MASSACHUSETTS
HEALTH POLICY COMMISSION

Meeting of the Market Oversight and Transparency Committee

February 27, 2019

MASSACHUSETTS
HEALTH POLICY COMMISSION

AGENDA

- Call to Order
- Approval of Minutes
- Update on Out-of-Network Billing Issues
- Preview of White and Brown Bagging Report Findings
- Registration of Provider Organizations (RPO)
- Schedule of Next Meeting (June 5, 2019)

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VOTE: Approving Minutes

MOTION: That the Committee hereby approves the minutes of the MOAT Committee meeting held on November 28, 2018, as presented.

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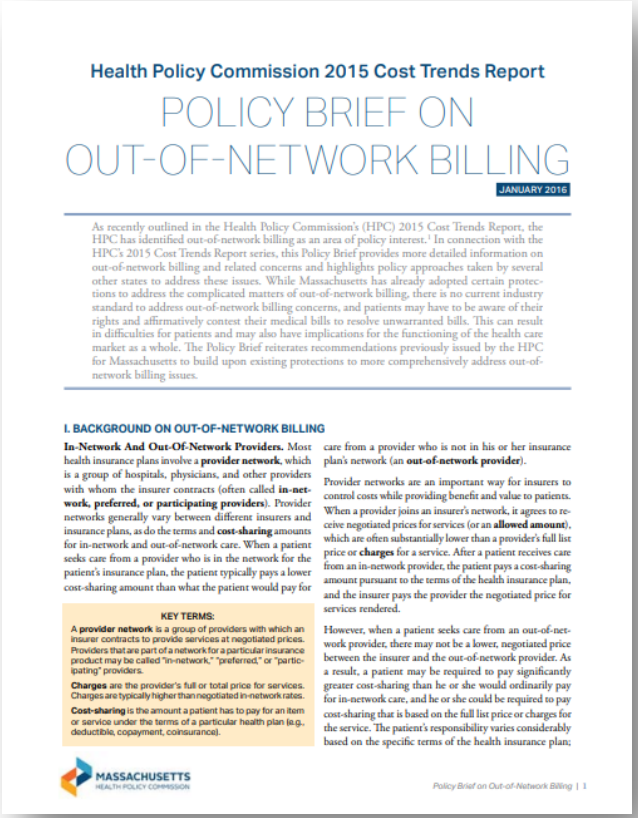
Introduction

Background

- The HPC first presented on out-of-network (OON) billing issues in connection with the 2015 Cost Trends Report, which was followed by publication of the HPC's Policy Brief on Out-of-Network Billing

- Today's presentation offers a series of OON billing updates from Massachusetts, other states, and the federal level



Health Policy Commission 2015 Cost Trends Report

POLICY BRIEF ON OUT-OF-NETWORK BILLING

JANUARY 2016

As recently outlined in the Health Policy Commission's (HPC) 2015 Cost Trends Report, the HPC has identified out-of-network billing as an area of policy interest.[1] In connection with the HPC's 2015 Cost Trends Report series, this Policy Brief provides more detailed information on out-of-network billing and related concerns and highlights policy approaches taken by several other states to address these issues. While Massachusetts has already adopted certain protections to address the complicated matters of out-of-network billing, there is no current industry standard to address out-of-network billing concerns, and patients may have to be aware of their rights and affirmatively contest their medical bills to resolve unwarranted bills. This can result in difficulties for patients and may also have implications for the functioning of the health care market as a whole. The Policy Brief reiterates recommendations previously issued by the HPC for Massachusetts to build upon existing protections to more comprehensively address out-of-network billing issues.

I. BACKGROUND ON OUT-OF-NETWORK BILLING

In-Network And Out-Of-Network Providers. Most health insurance plans involve a **provider network**, which is a group of hospitals, physicians, and other providers with whom the insurer contracts (often called **in-network, preferred, or participating providers**). Provider networks generally vary between different insurers and insurance plans, as do the terms and **cost-sharing** amounts for in-network and out-of-network care. When a patient seeks care from a provider who is in the network for the patient's insurance plan, the patient typically pays a lower cost-sharing amount than what the patient would pay for care from a provider who is not in his or her insurance plan's network (an **out-of-network provider**).

KEY TERMS:

A **provider network** is a group of providers with which an insurer contracts to provide services at negotiated prices. Providers that are part of a network for a particular insurance product may be called "in-network," "preferred," or "participating" providers.

Charges are the provider's full or total price for services. Charges are typically higher than negotiated in-network rates.

Cost-sharing is the amount a patient has to pay for an item or service under the terms of a particular health plan (e.g., deductible, copayment, coinsurance).

Provider networks are an important way for insurers to control costs while providing benefit and value to patients. When a provider joins an insurer's network, it agrees to receive negotiated prices for services (or an **allowed amount**), which are often substantially lower than a provider's full list price or **charges** for a service. After a patient receives care from an in-network provider, the patient pays a cost-sharing amount pursuant to the terms of the health insurance plan, and the insurer pays the provider the negotiated price for services rendered.

However, when a patient seeks care from an out-of-network provider, there may not be a lower, negotiated price between the insurer and the out-of-network provider. As a result, a patient may be required to pay significantly greater cost-sharing than he or she would ordinarily pay for in-network care, and he or she could be required to pay cost-sharing that is based on the full list price or charges for the service. The patient's responsibility varies considerably based on the specific terms of the health insurance plan;

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Policy Brief on Out-of-Network Billing | 1

Scope of OON Billing Concerns

Background

- Most insurance plans involve a provider network that contracts with the insurer to provide services to patients
- When a provider is OON, there may not be a contract between the insurer and provider that obligates the provider to accept a negotiated price, which would typically be lower than the provider's full list price or charges
- Patients may seek OON care in a variety of circumstances, but concerns arise when patients receive OON care that they **did not or could not intentionally choose to receive**, which predominantly occurs in two key scenarios:
  - **Emergency Care**
  - **OON care at an in-network facility** (e.g., radiology services)
- Patients and insurers may face high charges from OON providers in these circumstances, which can (1) create financial burdens for patients and (2) when such costs are borne by insurers, increase overall spending and impair tiered and limited network products

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Key OON Terminology

Background

Term	Definition
Balance Billing	A patient is billed for the difference between the OON provider's charge for services rendered and the insurer's payment to the OON provider
Surprise Billing	A patient receives an unexpected bill from an OON provider after seeking and receiving care at an in-network facility; the patient may not know that s/he received care from an OON provider until the patient receives a "surprise bill" for services rendered

For additional information, see the HPC's Policy Brief on Out-of-Network Billing.

Framework for Comprehensive OON Billing Solutions

Background

Objective	Description of Solution
<u>Reduce</u> OON billing scenarios	Disclosure and transparency requirements can increase access to timely and reliable information to ensure patients have a fair opportunity to choose in-network care to the extent possible (i.e., in non-emergencies) and understand the cost implications of receiving OON care.
<u>Remove</u> patient from the payment equation	Hold harmless provisions and balance billing prohibitions remove the patient from the payment equation that results after receiving unintentional OON care. Patients are responsible only for the applicable cost-sharing amount(s).
<u>Determine</u> OON provider payment	The determination of fair and reasonable payment to the OON provider for services rendered involves a complex balance of interests between insurers and providers. States have generally addressed this complicated issue by establishing OON payment levels (e.g., greater of the average contracted rate or 125% of Medicare) and/or dispute resolution processes (e.g., baseball style arbitration).

Laws in states that are considered to have comprehensive OON billing protections (e.g., New York, California, Connecticut) address all three objectives.

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HPC Recommendation to Strengthen OON Billing Protections in Massachusetts

Updates

- Consistent with previous Cost Trends Reports, the HPC recommends strengthening existing OON protections to comprehensively address both consumer protection issues and market implications in the 2018 Cost Trends Report (published Feb. 2019)
- Massachusetts should build upon the existing OON billing protections:
  - **Require advance patient notice:** Prior to delivery of non-emergency services, providers should be required to inform patients if they are OON
  - **Require consumer billing protections:** Consumers should be limited to their in-network cost-sharing levels for unintentional out-of-network services, and providers should be prohibited from balance billing consumers.
  - **Establish reasonable and fair provider reimbursement:** Policymakers should establish, by statute or an appropriate state regulatory process, a reasonable price for out-of-network services that will enhance the viability of limited and tiered network products, facilitate value-driven payer and provider rate negotiations, and ensure that out-of-network protections for consumers do not increase overall spending.

OON Billing Legislative Activity in Massachusetts

Updates

Takeaway from 2018: In the 2017-2018 legislative session, OON billing was addressed in multiple legislative proposals, including in comprehensive health care bills drafted in the House and Senate

- The House and Senate health care bills included multi-faceted approaches to enhance OON billing protections:
  - Both bills created new **disclosure and transparency requirements**, the extent and details of which varied
  - Both bills **prohibited balance billing** for patients
  - The bills differed in the approach to **OON provider payment determination** (e.g., the House bill established a dispute resolution process while the Senate bill did not)
- The conference committee process did not result in a compromise bill

What to watch for in 2019: Legislative proposals in the 2019-2020 legislative session that include solutions to enhance OON billing protections in Massachusetts

OON Billing Activity in Other States

Updates

Takeaway from 2018: States that recently passed, implemented, and/or amended OON billing laws include AZ, ME, MO, NH, **NJ**, and **OR**. Twenty-five states, including MA, now have at least partial OON billing protections in place.[1]

Ex: **New Jersey** passed a law in 2018 to strengthen existing OON billing protections for emergency and non-emergency services, after many years of failed attempts. In addition to other protections (e.g., new disclosure and transparency requirements), the law established a claims processing and arbitration system, whereby insurers and providers who cannot reach agreement on payment following negotiations can initiate binding, baseball style arbitration (if the minimum $1,000 threshold is met). Uniquely, the law also provides an opt-in for self-insured plans to be subject to the claims processing and arbitration provisions.

Ex: After the legislature considered different approaches, **Oregon's** 2017 law delegated the determination of OON provider payment to the Department of Consumer and Business Services (a state consumer protection and business regulatory agency), which convened an advisory group of insurers, providers, and consumer advocates. That group did not reach consensus on OON provider payment, but insurers and providers ultimately agreed on a payment standard (median allowed amount paid to in-network providers by commercial insurers in OR in 2015, adjusted annually), which resulted in an amendment to the law in 2018.

What to watch for in 2019: Efforts to address (or further address) OON billing are anticipated in many states, including CO, KY, MS, **NV**, NM, TX, UT, VA, WA, and WV.

Ex: **Nevada's** new governor identified OON emergency billing as a priority during his campaign, and the new legislative session is expected to include the introduction of new legislation (based in part on recent efforts of a working group that includes payers and providers), the reintroduction of vetoed OON billing legislation, and the reintroduction of a state constitutional amendment that addresses OON emergencies.

[1] Jack Hoadley et al, State Efforts to Protect Consumers from Balance Billing, *The Commonwealth Fund*, January 2019.

OON Billing at the Federal Level

Updates

Reminder: Due to ERISA preemption, state OON billing protections may not apply to self-funded employee health benefit plans. A comprehensive solution requires federal legislation.

Takeaways from 2018:

- Several **legislative proposals** were introduced in the 115th Congress, including a bill sponsored by Sen. Maggie Hassan (D-NH) that would establish binding, baseball style arbitration for OON provider payment determination – but also provides alternative options for states
- A bipartisan group of six senators, led by Sen. Bill Cassidy (R-LA) and former Sen. Claire McCaskill (D-MO), introduced a **draft bill** for discussion in fall 2018, which would establish an OON provider payment standard: an amount determined in accordance with applicable state law OR an amount at least equal to the greater of (1) the "average amount" (median in-network amount negotiated) or the (2) "usual, customary, and reasonable rate" (125% of average allowed amount)
- Industry **coalitions** formed and **lobbying efforts** appeared to increase
- **Media coverage** of OON billing issues increased (e.g., Kaiser Health News and NPR)

What to watch for in 2019:

- **Legislative proposals,** perhaps bipartisan, in the 116th Congress, including legislation introduced by Rep. Doggett (D-TX) and potential bills led by Sen. Cassidy and/or Sen. Hassan
- Continued **input from industry stakeholders**, particularly regarding OON provider payment
  - A bipartisan group of senators, led by Sen. Cassidy, recently sent information request letters – including requests for data – to industry stakeholders
- **Efforts by the Trump administration** following President Trump's declaration that the administration will end surprise billing

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Legislative Mandate for White and Brown Bagging Report

Section 130 of Chapter 47 of the Acts of 2017

The Massachusetts Health Policy Commission (HPC), in consultation with the Department of Public Health (DPH) and the Division of Insurance (DOI), shall:

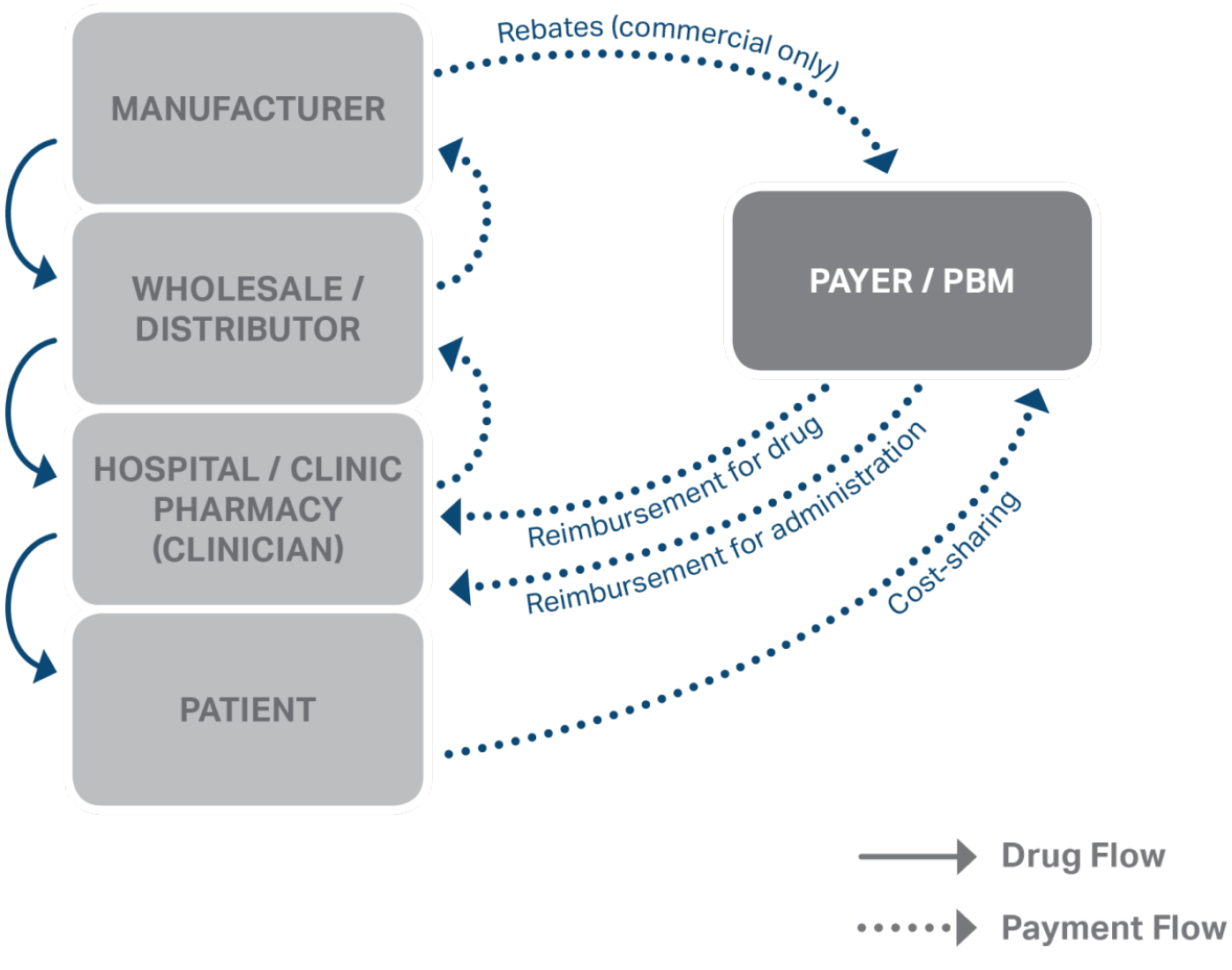
- **Study and analyze health insurance payer practices** that require certain categories of drugs (e.g. those administered by injection or infusion) to be dispensed by a third-party specialty pharmacy directly to a patient or to a health care provider with the designation that such drugs shall be used for a specific patient and not for the general use of the provider

- **Submit a report of its findings and recommendations** to the joint committee on health care financing and the joint committee on public health

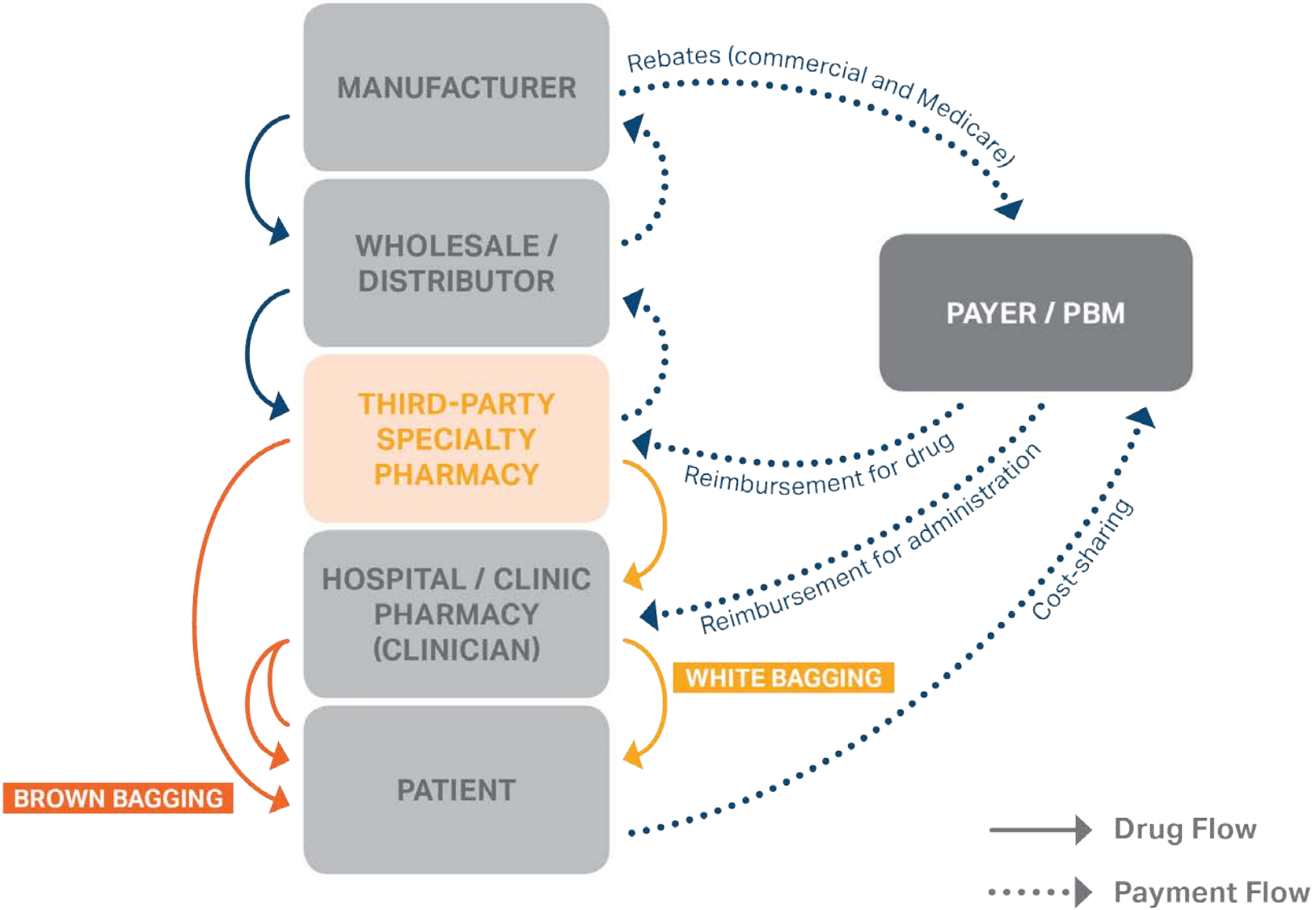
Presentation Agenda: Preview of White and Brown Bagging Report Findings

1. **Overview**
2. Prevalence and Payer Policies
3. Financial Implications
4. Safety and Access
5. Legislative Activity
6. Considerations for Recommendations

Flow of Payments and Drugs with Buy and Bill (Traditional Model)



Flow of Payments and Drugs with White and Brown Bagging (Payers Reimburse Third-Party Specialty Pharmacy for Drugs)



White and Brown Bagging Report: Outline

1. **Prevalence and payer policies**
2. **Financial implications: Impact on healthcare spending and patient cost-sharing**
   a) Commercial
      i. Results with BCBSMA data (APCD)
      ii. U.S. data
   b) Medicare
3. **Patient safety and access to care**
   a) Brown bagging
   b) Home infusion
   c) White bagging
4. **Other unintended consequences**
   a) Drug waste
   b) Additional provider expenses
5. **Legislative action**
   a) State level activity
   b) Federal activity
6. **Policy Recommendations**

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White and Brown Bagging Report: Methods and Data Sources

Study Approach

Identified Relevant Published Literature

- Limited information on prevalence of white and brown bagging in U.S.
- Comparison of prices for some drugs in U.S.
- Little information on safety and access; no Massachusetts-specific information

Held Public Listening Session (May 9, 2018)

- Sought written testimony from diverse set of stakeholders, including providers and health plans

Analyzed Price Data from All-Payer Claims Database (APCD)

Conducted Survey of Commercial Payers

- 6 commercial payers, representing 72% of commercial member lives in Massachusetts
- Focused on prevalence, drug selection, policies related to safety and access
- Supplemented survey by searching publically available plan documents

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Presentation Agenda: Preview of White and Brown Bagging Report Findings

1. Overview
2. **Prevalence and Payer Policies**
3. Financial Implications
4. Safety and Access
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Prevalence of White and Brown Bagging in the U.S. and Massachusetts

Prevalence in the U.S.

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

Prevalence in Massachusetts

- Among HPC survey participants, most payers allow the ***option*** of white bagging, brown bagging, or home infusion. In addition:
  - **Two payers require white bagging for select drugs**
  - **Two payers require home infusion for select drugs,**
  - **No payers require brown bagging**
- Data 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

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Magellan Rx Management. Medical Pharmacy Trend Report: 2015 Sixth Edition. 2015. Available at: https://www1.magellanrx.com/media/409913/2015trendreport_mayfinal.pdf

White and Brown Bagging: Payer Exception and Payment Policies

HPC Findings on Payer Exception and Payment Policies in Massachusetts

- Among payers that ***require*** white bagging or home infusion, there are a wide range of exception policies:
  - Fallon and Neighborhood Health Plan (NHP) **require home infusion for certain drugs**; both only allow exceptions if medical necessity criteria are met
  - Tufts Health Plan (THP) **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 Blue Shield of Massachusetts' (BCBSMA) white bagging policy requires certain drugs to be filled by a contracted network specialty pharmacy; however, BCBSMA offers a **site neutral payment policy**
  - Any qualified facility may join the plan's specialty pharmacy network, which allows providers to use a buy and bill system, **with reimbursement set at the third-party specialty rate**
  - Providers that do not have pharmacies that meet the plan's criteria may also gain an exception to **buy and bill at the site neutral rate**

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The HPC analyzed claims data to examine the impact of white and brown bagging on healthcare spending and patient cost-sharing

Commercial

- Results based on All-Payer Claims Database (APCD) analysis of BCBSMA prices
  - BCBSMA was the only payer in the APCD with a robust sample size of claims in both the medical and pharmacy claim files in 2015
  - BCBSMA's site neutral payment policy was implemented in the fourth quarter of 2015
- Data do not account for rebates, which commercial payers may receive with buy and bill or white bagging
- HPC analyzed price per unit for Botox, Xgeva, and Remicade

Medicare

- HPC analyzed Medicare prices and patient cost-sharing using the Part B fee schedule and Part D plan finder (used plan with second-lowest premium, Aetna Medicare Rx Select)
- Prices do not include rebates that a plan may receive under Part D
- HPC analyzed price per unit for Xgeva, Remicade, Sandostatin LAR, Gammagard

Commercial drug prices are substantially lower with white bagging; average cost-sharing is low with buy and bill and white bagging

Commercial price and patient cost-sharing per billing unit of drug with buy and bill versus white bagging, BCBSMA, 2013 and 2015

2013	Total price per unit		Difference	Patient cost-sharing per unit		Difference
Drug (unit)	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

Drug (unit)	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 (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 All-Payer Claims Database, 2013 and 2015

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While commercial cost-sharing is low under both systems, on average, some consumers face high cost-sharing under buy and bill, likely reflecting whether patients have already met their medical deductible

Distribution of patient cost-sharing per unit of Remicade (100 mg) with buy and bill versus white bagging, BCBSMA, 2015

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

For both buy and bill and white bagging, total patient cost-sharing depends on the price of the drug and on the benefit design

Notes: Results are for Blue Cross Blue Shield of Massachusetts. 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 (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 All-Payer Claims Database, 2015

Medicare prices appear higher with Part D than Part B, although these prices do not include rebates that a plan may receive under Part D

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

	Total drug cost			Patient cost-sharing			Percent cost-sharing	
	Part B	Part D	Difference	Part B	Part D	Difference	Part B	Part D
Remicade (100 mg)	$871	$1,234	41.6%	$190	$260	37%	22%	21%
Sandostatin LAR (10 mg)	$1,836	$3,290	79.1%	$383	$363	-5%	21%	11%
Gammagard Liquid (2.5 mg / 25 ml)	$199	$352	77.0%	$55	$117	113%	28%	33%
Xgeva / Prolia (1.7 ml)	$2,080	$2,342	12.6%	$432	$315	-27%	21%	13%

Patient cost-sharing trends varied substantially by drug, suggesting that white bagging has the potential to result in much greater cost-sharing for some Medicare beneficiaries

Sources: Medicare OPPS fee schedule 2018, Addendum B (Part B). Part D Plan Finder (Part D).
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. Neither 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.

Summary of Financial Implications

Commercial Market

- Consistent with national estimates, **drug prices in Massachusetts were substantially lower with white bagging**
  - U.S. data: Buy and bill prices for drugs administered in a hospital outpatient department are much higher than prices in the physician office, highlighting how white and brown bagging may affect different types of providers differently
- White bagging had higher cost-sharing than buy and bill for most of the four drugs studied, but **differences were relatively minimal** and overall amounts were relatively low
- For both buy and bill and white bagging, total patient cost-sharing depends on the price of the drug and on the benefit design

Medicare Market

- 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
- Patient cost-sharing trends varied substantially by drug, suggesting that **white bagging has the potential to result in much greater cost-sharing for some Medicare beneficiaries**

HPC

Magellan Rx Management. Medical Pharmacy Trend Report: 2017 Eighth Edition. 2017.

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3. Financial Implications
4. **Safety and Access**
5. Legislative Activity
6. Considerations for Recommendations

Safety and Access: Brown Bagging

- Provider testimony was **virtually unanimous** in detailing 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
  - Difficulty maintaining **accurate documentation** related to the drug

"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." (Provider Testimony)

Safety and Access: Home Infusion

- Some providers and patients have 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

"It only took my first visit to realize [home infusion] wasn't for me. …They sent me an incorrect itemization list, the incorrect amount of sodium fluoride 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…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 nearby] infusion center to request an immediate early infusion…This home infusion requirement was thrown at me…This is something I should have been informed of in detail which I wasn't."
(Patient Letter Submitted)

Safety and Access: White Bagging

- Testimony regarding safety and access was **mixed for white bagging**: providers expressed concerns, but some also detailed safeguard that they employ to successfully manage use of white bagging in their practices

- Safety concerns with white bagging included:
  - Drugs that arrive can be incompatible with in-house equipment to deliver the infusion
  - Provider 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
  - Drugs may not be streamlined with in-house pharmacy systems that provide safety controls and manage inventory

"…[W]hen a specialty pharmacy sends a different size vial than what we have in [our] system…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 [a pharmacist verifying] every step of the preparation). Bypassing DoseEdge may contribute to [a] mistake during the preparation of the medication."
(Provider Testimony)

Safety and Access: White Bagging

Access to Care

- **White bagging has challenges that do not exist under buy and bill**
  - 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

- Despite these challenges, **white bagging can improve access for patients under certain circumstances**, especially with smaller providers
  - Insurers frequently place utilization management restrictions on drugs whether they are covered through buy and bill or white bagging; smaller providers may find advantages in working with a specialty pharmacy with expertise and staff resources to negotiate utilization management requirements with insurers and can offer specialized medication adherence and education programs

Provider and payer testimony detailed varied approaches to maximize safety and access with white bagging

Best practices for payer policies include:

- **Adopt a site neutral payment policy allowing providers to use a buy and bill system with reimbursement levels set at the specialty pharmacy rate**
  - Allows payers to achieve similar savings to coverage under 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.

- **Patient and provider notification**
  - Provide sufficient notice and education to both providers and patients prior to implementing a white bagging policy.

- **Exception process**
  - 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.

Provider and payer testimony detailed approaches to maximize safety and access with white bagging

Best practices for third-party specialty pharmacies include:

- Same day delivery and 24/7 member on-call access to a pharmacist or nurse.
- Ability to provide cold chain logistics, 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.
- 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.
- Expertise in Risk Evaluation and Mitigation Strategy (REMS) reporting.
- Accreditation through relevant groups (e.g. Joint Commission on the Accreditation of Healthcare Organizations, National Association of Board of Pharmacy, etc)

Provider and payer testimony suggested considerations for selecting drugs appropriate for white bagging

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.

Presentation Agenda: Preview of White and Brown Bagging Report Findings

1. Overview
2. Prevalence and Payer Policies
3. Financial Implications
4. Safety and Access
5. **Legislative Activity**
6. Considerations for Recommendations

Legislative Activity at the State and Federal Level

State level activity

- Few states have acted to regulate white and brown bagging
- Ohio enacted legislation in 2014 prohibiting brown bagging in certain cases
  - Legislation prohibits brown bagging for "dangerous" drugs for the treatment of cancer or a cancer-related illness

Federal activity

- Recent Federal activity signals the 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 strategies to lower drug prices that recommended shifting Medicare coverage of some drugs from Part B to Part D
  - In October 2018, HHS requested comments on a proposal for a Part B payment model which would significantly change the buy and bill system
    - 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 of the drug

American Patients First: The Trump Administrations Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018. Available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
HHS Press Office. HHS advances payment model to lower drug costs for patients. Oct 25, 2018. Available at: https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html

Presentation Agenda: Preview of White and Brown Bagging Report Findings

1. Overview
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5. Legislative Activity
6. **Considerations for Recommendations**

Committee Discussion: Considerations for Recommendations

Data indicate that drug costs are generally lower with third-party specialty pharmacies, but HPC recommendations should balance considerations for health care costs, safety, and access

- **Brown bagging:** *Recommendations should reflect conclusions of strong clinical consensus that brown bagging requirements jeopardize patient safety by requiring patients to properly store and then transport a drug to their clinician for administration.*
- **Home infusion:** *Recommendations should reflect conclusions of potential for safety and access concerns and range of patient preferences.*
- **White bagging:** *Recommendations should reflect conclusions of potential for safety and access concerns and evidence that use of key best practices can support appropriate white bagging use*

MASSACHUSETTS
HEALTH POLICY COMMISSION

AGENDA

- Call to Order
- Approval of Minutes
- Update on Out-of-Network Billing Issues
- Presentation of White and Brown Bagging Findings
- **Registration of Provider Organizations (RPO)**
  - MA-RPO Program: 5-Year Reflection
  - MA-RPO Program: 2019 Filing Update
- Schedule of Next Meeting (June 5, 2019)

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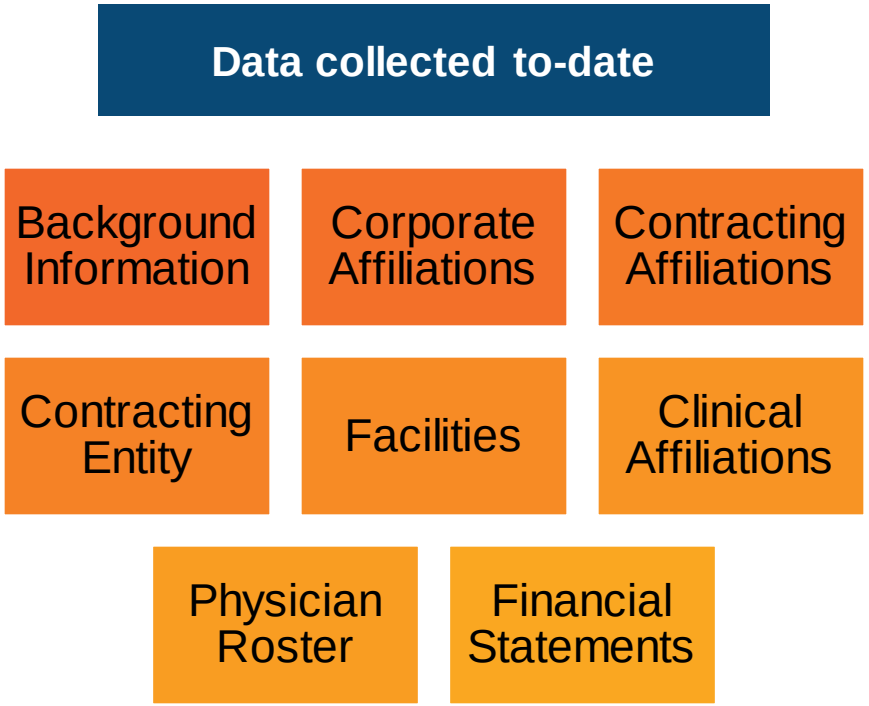
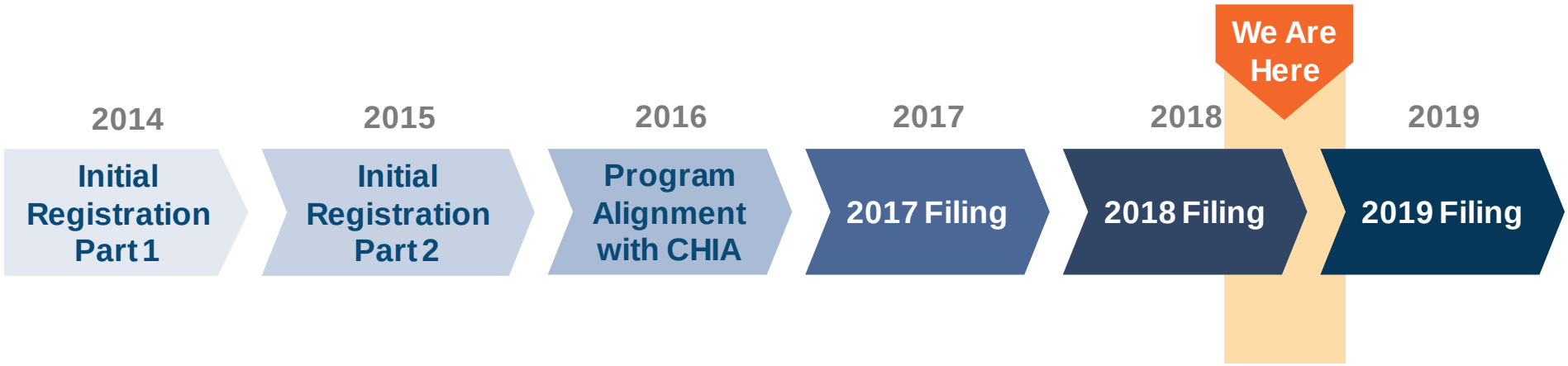
Overview of the MA-RPO Program

- The MA-RPO Program is a **first-in-the-nation** initiative for collecting public, standardized information on Massachusetts' largest health care providers annually
- The data contribute to a foundation of information needed to support **health care system transparency and improvement**
- This regularly reported information on the health care delivery system supports many functions including: care delivery innovation, evaluation of market changes, health resource planning, and tracking and analyzing system-wide and provider-specific trends



MA-RPO Program Timeline

The 2019 filing will be the fifth data collection cycle since the program's inception



First-in-the-nation Initiative

Before MA-RPO, basic data about the structure of the Massachusetts market were not available in a standardized, accessible format

Value to End Users

Researchers
Ariadne Labs
BU, Harvard, UC Berkeley
NBER
RAND

Market Participants
Providers
Payers
Trade Organizations
Unions

Government
HPC
EOHHS
CHIA
AGO
US Dept. of Labor
Federal Trade Commission

- The HPC uses MA-RPO data as a major input into several ongoing analyses:
  - **Provider Organization Performance Variation**
  - **Cost and Market Impact Reviews**
  - **Performance Improvement Plan assessments**
- Teams across the agency regularly use the data to answer specific questions

Guiding Principles

From its inception, the MA-RPO Program has used the following principles to guide its work

1. Administrative simplification
2. Phasing in the types of information that Provider Organizations must report over time
3. Avoiding duplicative data requests through ongoing coordination with other state agencies
4. Balancing the importance of collecting data elements with the potential burden to Provider Organizations

Guiding Principles

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Online Submission Platform

- Provider Organizations use the online submission platform to complete their filings
- Data submitted in the previous year's filing are prepopulated
- Features and tools added based on user feedback

Commitment to Providing Excellent Customer Service

Targeted training sessions

General and customized resources

One-on-one meetings

Online submission platform assistance

MA-RPO Feedback Surveys

The MA-RPO Program regularly seeks anonymous feedback from registrants about their experience and uses the data to improve the program

Registrants expressed interest in a data resource that would map relationships **between existing files** (e.g., contracting relationships and clinical relationships)

Provider Organizations are interested in linking MA-RPO with other datasets, including the **APCD** and other **CHIA** data

Multiple respondents have used, are currently using, or are interested in **using MA-RPO data**

Respondents recommended **increased coordination** with other programs, including ACO Certification and the Risk-Bearing Provider Organization process

Guiding Principles

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Overview of MA-RPO Data Collection

1. Background Information File
2. Corporate Affiliations File
3. Contracting Affiliations File
4. Contracting Entity File
5. Facilities File
6. Clinical Affiliations File
7. Physician Roster
8. Financial Statements File

Initial Registration Part 1

In the first year of the program, registration was divided into two parts to minimize the burden on Provider Organizations

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Initial Registration Part 2

Much of the required information is static year-over-year, allowing Provider Organizations to confirm the existing information or make updates as needed

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2018 Filing

Some categories of information in HPC and CHIA's statutes have not yet been required

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Avoiding Duplicative Data Requests

There are several categories in the statute for which the MA-RPO program does not require organizations to submit information

1. Copies of risk certificates and risk certificate waivers are available through DOI
2. Community benefits information is available through the AGO

The MA-RPO Program allows for attestation when information is available through another state agency

3. Provider Organizations can indicate that financial statements are available through CHIA, DOI, or the AGO

The MA-RPO Program minimizes duplicative reporting across Provider Organizations

4. Provider Organizations are not required to submit a physician roster if each of their physicians is reported by another Provider Organization
5. Clinical Affiliations are typically only reported by one party to the affiliation due to reporting directionality requirements
6. Corporate systems submit a single filing

Aligning RPO Reporting Between HPC and CHIA

	HPC RPO	CHIA RPO		MA-RPO Program
Who	▪ Provider Organizations with $25 million in commercial NPSR ▪ Risk Bearing Provider Organizations	All Provider Organizations that register with the HPC	Aligned →	**Same** organizations
What	4 statutory categories of information	10 statutory categories of information, 4 of which are identical to the HPC's categories	Opportunity →	Submit the **same** information
When	Biennially, with off-cycle updates in certain circumstances	Annually	→	**Once** a year
How	Shared online submission platform	Shared online submission platform	Aligned →	Through **one** submission process

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Balancing Burden and Value

Routinely reevaluate questions

- Service lines at licensed facilities
- APM & Other Revenue file

Consider competing priorities

- No new data elements during MassHealth ACO launch
- Moved deadline to summer based on feedback

Seek constant feedback

- Biennial survey of Provider Organizations
- Stakeholder engagement sessions
- New data elements based on end user priorities

HPC

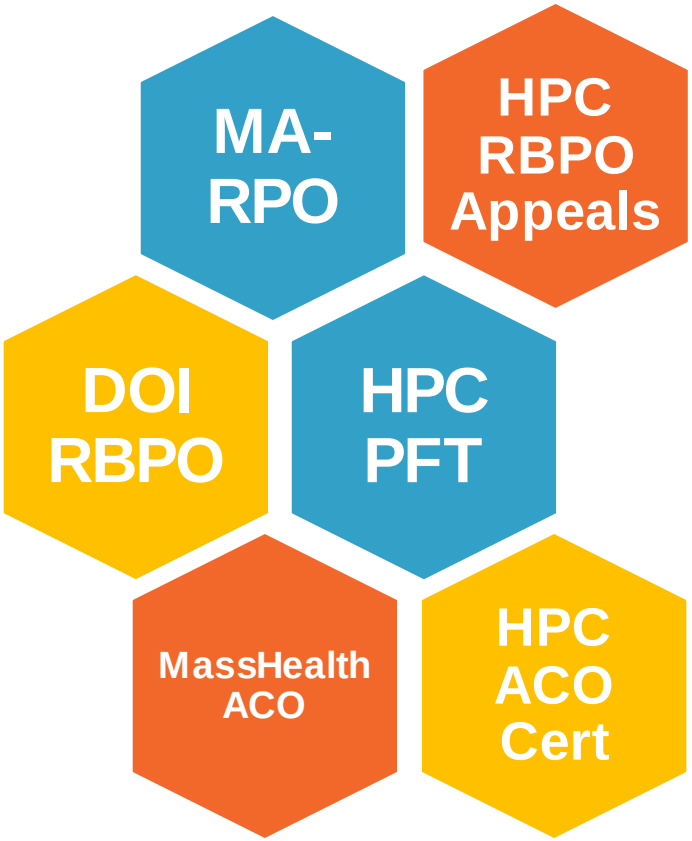
Five Years Later: A Mix of Successes and Opportunities

- Aligning HPC and CHIA RPO programs
- Routinely reevaluate questions*
- Wide range of organizations and projects using data
- Successful customer service

- Routinely reevaluate questions*
- Increase lead time for new reporting requirements
- Ongoing assessment of areas where information can be sourced from existing datasets
- Wider variety of formats and resources for data release
- Increased alignment across programs

Administrative complexity without value is a key HPC focus area

Commitment to Reduce Administrative Complexity



The HPC commits that:

Over the next 12-18 months, HPC will convene staff from related programs to identify opportunities for administrative simplification and enhanced alignment and develop a plan for implementation

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Proposed Updates to the 2019 Filing

The MA-RPO Program released the proposed updates to the 2019 filing for public comment in November

	Overview	Purpose
Facility Fees	Replacing a data element in the Facilities file to better capture information about **facility fees** paid to the Provider Organization by different payers	Allow users (e.g., policymakers) to better understand which facilities are currently charging facility fees to commercial payers, an area for which there is relatively little data available in Massachusetts
IP Beds / EDs	Adding new data elements to the Facilities file to capture information on the **presence of inpatient beds and EDs** at hospitals and clinics	Enhance transparency around certain service offerings (i.e., inpatient capacity and presence of emergency departments) at hospitals and clinics

Proposed Updates to the 2019 Filing

The MA-RPO Program released the proposed updates to the 2019 filing for public comment in November

	Overview	Purpose
APP Roster	Requiring a roster of employed **Advanced Practice Providers (APPs)** from each Provider Organization	Provide a better understanding of care delivery practices and access to primary care services
Payer Mix	Collecting **payer mix** information from each of the Provider Organization's corporate affiliates that are physician practices	Users can currently calculate a hospital's payer mix using CHIA financial and hospital discharge data. Collecting payer mix data for physician practices will complement hospital-level data

Public Comment

The MA-RPO Program received written comments from **17 organizations** during the comment period. Program staff extends sincere thanks to the individuals and organizations that provided feedback and insight on the proposed requirements

Summary of Comments

Facility Fees	Variation and complexity in how providers are paid reduces the value of this question; responses are not comparable across organizations and risk to policymakers and patients of misinterpreting data is high
IP Beds / EDs	Commenters expressed appreciation that program staff are going to populate responses using DPH data
APP Roster	Burden of providing data on APPs is high Provider Organizations indicated that they do not track specialty data for APPs the same way that they do for physicians
Payer Mix	Many organizations indicated that they do not have systems in place to report the visit count data requested

2019 Filing

A key value of the MA-RPO Program is to balance registrant reporting burden with the utility of the dataset to end users

Facility Fees	Do not collect in 2019
IP Beds / EDs	Collect as proposed, using data from DPH
APP Roster	Do not collect in 2019
Payer Mix	Collect with modifications to proposal - Remove visit count

2019 Filing Timeline and Next Steps

November 29, 2018 *– Released proposed updates for public comment*

December 21, 2018 – *Comments due to MA-RPO program*

February 27, 2019 – MOAT Committee Update

March 2019 – Release Final 2019 Data Submission Manual and filing templates

Spring 2019 – Training sessions and prep work with Provider Organizations

July 31, 2019 – Anticipated filing deadline for 2019 filing

HPC

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2019 Hearing on the Health Care Cost Growth Benchmark

Wednesday, March 13
12:00 PM
Massachusetts State House
Gardner Auditorium

Public Testimony

If you are interested in providing public testimony, please email Ben Thomas:

Benjamin.A.Thomas@mass.gov

Upcoming 2019 Meetings and Contact Information

Board Meetings

Wednesday, March 13 – Benchmark Hearing
Wednesday, April 3 (3:00 PM) – NEW
Wednesday, May 1 (1:00 PM)
Wednesday, July 24
Wednesday, September 11
Monday, December 16 – RESCHEDULED

Committee Meetings

Wednesday, February 27
Wednesday, June 5
Wednesday, October 2
Wednesday, November 20

Contact Us

Mass.Gov/HPC
@Mass_HPC
HPC-Info@state.ma.us

Special Events

2019 Cost Trends Hearing
Day 1 – Tuesday, October 22
Day 2 – Wednesday, October 23