder testimony.

xx While the Medicare program does not receive rebates on drugs covered under Part B, Part D plans may receive rebates. Commercial payers and PBMs receive rebates for drugs covered under specialty pharmacy. Commercial payers may also receive rebates from manufacturers for drugs covered under the medical benefit (buy and bill) for giving certain drugs preferential status in their internal formularies. Rebates that a payer receives are not typically shared directly with patients.

xxi Original Medicare typically pays for the drug and the drug's administration separately. The patient's cost-sharing for the drug's administration would be the same whether the drug was paid for under Part B or Part D.

BROWN BAGGING: Providers who testified were virtually unanimous in raising safety concerns associated with brown bagging, including comments from Dana Farber Cancer Institute (DFCI), Beth Israel Deaconess Medical Center, Atrius Health, Massachusetts General Hospital (MGH), and Boston Medical Center Health System (BMC). These concerns stem from the challenge of ensuring drug integrity in a chain of custody that includes the patient. For example, DFCI stated that "the integrity of the affected prescription drugs, which have specific handling, storage, and temperature control requirements, may be compromised while in the custody of a patient." Providers noted that maintaining accurate documentation related to the drug (e.g. amount, manufacturer, etc.) is particularly difficult under brown bagging because the patient may not know all relevant details, preventing the provider care team from having a complete record of drugs administered to the patient. Information that may not be logged with brown bagging, such as the expiration date and drug specific lot numbers, is important for reporting side effects and adverse reactions, as well as responding to medication recalls. BMC stated, "No legislation, regulation, guidance or standard can manage patient behavior adequately to ensure the safe delivery of sensitive medications. The temperature swings in New England alone are enough to compromise the efficacy of many specialty medications." Atrius Health summarized safety concerns with brown bagging as follows:

> "While 'white bagging' typically requires the specific medication to be delivered to a pharmacy or health care provider who will understand and can implement any necessary processes to attempt to ensure the integrity of the drug (e.g. refrigerate it), 'brown bagging' has no similar assurance. When a patient brings a medication to the provider for administration, the provider has no way of knowing whether the medication has been appropriately handled and is reliant on the patient's self-report. Although we are not aware of any specific adverse outcomes as a result of administration of 'brown bagged' medications within our practice, the break in the chain of custody associated with this practice is concerning to our clinicians."

While many providers urged a ban on brown bagging, some providers also expressed caution that approaches to prevent brown bagging should avoid unintended consequences of creating barriers to patient access to care.

HOME INFUSION: Home infusion typically relies on sending specialty medication directly to the patient's home. Unlike brown bagging, the patient does not transport the medication; rather, a clinician comes to the patient's home to administer the drug. While some providers and patients have raised safety concerns with home infusion, other patients support having the option of home infusion, and some literature suggests that home infusion can be safely performed in the home environment.

Provider safety concerns generally focused on the lower level of expertise and resources available in a home setting compared to a clinic setting. For example, a group of rheumatologists detailed safeguards in place for its in-clinic administration of Remicade that may not be available in a home administration setting, including that their technicians specialize in rheumatology, and that physicians or other advanced practitioners are available should the patient experience an adverse reaction.

Patients have reported concerns about drug administration and the difficulty of navigating plan requirements under mandated home infusion. In a provider's submitted materials, a state employee detailed a negative experience with mandated home infusion of Remicade under the patient's Unicare GIC plan, explaining:

> "It only took my first visit to realize this option wasn't for me. …They sent me an incorrect itemization list, the incorrect amount of sodium chloride and bag sizes which goes hand-in-hand with the mixing dilution process, no IV pole and a number of miscellaneous items I overheard the assigned nurse mention while at my home…The nurse appeared to be very uncomfortable and unconfident with herself in this procedure, as I noticed her hands shaking and appeared also to be sweating. This made me feel very vulnerable because I knew my care was in her hands. Due to the lack of supplies, the nurse began making due with what she had…personally I felt like I wasn't given my Remicade infusion correctly which has caused me a very painful and depressing flare-up. I was forced to make an emergency call to [a hospital] infusion center to request an immediate early infusion that required a newly written prescription order from my gastroenterologist for authorization. …This home infusion requirement was thrown at me…This is something I should have been informed of in detail which I wasn't."

However, some patients prefer the option of receiving drug infusions in their own homes. Home infusion may allow patients to eliminate burdensome travel, and some patients find that their home environment provides more physical and emotional comfort than the clinic environment.[13] Some studies have concluded that infusion can safely be performed in the home environment.[12,14] Some providers may recommend home infusion in certain cases based on the patient's preference, the particular drug, and the patient's ability to safely receive medications delivered directly to their home. While home infusion may increase the risk of adverse safety outcomes in some cases, it may also result in positive benefits for patients in other cases.

WHITE BAGGING: Testimony regarding safety concerns was mixed for white bagging. Providers expressed safety-related concerns, but some also described safeguards that they employ to successfully manage use of white bagging in their practices. In testimony submitted to the HPC, some providers argued that white bagging should be prohibited, while others supported allowing the practice to continue.

Provider testimony outlined a variety of safety concerns with white bagging, including:

- White bagging may not be streamlined with in-house pharmacy systems to manage inventory, including entering complete documentation.
- The drugs that arrive can be incompatible with the in-house equipment to deliver the infusion.
- The provider cannot control which specific formulation of the drug the patient receives, which can impact side effects.
- Unlike in contracts under the buy and bill method, providers lack leverage with specialty pharmacies and distributors to correct safety issues.

Boston Children's Hospital outlined some of these concerns in its testimony. Examples include:

- Potential for medication delays that can cause adverse patient reactions:
  - "When the hospital pharmacy is forced to deal with a third party (e.g. a specialty pharmacy), we have no control of when the medication is going to arrive. The specialty pharmacy doesn't communicate if there is a shipping delay. A scheduled medication may be delayed by the specialty pharmacy for a number of reasons, for example, when a Prior Authorization is expired, the patient did not authorize the shipping, or the patient did not pay the copay."
  - "In many situations, patients do not know that they have to use a specialty pharmacy and only find out about it when the specialty pharmacy contacts them to enroll and collect the copay. Since the patients don't expect to deal with a specialty pharmacy, they do not respond to the calls."
  - "With certain medications, for example Infliximab [Remicade], which is used to treat Crohn's Disease and Ulcerative Colitis, delaying scheduled treatment dose may lead to antibodies development which, in turn, may lead to a reaction during the medication administration and/or the patients may stop responding to the medication which in turn leads to a medication discontinuation."
- Bypassing in-house pharmacy safety controls:
  - "A further example of a safety and quality issue occurs when a specialty pharmacy sends a different size vial than what we have in the Boston Children's Hospital system. When that happens, we have to prepare medication on paper bypassing DoseEdge (electronic system we have with scanning medications and walking a technician step by step during the preparation, as well as [letting a] pharmacist see and verify every step of the preparation). Bypassing DoseEdge may contribute to [a] mistake during the preparation of the medication."

Due to concerns about safety, DFCI does not permit white bagging under any circumstances. DFCI summarized its position as follows:

> "…[A]s part of Dana-Faber's rigorous quality and safety protocols, we typically batch order medications at a volume we anticipate necessary to accommodate all of our in-clinic patients. When drugs are brown or white bagged, an individual dose of injectable medication arrives labeled for a specific patient. This subverts our unique and specialized pharmacy systems, which incorporate state-of-the-art safety features that Dana-Farber has spent years developing. These systems simply cannot safely accept drugs and manage inventory for an individual patient from a third-party specialty pharmacy outside of our typical distributors."

Other providers described approaches that have allowed them to safely integrate white bagging. For example, MGH has invested in adapting its systems to accommodate white bagging. MGH's Department of Pharmacy stated in a comment letter that it "currently allows the practices of 'white bagging' with policies and procedures in place to ensure safe practice for receiving, tracking, compounding, and administering specialty medications."

BMC operates its own specialty pharmacy that serves patients at BMC and other smaller providers. BMC testified that its pharmacy serves BMC patients and 30 other provider groups, filling approximately 800 white bagging prescriptions a month. Twenty-five percent of these prescriptions are for patients at BMC, and 75 percent are for patients at other provider groups.

BMC detailed numerous standards for its specialty pharmacy to ensure safety in white bagging, including cold chain logistics (the ability to ensure the drug remains at the appropriate temperature through all stages of supply and storage), establishing systems for reliable delivery within clinics, co-developing logistic and storage solutions for providers, and providing the drug's pedigree (history of transaction for each drug or batch of drugs) to the hospital pharmacy. The issue of safety standards for specialty pharmacies is discussed in more detail in **Sidebar: Maximizing safety and access under white bagging.**

BMC also explained that integration of its specialty pharmacy with the electronic health record (EHR) allows for further patient safeguards, coordinated care, and administrative simplification. For example, in cases where a patient must use a specialty pharmacy, the physician can enter the order into the EHR, enabling EHR safety checks such as interactions and dose limitations. BMC's specialty pharmacy also has patient liaisons to help ensure safety and access with white bagging.

ACCESS TO CARE

White bagging can result in both advantages and disadvantages for patient access. White bagging has inherent challenges that do not exist with the buy and bill method, such as that a drug ordered through white bagging could fail to arrive in time for the patient's appointment. Similarly, if changes in patient measures (e.g. weight gain) result in the need for a higher dosage than what was delivered, the medication would not be available to the patient at the time of their appointment. If the appropriate drug is not available at the time of the patient's appointment, the patient may experience a number of adverse results: wasted time; the burden of additional expenses for transportation, child care, and time away from work; and potentially missed doses or lower drug adherence. While it may not be possible to eliminate these scenarios entirely, providers noted that their likelihood can be minimized with appropriate safeguards.

Despite these challenges, white bagging can improve access for patients under certain circumstances. Insurers frequently place utilization management restrictions, such as prior authorization, on drugs whether they are covered through the buy and bill method or white bagging. Smaller providers, including smaller hospitals or physician clinics, may find it advantageous to work with a specialty pharmacy with expertise and staff resources to negotiate utilization management requirements with insurers. BMC, which provides specialty pharmacy services for smaller providers, noted, "Navigating distribution channels and insurance formularies for drugs is often beyond the core expertise of the administration site. Specialty pharmacy providers are focused entities that navigate these challenges routinely, which can lower access time, if they are well interfaced with clinicians."

Specialty pharmacies can also help smaller providers by providing consolidated data reporting on drugs, expertise in compliance with the U.S. Food and Drug Administration's (FDA) requirements to manage safety risks for certain drugs (Risk Evaluation and Mitigation Strategy (REMS) program), and specialized programs focusing on medication adherence. BMC also cited that its in-house specialty pharmacy program has resulted in higher rates of adherence to high-cost Hepatitis C medications, resulting in statistically significantly more patients cured (achieving sustained viral response).[xxii] Payer and provider comments highlighted best practices that could be used with white bagging to support patient access to care, detailed in **Sidebar: Maximizing safety and access with white bagging.**

xxii See listening session testimony and Tran AN, Sachdev R, Fricker ZP, et al. Intensive Pharmacy Care Improves Outcomes of Hepatitis C Treatment in a Vulnerable Patient Population at a Safety-Net Hospital. Digestive Diseases and Sciences. 2018; 63(12):3241-3249.

MAXIMIZING SAFETY AND ACCESS WITH WHITE BAGGING

Massachusetts payers currently use a wide range of policies and minimum safety standards for their specialty pharmacy partners. Based on testimony from payers and providers, the following are practices for third-party specialty pharmacies and drug selection that could be employed to promote safety and access under white bagging:

ADOPTING A SITE NEUTRAL PAYMENT POLICY

Adopting a site neutral payment policy allows providers to use a buy and bill system with reimbursement levels set at the specialty pharmacy rate. Employed by BCBSMA, this policy allows payers to achieve similar savings to coverage with white and brown bagging, while enabling providers to maintain a revenue stream with clinician-administered drugs (although at lower rates) and avoiding the safety and access concerns that providers have raised with use of third-party specialty pharmacies.

BCBSMA allows any qualified facility to join its specialty pharmacy network for purposes of coverage only for the drugs requiring white bagging, which allows providers to use a buy and bill system with drug reimbursement levels set at the third-party specialty pharmacy rate. Providers that do not have pharmacies that meet BCBSMA's qualifications for its specialty pharmacy network may also gain an exception for the drugs requiring white bagging allowing them to buy, store and bill for the eligible drugs, with drug reimbursement also set at the third-party specialty pharmacy rate.

Some payers expressed concerns about allowing a hospital's pharmacy to join the payer's specialty pharmacy network. Some payers have exclusivity arrangements with a single specialty pharmacy chain and expressed concerns that adding a hospital's pharmacy would violate the exclusivity contract. However, payers concerned about violating exclusivity contracts could provide an alternate mechanism of site neutral payment in their contracts with providers. Furthermore, some payers expressed concerns about potential revenue loss if they were required to include a hospital pharmacy in their networks for all specialty drugs, if the hospital qualified for the 340B program. If a hospital qualifies for the 340B program, manufacturers provide deep discounts on the drugs that the hospital buys for outpatient administration or retail pharmacy use.[xxiii] Manufacturers may be less likely to provide rebates to payers (for example, in exchange for favorable utilization management requirements) for drugs that were purchased through the already discounted 340B program, compared to drugs purchased through a third-party specialty pharmacy. More transparency is needed on the 340B program and its financial impact on providers and payers. However, a payer policy that allows a hospital pharmacy to join the payer's network for purposes of site-neutral payment would apply only to the specific drugs subject to white and brown bagging, and not necessarily to all specialty drugs that a payer covers.

OTHER PAYER POLICIES

Other best practices for payer policies include:

- **Patient and provider notification:** Payers should provide sufficient notice (such as at least 60 days) to both providers and patients prior to implementing a white bagging policy. Education should be provided to patients on process changes affecting them.
- **Exception process:** Payers should establish a patient-specific expedited exception process for cases in which a provider certifies that it is unsafe for a patient to receive medication from a third party specialty pharmacy or to have the drug administered in the home setting.

STANDARDS FOR SPECIALTY PHARMACY CAPABILITIES

Best practice capabilities for third-party specialty pharmacy include:

- Same day delivery and 24/7 member on-call access to a pharmacist or nurse. Other related best practices in member services include patient education and disease management, and auto-refill if requested by the patient.

xxiii The federal 340B Drug Discount Program requires that pharmaceutical drug manufacturers provide drugs to hospitals that serve disproportionately low-income patients at significantly reduced prices in order to relieve the burden of high drug prices on these hospitals.

- Provide cold chain logistics (the ability to ensure the drug remains at the appropriate temperature through all stages of supply and storage), use overnight delivery or courier systems, establish systems for reliable delivery within clinics (e.g. an assigned lead and backup system) and co-develop logistic and storage solutions for providers, such as refrigeration and stock storage solutions.
- Provide a hospital's in-house pharmacy with the drug's pedigree (history of transaction for each drug or batch of drugs) to certify to the hospital pharmacy that the drug was handled appropriately through the supply chain.
- Have expertise and reliability in Risk Evaluation and Mitigation Strategy (REMS) reporting in order to comply with the U.S. Food and Drug Administration's (FDA) REMS program requirements applicable to certain drugs.[xxiv]
- Regular reporting to the payer on metrics such as cost, utilization, and medication adherence.
- Accreditation through groups such as the Accreditation Commission for Health Care, Joint Commission on the Accreditation of Healthcare Organizations, Utilization Review Accreditation Commission, National Committee for Quality Assurance, and National Association of Board of Pharmacy – Certified Internet Pharmacy Practice Sites.

STANDARDS FOR DRUG SELECTION

Considerations for selecting clinician-administered drugs appropriate for white bagging include:

- **A third-party specialty pharmacy must be able to deliver the medication to a health system pharmacy in a ready-to-administer dosage form and clinically appropriate dosage.** In addition, any medication requiring sterile compounding by the health system pharmacy staff is inappropriate for white bagging. These requirements are also necessary for pharmacy compliance with the Board of Pharmacy regulation 247 CMR 9.01 (4) prohibiting redispensing of medication.
- **Any medication with a patient specific dosage requirement dependent on lab or test results on the day of the clinic visit (e.g. based on the patient's weight) is inappropriate for white bagging.** Changes to a patient's required dosage at the time of the patient's appointment can create access challenges if a specific quantity of the drug must be ordered through a specialty pharmacy beforehand.[xxv]

OTHER UNINTENDED CONSEQUENCES

DRUG WASTE

White and brown bagging can produce drug waste, with implications for payer and patient spending. Since a drug obtained through white and brown bagging can only be administered to the patient for whom it was ordered, any excess of the drug in the vial must be discarded. For example, if a patient's dosage requires half a vial, the other half of the vial would be discarded, and the payer's cost and patient cost-sharing would still apply to the entire vial. A drug may also need to be discarded if it arrives too late or the patient misses their appointment. In contrast, under buy and bill, since drugs are not acquired on a patient-specific basis, the provider may be able to administer (and bill) excess drug within a vial to additional patients, and the cost to each payer and patient would only be for the amount of drug required for each patient's dosage. However, some providers, particularly smaller practices, may find it advantageous to use white bagging to avoid concerns about stocking drugs that may not be used before their expiration.

BCBSMA stated in testimony that white bagging produces payer savings, even net of any drug waste. Additional research is needed on the net financial effect of this dynamic, particularly for patient cost-sharing. Further discussion

xxiv A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns. REMS focus on preventing, monitoring, or managing a specific serious risk. REMS may require roles for patients, health care providers, pharmacists and health care settings that dispense or administer the medication. For example, pharmacists must ensure that drugs with risks requiring REMS are dispensed and used safely. For some REMS, pharmacists and other dispensers will receive REMS communications from the manufacturers.

xxv Many payers and providers agreed on the criterion that a patient must be maintained on a stable dosage for a drug to be appropriate for white bagging. However, clinical opinions differed on whether certain drugs meet this criterion. For example, BMC, which operates a specialty pharmacy, and BCBSMA both testified that they consider Remicade to meet this criterion, while clinicians from Rheumatology & Internal Medicine Associates, a large clinic, testified that they do not consider Remicade to meet this criterion.

of strategies to address this issue, such as increasing the opportunity for patients to partially fill, or "split fill," their prescription through white bagging, is also warranted.

Additional provider expenses

White and brown bagging can have unintended consequences of creating uncompensated provider expenses, as well as increasing administrative complexity in the health care system. With the buy and bill method, reimbursement to the provider for the drug compensates providers for both the costs of acquiring and storing the drug. White bagging still requires provider resources for intake and storage of the drug after receiving it from the third-party specialty pharmacy, but providers are not compensated for these expenses. Payers that mandate white bagging could allow providers to bill for drug intake and storage.[xxvi]

Payers in Massachusetts have disparate policies for white and brown bagging, as highlighted in the "payer policies" section. Each respondent's white and brown bagging policy includes different coverage rules, applicable drugs, exceptions processes, and networks and standards for specialty pharmacies. Providers have stated that compliance with the wide range of payer policies and exceptions consumes staff resources and increases their administrative expenses. Research indicates that administrative expenses represent a significant factor in high health care spending in the U.S.[15] The HPC has supported reducing unnecessary administrative expenses, or administrative waste, as a strategy to reduce health care spending growth.[16] Greater alignment between payer policies, including streamlined exceptions processes, could reduce administrative expenses associated with white and brown bagging and support more efficient health care spending in the Commonwealth.

LEGISLATIVE ACTION

STATE LEVEL ACTIVITY

Few states have acted to regulate white and brown bagging.[17] Ohio enacted legislation in 2014 prohibiting brown bagging for "dangerous" drugs for the treatment of cancer or a cancer-related illness that need to be administered intravenously or by subcutaneous injection.[xxvii] This law made it illegal to deliver these drugs to a patient, their representative, or their private residence unless they live in a care center.[18]

xxvi Alternatively, payers could build expenses for drug intake and storage into payment for the drug's administration. However, this approach has less precision as circumstances, such as a missed patient appointment, could result in a drug being stored but not ultimately administered.

FEDERAL ACTIVITY

Federal reports signal the Trump Administration's interest in white and brown bagging in Medicare. In May 2018, the Federal Department of Health and Human Services (HHS) published a report on potential strategies to lower drug prices that included a recommendation to shift Medicare coverage of some drugs from Part B to Part D.[19] The report also sought information on which drugs would be appropriate to shift to the pharmacy benefit and how beneficiaries could be protected from higher out-of-pocket costs if their Part B drugs were shifted to Part D.

In October 2018, HHS requested comments on a proposal for a Part B payment method in which providers would no longer buy and bill for most drugs. Providers would place orders for drugs through private vendors, and Medicare would reimburse the vendor for the drug and pay providers a flat fee for storage and handling of the drug.[20] The Federal interest in shifting drug coverage from the medical to the pharmaceutical benefit is likely to increase attention to this issue.

SUMMARY AND RECOMMENDATIONS

The growth of white and brown bagging policies reflects many of the problems in the current U.S. health care system. Not only are specialty drugs very high-cost, but unaligned reimbursement systems and differential market leverage result in very different prices for the same product based on site of care and drug distribution method. Payers have implemented third-party specialty pharmacy distribution as an innovation to reduce cost growth. However, this strategy bypasses systems that providers have developed to deliver drugs through buy and bill, and leads to provider concerns regarding patient safety and access. These policies may also have unintended consequences such as drug waste and uncompensated provider expenses.

xxvii A dangerous drug is defined in this statute as: (1) Any drug to which either of the following applies: (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription; (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription. (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply; (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body; (4) Any drug that is a biological product.

With appropriate safeguards and flexibilities in place, experience from the market suggests that some of these practices can reduce cost growth without sacrificing quality of care. Use of best practices to support safety and access are critical, as well as use of site neutral payment. The recommendations below reflect the HPC's analysis of the implications of white and brown bagging practices for health care costs, patient safety, and access to clinician-administered infused or injected prescription drugs.

- **RECOMMENDATION #1: Payers should not require brown bagging for any drug.** Payers should not require direct dispensing to a patient of any specialty drug that must be administered by a clinician. There is strong clinical consensus that requiring patients to properly store and then transport a drug to their clinician for administration jeopardizes patient safety.
- **RECOMMENDATION #2: Payers should offer home infusion as an optional benefit, not as a requirement.** Use of home infusion should be an individual decision by the provider and patient in cases where a provider and patient determine that drugs can be safely shipped, stored, and administered in the patient's home. While home infusion may increase the risk of adverse safety outcomes in some cases, it may also result in positive benefits for patients in other cases. This range of possible consequences underscores the need for home infusion to be an optional benefit, rather than a mandatory one, based on patient preference and clinician judgment that drugs can be safely shipped, stored, and administered in the patient's home. While home infusion should remain available for cases in which patients and providers conclude that it is the best option for the patient, it is important that patients and providers, rather than payers, are able to make this determination. Policies that allow exceptions only for demonstrated medical necessity may result in treatment delays and place an unnecessary burden on the patient.
- **RECOMMENDATION #3: Payers that require white bagging should use best practices in policies and ensure minimum safety standards and capabilities in the third-party specialty pharmacies with which they contract.** While some providers voiced concern regarding safety and access, other providers supported the use of white bagging in their practices in some cases. White bagging may also offer particular advantages for some small providers. This range of practices and perspectives suggest that white bagging can be used safely in some cases, but for payers that require white bagging, use of best practices in payer policies is critical to the safe implementation of white bagging. Best practices for payer policies include a patient-specific expedited exception process, minimum safety standards for third-party specialty pharmacies, and criteria for selection of drugs appropriate for white bagging.
- **RECOMMENDATION #4: Payers that require white bagging should offer site neutral payment for those drugs that are subject to white bagging requirements, allowing providers the option to use the buy and bill method with reimbursement for the drug set at the third-party specialty pharmacy rate.** The site neutral payment option would only need to apply to the drugs for which a payer required white bagging. This policy lowers drug prices, reduces provider administrative expenses associated with compliance with multiple different policies, and addresses concerns about safety and access.
- **RECOMMENDATION #5: Lawmakers should take action to increase public transparency and public oversight for the full drug distribution chain.** Increased transparency, including regarding rebates, would enable a more precise accounting of payer incentives in white and brown bagging. Consistent with previous HPC recommendations, lawmakers should enable increased public transparency and public oversight for pharmaceutical manufacturers, medical device companies, pharmacy benefit managers, including rebates to payers, consistent with existing requirements on payers and providers, including through mandated participation in the HPCs annual cost trends hearing and inclusion in the Center for Health Information and Analysis' and HPC's annual reports on health care cost drivers.
- **RECOMMENDATION #6: The Group Insurance Commission, the Massachusetts Health Connector, MassHealth, and all other state payers should consider requiring all plans with which they contract to adopt best practice provisions, which should include prohibiting requirements for brown bagging and home infusion, implementing safety standards, and providing a site neutral payment option.** The Commonwealth should use its power as a major health care purchaser to set expectations for the market. By implementing best practices in its plan contracts, the Commonwealth would support alignment in the market while also providing the highest quality care to its health plan members.

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August 11, 2020

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Via Email: Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulation Title 16, Section 1711, Section 1713, Section 1715.1, Article 2 Division 17, of Title 16 of the California Code of Regulations

The California Hospital Association and its 400 plus members appreciate the focused efforts the Board of Pharmacy has placed on the automated drug delivery system (ADDS) regulations and the specification of the two categories of ADDS, automated patient dispensing system (APDS), and automated unit dose system (AUDS). We particularly appreciate the exception granted in California Code Section 4427. 2, that states:

> (i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request.

With this in mind, we believe the proposed addition to 16 CCR 1711(f), "Further any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review " is a statement specifically directed for licensed ADDS and not unlicensed AUDSs used in a general acute care hospital facility or a licensed acute psychiatric hospital facility. As the proposed regulation is presently worded, we believe that a GACH would be required to submit quality assurance records for all medication errors related to the use of ADDs because these are technically categorized under the Board of Pharmacy's definition of ADDS.

Our members describe a robust process for quality assurance measures for AUDSs. Medication errors are evaluated and documented as part of our existing quality assurance program under California code 4125. Events involving controlled substances diversion are reported immediately. In addition, hospital and health system policies, procedures and security measures are in place to prevent diversion and theft as existing standards of practice. The current hospital pharmacy self-assessment includes a section on ADDs and review of ADDS to demonstrate that the elements are consistent with current and customary practices.

We therefore offer two recommendations to 1711(f)- Quality Assurance Program. First, to specify that the ADDS is a ”licensed” ADDS, to expressly exclude the AUDS units operated by GACH acute and psychiatric hospitals. And second, for the licensed ADDSs to “notify” the board of quality assurance records related to the use of APDS or other ADDS, versus submitting a copy of the report within 30 days. We believe that if any quality assurance records related to the use of an APDS were generated they could be reported to the board during license renewal. An additional field could be added to the ADDS license renewal form to achieve this.

And finally, we offer our observation that Section 1713(d)(2) is not congruent with California Code 4427.6(c), which states, “(c) The APDS shall have a means to identify each patient and only release the identified patient’s drugs and devices to ***the patient or the patient’s agent.***” Adding this would add clarity and consistency with the code section.

Section	BoP Proposed Language	Recommendations
1711(f) – Quality Assurance Program	Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.	Further, any record related to the use of a *licensed* automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.
	Further, any record related to the use of an automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review.	Further, *any licensee with a record* related to the use of an automated drug delivery system, must also *notify* the board during license renewal if any quality assurance records related to the use of APDS were generated.
1713(d)(2) -	The APDS has a means to identify each patient and only release that patient’s prescription medications.	The APDS has a means to identify each patient and only release the patient’s prescription medication *to the patient or the patient’s agent*

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

BJ Bartleson, RN, MS, NEA-BC
VP Nursing and Clinical Services

AMENDED IN SENATE AUGUST 13, 2020

AMENDED IN SENATE JULY 2, 2020

AMENDED IN ASSEMBLY MAY 20, 2019

AMENDED IN ASSEMBLY APRIL 30, 2019

AMENDED IN ASSEMBLY APRIL 4, 2019

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 1710

Introduced by Assembly Member Wood

February 22, 2019

An act to amend Section 4052.8 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1710, as amended, Wood. Pharmacy practice: vaccines.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime. Existing law authorizes a pharmacist to independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons 3 years of age or older.

This bill would also authorize a pharmacist to independently initiate and administer *any COVID-19* vaccines approved by the federal Food

and Drug Administration (FDA) under the circumstances described above. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.8 of the Business and Professions Code is amended to read:

4052.8. (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer *any COVID-19* vaccines approved by the federal Food and Drug Administration (FDA), or *vaccines* listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Pharmacy Law Waivers

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code (BPC) section 4062, the California State Board of Pharmacy (Board) or the Board president through delegated authority has issued the following waivers.

The Board will make every effort to send a notice via a subscriber alert when the declaration of emergency has been lifted to signal the expiration of any waivers. The Board urges interested parties to sign up to receive subscriber alerts for the most up-to-date information.

- Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision - Immunizations - BPC section 4114
- Reassessment/Revalidation/Re-evaluation Requirements for Sterile Compounding Staff Competencies – Title 16, California Code of Regulations, sections 1751.6(e)(2) and 1751.7(b) and (d)
- Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS) - Business and Professions Code sections 4119.11(a)(9) and BPC 4427.2(e)
- Certification in Basic Live Support - Business and Professions Code section 4052.8(b)(2)
- Restoration of Retired or Canceled Pharmacist License – BPC section 4200.5(d), Related to Retired Licensees; BPC section 4402(b), Related to Canceled Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for Reissuance or Renewal of License
- Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))
- Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)
- Remote Processing (BPC section 4071.1(a))
- Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)
- Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))
- Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic (BPC sections 4182(a) and (b)/BPC 4192(a) and (b))
- USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8)
- All Pharmacy Law Waiver

Expired Waivers

- Use of Alcohol Sanitizer before Donning Sterile Gloves (Title 16, California Code of Regulations, section 1751.5(a)(5))
- Prohibited Acts involving Dangerous Drugs or Devices (BPC sections 4169(a)(1) and 4161(b))
- Pharmacist Direct Supervision of Interns - Business and Professions Code section 4114
- Intern Pharmacist Licenses (BPC section 4208)
- Sterile Compounding Renewal Requirements for Facilities Located Within a Hospital (BPC sections 4127.1(c) & (d) and 4127.15(b))
- Use of Sterile Disinfectant Agents – Title 16, California Code of Regulations, section 1751.4(d)(1)
- Inventory Reconciliation Report of Controlled Substances (Title 16, California Code of Regulations, section 1715.65(c))
- Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b))
- Staffing Ratio of Pharmacists to Pharmacy Technicians (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7)

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Doug O'Brien, Pharm.D	Chair	Kaiser Foundation Hospitals	Sacramento
Eddie W. Avedikian, PharmD	Member	Providence Holy Cross Medical Center	Los Angeles
Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS	Member	UCSF Medical Center	San Francisco
Kevin Dorsey Tyler, MD, PhD	Member	Enloe Medical Center - Esplanade Campus	Butte
Leah Hatfield, PharmD, BCPS	Member	Sutter Valley Hospitals	Sacramento
Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN	Member	Providence Little Company of Mary Medical Center Torrance	Los Angeles
Nasim Karmali, RPh	Member	Kaiser Permanente Redwood City Medical Center	San Mateo
Reynaldo Rosario, MSN, RN-BC, CPHQ	Member	Santa Clara Valley Medical Center	Santa Clara
Richard B. Rabens, MD, MPH, FAAP	Member	Kaiser Permanente	Alameda
Rita Shane, Pharm.D, FASHP, FCSHP	Member	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens, Pharm. D, BCPS, CPPS	Member	Kaweah Delta Health Care District	Tulare
Anne Sodergren	Ex-officio	California Board of Pharmacy	
Art Woo, Pharm.D	Ex-officio	California Department of Public Health	
Cari Lee, Pharm.D	Ex-officio	California Department of Public Health	
John Christensen, Pharm.D	Ex-officio	California Department of Public Health	
Loriann DeMartini, Pharm.D	Ex-officio	California Society of Health System Pharmacists	
Patti Owens	Ex-officio	California Association of Health Facilities	
Randy Kajioka, Pharm.D	Ex-officio	California Correctional Health Care Systems	
Lisa Gunther Lum	Ex-officio	California Society of Health System Pharmacists	
Keith Yoshizuika, PharmD, MBA, JD, FCSHP	Ex-officio	California Society of Health System Pharmacists	

Medication Safety Committee
Hospital Representation

BY COUNTY

As of August 26, 2020

Denotes number of hospitals/health systems represented within that county.