# 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.

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.

## 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.

### 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.

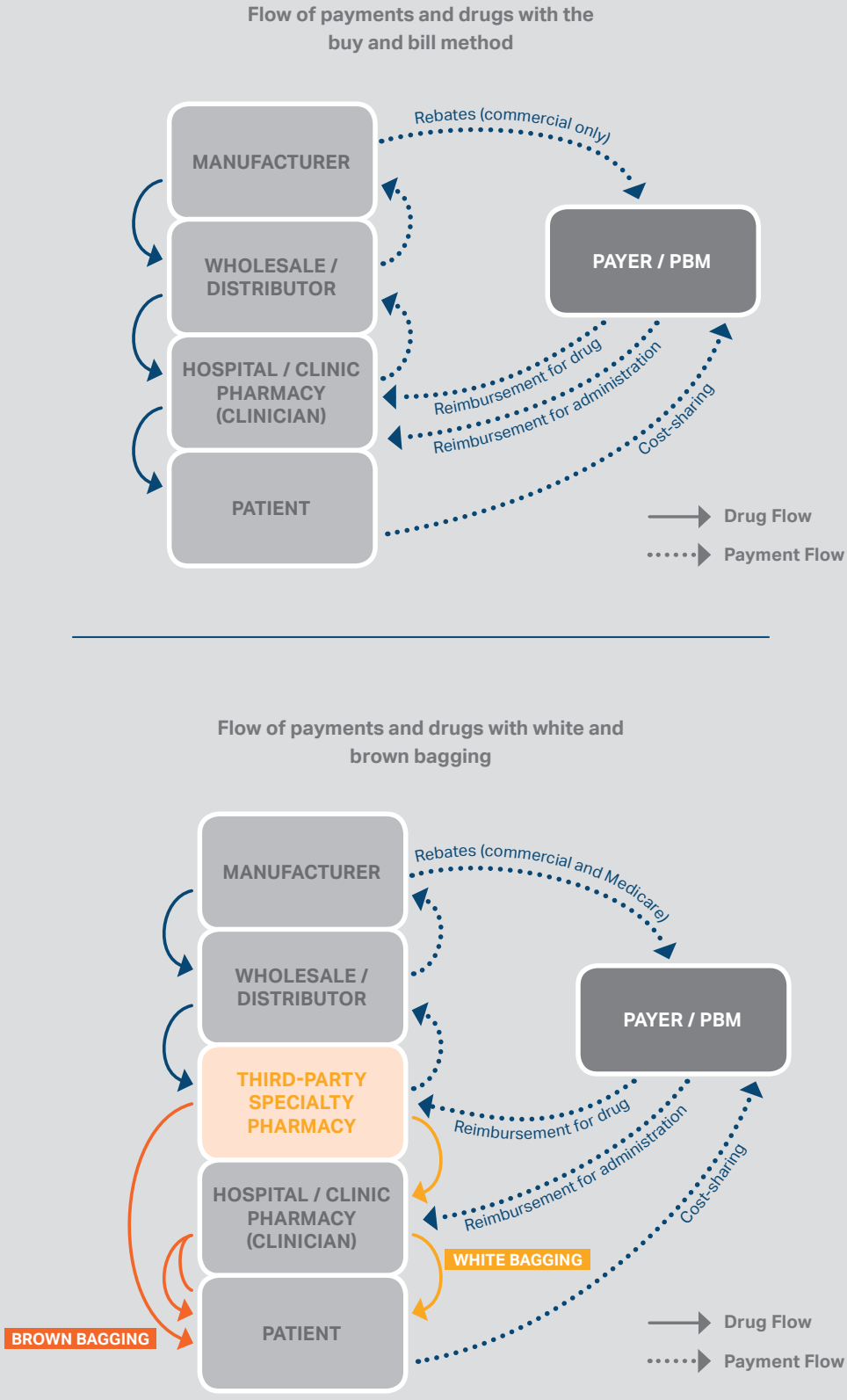
Medicare covers these drugs under Part D (Medicare's prescription drug benefit). Commercial payers also cover these drugs under their prescription drug benefit (the benefit that also covers traditional drugs that a patient would obtain at a pharmacy). With these channels, commercial payers and Medicare 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.

## ACKNOWLEDGEMENTS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