

Health Policy Commission Board Meeting February 5, 2020



AGENDA

- Call to Order
- Approval of Minutes from November 20, 2019 Meeting
- Market Oversight and Transparency
- Executive Director's Report
- Executive Session: Performance Improvement Plans (VOTE)
- Schedule of Next Meeting (March 11, 2020)



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VOTE: Approving Minutes

MOTION: That the Commission hereby approves the minutes of the Commission meeting held on **November 20, 2019** as presented.



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 - 2019 Annual Cost Trends Report: Findings and Policy Recommendations (VOTE)
 - Drug Pricing Review: Final Regulation (VOTE)
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Types of Transactions Noticed

TYPE OF TRANSACTION	NUMBER	FREQUENCY
Physician group merger, acquisition, or network affiliation	23	21%
Clinical affiliation	23	21%
Acute hospital merger, acquisition, or network affiliation	22	21%
Formation of a contracting entity	20	19%
Merger, acquisition, or network affiliation of other provider type (e.g., post-acute)	13	12%
Change in ownership or merger of corporately affiliated entities	5	5%
Affiliation between a provider and a carrier	1	1%



Proposed merger between two federally qualified health centers, **East Boston Neighborhood Health Center** (East Boston) and **South End Community Health Center** (South End), under which South End would merge into East Boston.



Proposed joint venture between **Baystate Medical Center** (Baystate) and **Greater Springfield Surgery Center** (GSSC), an ambulatory surgery center located in Springfield, under which Baystate would acquire 51% of GSSC.

Proposed acquisition of **Exeter Health Resources** (EHR) by **Partners HealthCare System** (Partners). EHR includes Exeter Hospital, an acute care hospital in Exeter, New Hampshire, as well as a multi-specialty physician practice, Core Physicians, and a visiting nurse association and hospice.





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2019 HEALTH CARE COST TRENDS REPORT SELECT FINDINGS

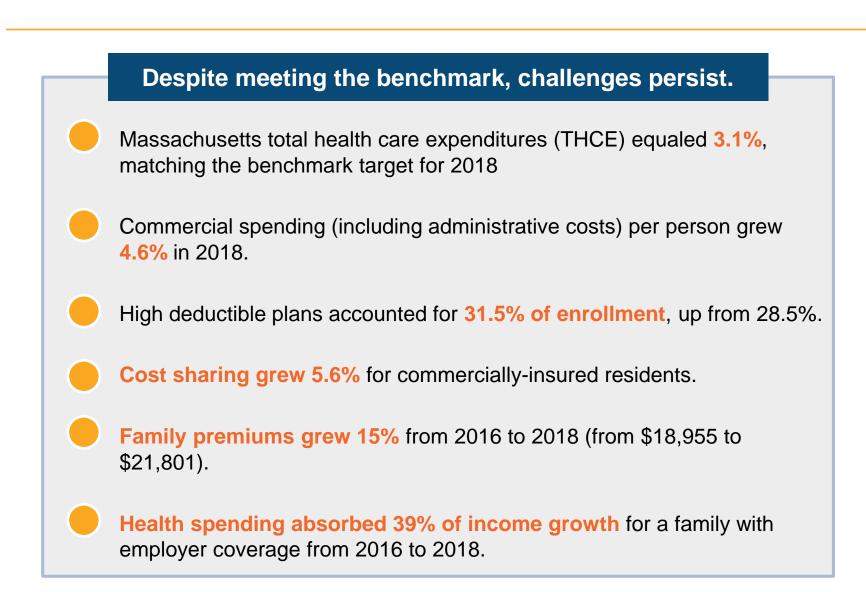


Outline of 2019 Annual Health Care Cost Trends Report

Main Report		Chartpack	
	Overview of trends in spending and affordability	•	Provider organization performance variation (spending, utilization, and low-value care)
•	Commercial hospital inpatient trends	•	Hospital utilization
•	Commercial hospital outpatient trends	•	Post-acute care
•	Policy recommendations and dashboard of performance metrics	•	Alternative payment methods

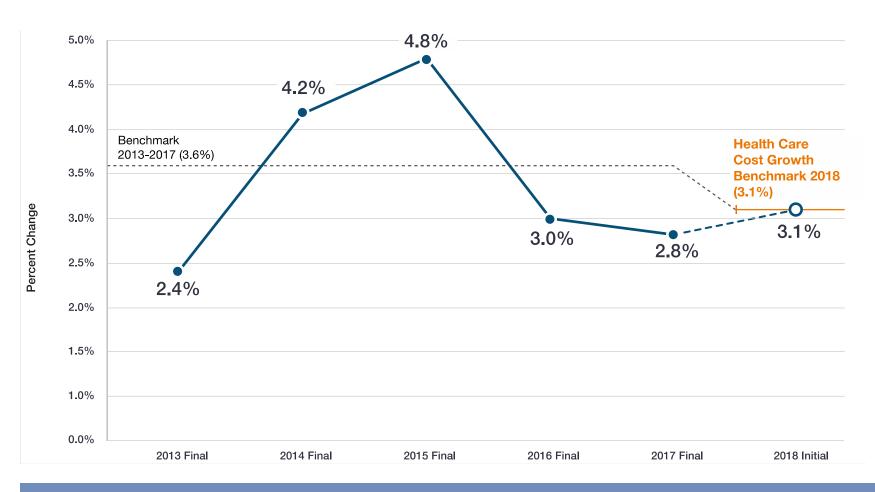


Overview of Trends in Spending and Affordability: Key Findings





From 2012 to 2018, annual health care spending growth averaged 3.4%, below the state benchmark.

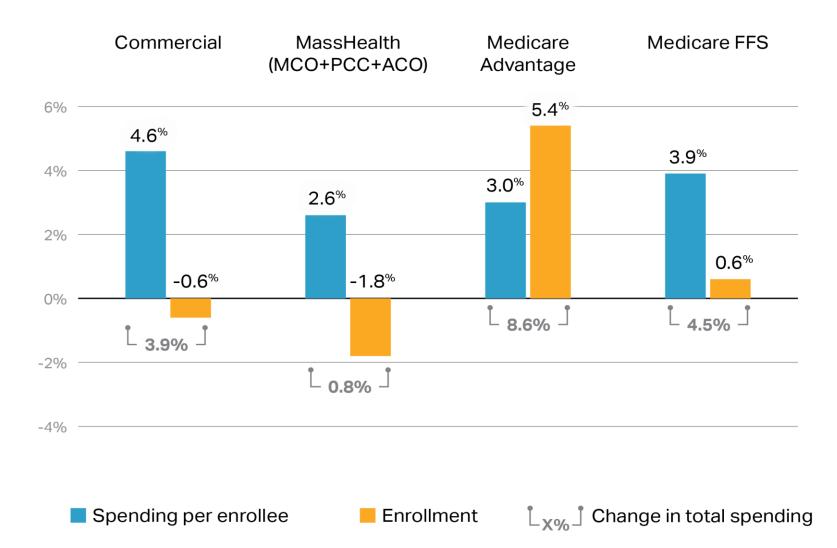


The initial estimate of THCE **3 1 0**

IPC

This is the third consecutive year it met or fell below the health care cost growth benchmark.

Spending per enrollee grew above the benchmark rate for both the commercial and Medicare fee-for-service sectors.





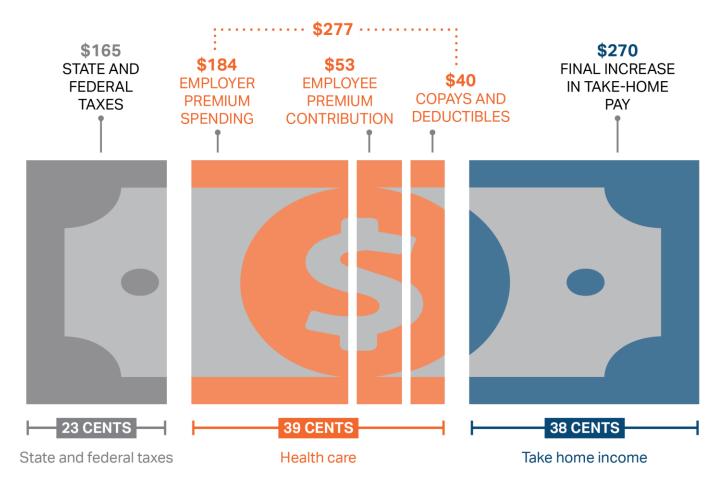
Notes: Medicare FFS spending does not include Part D prescription drug coverage. Commercial spending and enrollment growth includes enrollees with full and partial claims and the net cost of private health insurance. MassHealth includes only full coverage enrollees in the MCO, PCC, and ACO programs. Figures are not adjusted for changes in health status.

Sources: Center for Health Information and Analysis Annual Report, 2019

Commercial

Nearly 40 cents of every additional dollar earned by Massachusetts families between 2016 and 2018 went to health care.

Allocation of the increase in monthly compensation between 2016 and 2018 for a median Massachusetts with health insurance through an employer



Notes: Data represent Massachusetts families who obtain private health insurance through an employer. Massachusetts median family income grew from \$95,207 to \$101,548 over the period while mean family employer-sponsored insurance premiums grew from \$18,955 to \$21,801. Compensation is defined as employer premium contributions plus income as recorded in the ACS and is considered earnings. All premium payments are assumed non-taxable. Tax figures include income, payroll, and state income tax.



Sources: HPC analysis of Agency for Healthcare Research and Quality (AHRQ) Medical Expenditure Panel Survey Insurance Component (premiums) American Community Survey (ACS) 1-year files (income), and Center for Health Information and Analysis 2019 Annual Report (cost-sharing).

Commercial Hospital Inpatient Trends: Key Findings

Total hospital inpatient spending grew 3.7% in 2018.



For commercial patients, spending grew 11% while volume fell 14% from 2013 to 2018.

Volume fell due to declining birth rates and fewer scheduled admissions.



Spending growth was driven by price increases and increased patient acuity:

Patients acuity increased more than 10% from 2013 to 2018.

- Evidence indicates that increases in patient risk scores and acuity are better explained by changes in clinical documentation and coding practice than by changes in actual patient health status. Increased coding efforts are not unique to Massachusetts and are subject to auditing and oversight by payers.¹
- While there are **benefits to more complete and accurate coding**, increased coding intensity may impair accurate performance measurement and has resulted in **millions in additional spending**.



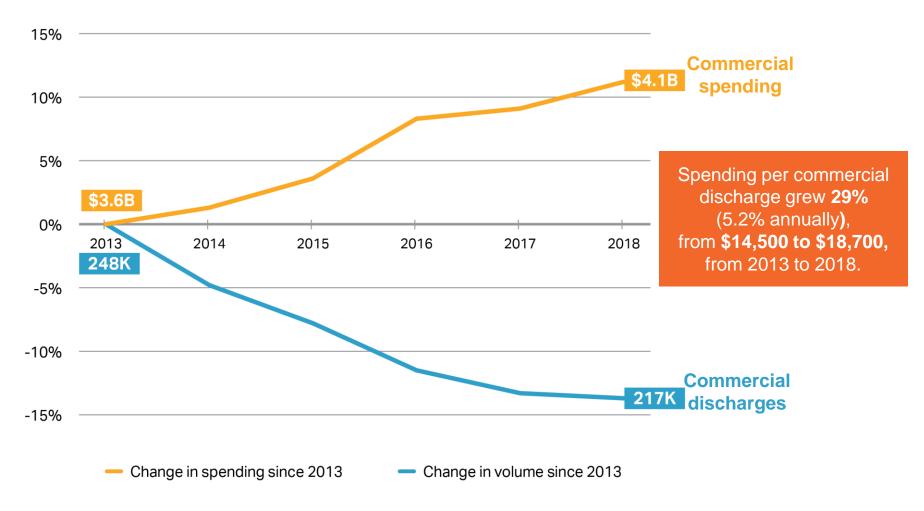
Some inpatient care is shifting to hospital outpatient settings, yet not all potential savings are being realized.

Notes: ¹See, for example, Seibold, Michael F. "Impact of commercial over-reimbursement on hospitals: the curious case of central Indiana." *International journal of health economics and management* 19.1 (2019): 99-114. Massachusetts' acuity increase for Medicare patients is similar to US trends. See MedPAC, March 2019 Annual Report **17**

Commercial

Commercial inpatient spending grew 11% even as volume fell 14% between 2013 and 2018.

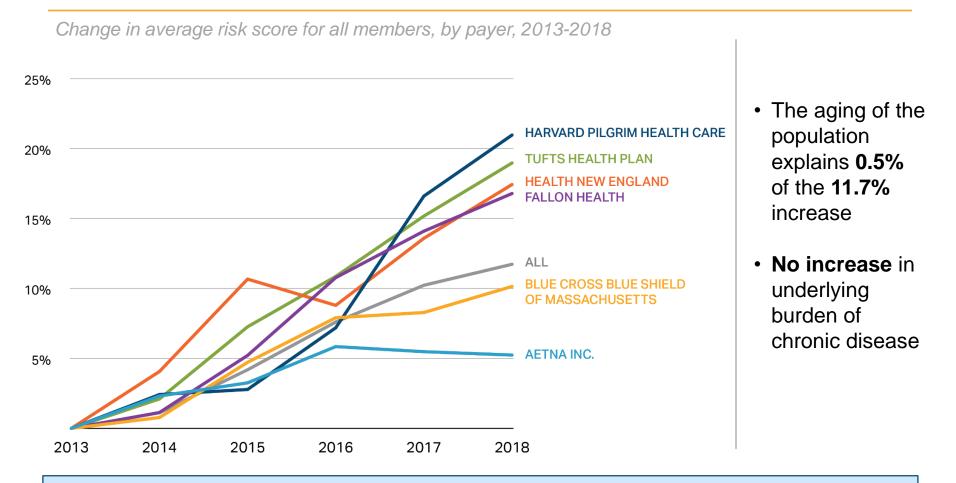
Cumulative change in commercial inpatient hospital volume and spending per-enrollee (percentages) and absolute, 2013-2018





Notes: Data points indicate % growth from previous year (2013=0). Volume data correspond to fiscal years while spending data are calendar years. Sources: CHIA Hospital Inpatient Discharge Data, 2013-2018. Commercial full-claims TME from CHIA Annual Report TME Databooks. 2019 Annual report (for 2017-8 growth and 2016-7 growth), 2018 Annual Report (for 2015-6), 2017 annual report (for 2014-2015) and 2016 Annual Report (for 2013-4 growth).

Statewide commercial member risk scores rose 11.7% between 2013 and 2018.



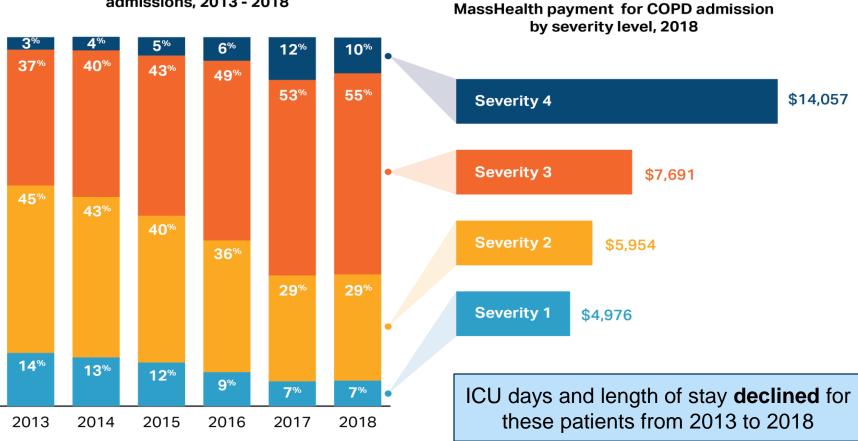
This amount of increased risk is equivalent to **430,000** more privately-insured Massachusetts residents with complex diabetes or **920,000** more residents with cerebral palsy.



Notes: Risk scores normalized to 1.0 in 2013. United, Cigna, BMC Healthnet, Minuteman, NHP and Celticare excluded due to data anomalies or fluctuating membership. Sources: CHIA TME databooks, 2016 and 2018. Federal Register vol 78 no. 47 March 11, 2013, Adult Risk Adjustment Model Factors. Burden of chronic disease analyzed using the CDC's BRFSS survey; rates of arthritis and diabetes among Massachusetts residents increased while COPD and asthma decreased from 2013 to 2016. Life expectancy was unchanged. Impact of population aging assessed using insurer demographic data combined with age/sex/spending profiles from the APCD.

As illustrated by COPD patients, the acuity change is driven mostly by more patients coded as high-severity for a given diagnosis.

MassHealth hospital payment for a patient with COPD for each severity level and percent of COPD discharges (all payer) at each severity level



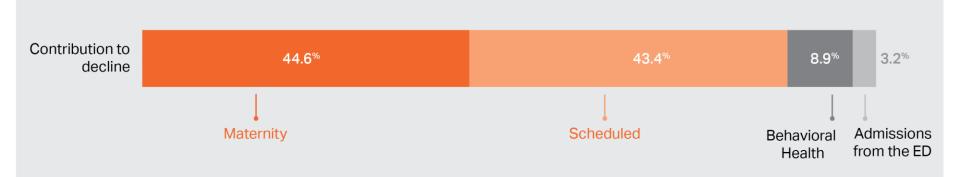
Distribution of severity level for COPD admissions, 2013 - 2018



Note: For these patients, average length of stay dropped 3% between 2013 and 2018 as did ICU days. Severity levels reflect APR-DRG system used by MassHealth and most commercial payers in Massachusetts. Payments estimated based on publically available MassHealth weights.

Source: CHIA Hospital Inpatient Discharge Database, 2013-2018; MS-DRG classification system, APR-DRG classification system

Over 90% of the decline in hospital inpatient volume since 2014 is attributable to decreases in maternity and scheduled stays.



Inpatient discharges per 1,000 commercial population, FY2014 - FY2018 Commercial discharges, raw number, FY2014 - 2018



Year	Disharges	Cumulative
2014	232,856	0.0%
2015	226,564	-2.7%
2016	221,044	-5.1%
2017	215,941	-7.3%
2018	213,486	-8.3%

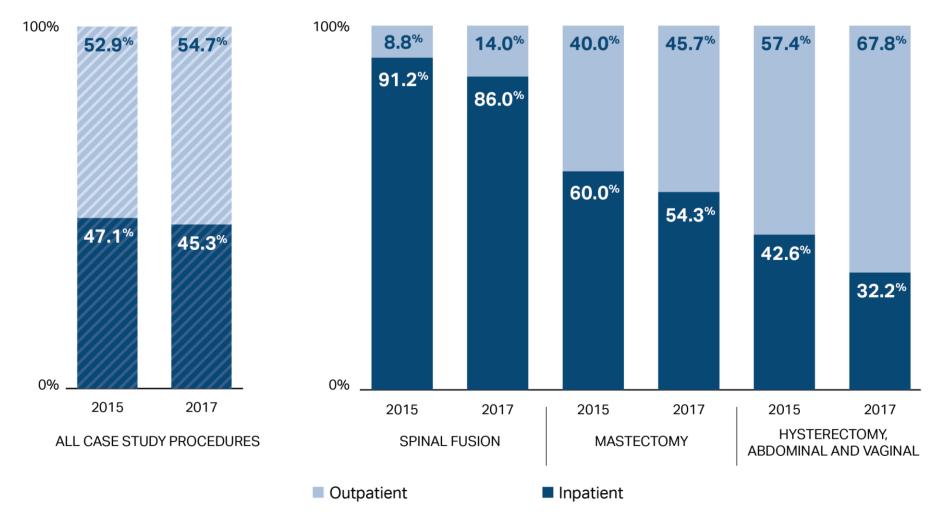


Notes: Maternity includes all discharges with a maternity DRG. ED admissions include all discharges with an ED flag or revenue code. Behavioral health discharges include all discharges with a BH diagnosis as the primary diagnosis. Scheduled includes remaining discharges. All figures reflect rounding.

Sources: HPC analysis of Center for Health Information and Analysis HIDD, FY2014 - FY2018

A comparison of inpatient and outpatient volume confirms a shift to outpatient settings between 2015 and 2017.

Percent of surgeries taking place in inpatient and outpatient settings for select case studies, 2015 – 2017





Notes: Case study procedures identified by CCS categories and combined into encounters (same patient, same procedure, same day). This analysis may not reflect the true reason for the inpatient stay (e.g., hysterectomy immediately after delivery). All figures reflect rounding.

Sources: HPC analysis of Center for Health Information and Analysis APCD 7.0, 2015 - 2017

Commercial Outpatient Hospital Trends: Key Findings

Total hospital outpatient spending grew 3.8% in 2018.

- **60% of commercial hospital spending** occurs in the outpatient setting. Surgery accounts for 1/3 of commercial hospital outpatient spending and growth.
- Growth in commercial outpatient surgery spending was driven by **10% growth in** hospital payment per episode from 2015 to 2017.
- Commercial volume was concentrated in higher-priced systems; **20-25% of outpatient surgeries** were performed at Partners hospitals in 2017, which are paid **up to twice as much** as other high-volume hospitals.

Shifting care from inpatient to outpatient settings can save money.

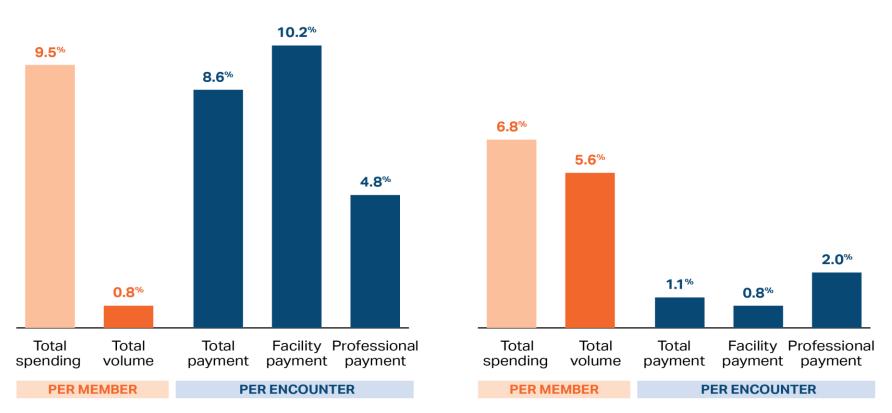
 Savings have been limited due to decreases in volume at lower-priced systems and gains in volume at higher-priced systems.



Spending grew for both major (9.5%) and minor (6.8%) outpatient surgeries from 2015 to 2017, but drivers of spending growth differed.

MINOR SURGERY

Percent growth by commercial spending, volume, and average price for major and minor OP surgery, 2015-2017



MAJOR SURGERY

Notes: Results adjusted for member months. Total spending and price includes all facility and professional claim lines associated with an encounter.

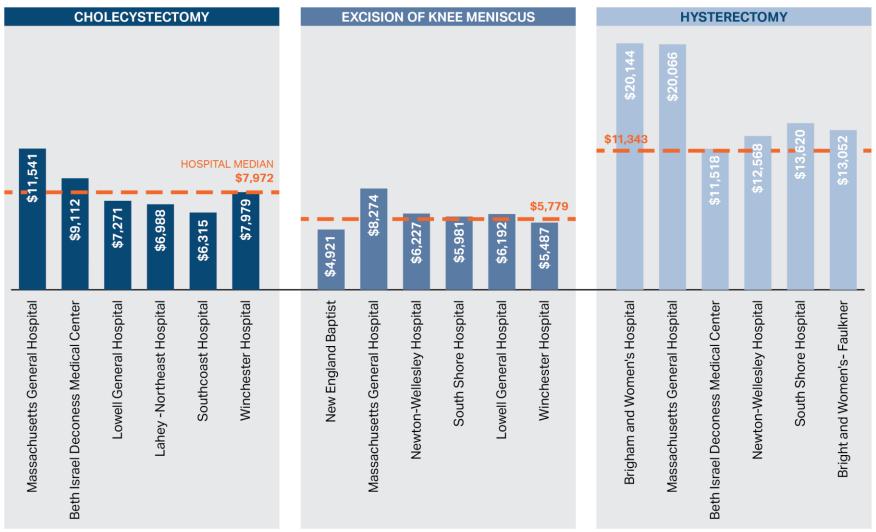
The average payment for a major surgery in 2017 was **\$8,955**, \$710 higher than in 2015.

N is total number of distinct surgery encounters with at least one surgery facility fee.

Sources: HPC analysis of CHIA APCD 7.0, 2015-2017. Out of state and non-acute care hospitals excluded.

Average payments for major outpatient surgeries varied nearly two-fold across top-volume hospitals.

Average commercial payment for major surgery episodes by hospital, 2017.

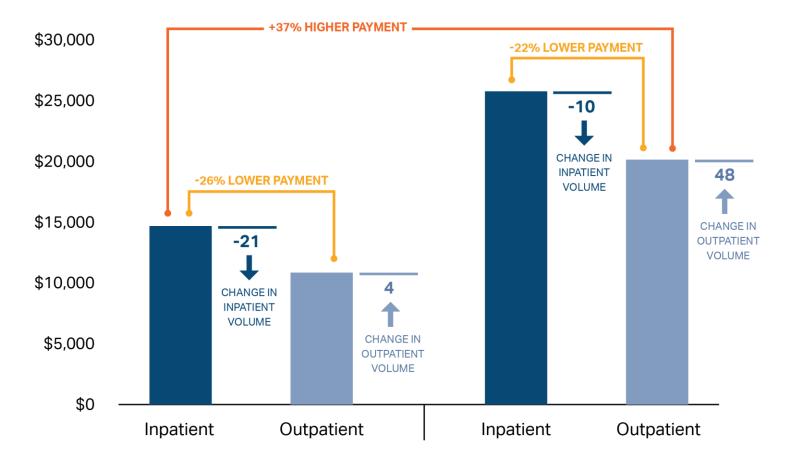




Notes: Top six hospitals by volume shown, sorted left to right by volume. Results adjusted for member months. Total spending and price includes all facility and professional claim lines associated with an encounter. N is total number of distinct surgery encounters with at least one surgery facility fee. Sources: HPC analysis of CHIA APCD 7.0, 2015-2017. Out of state and non-acute care hospitals excluded.

Due to wide price variation, outpatient surgeries at some hospitals may be more expensive than inpatient surgeries at others.

Payments per hysterectomy episode at two hospitals and net change in volume, 2015-2017



High Volume Community Hospital

High Volume AMC

Notes: Notes: The hospitals shown had the largest loss in inpatient hysterectomy volume (Good Samaritan) and the largest gain in outpatient hysterectomy volume (Brigham and Women's Hospital). These data do not imply that any specific patient chose Brigham and Women's hospital instead of Good Samaritan, but rather are an example to highlight the potential associated spending impact. Cases included in the figure exclude complicated hysterectomy as well as hysterectomies related to ovarian cancer or maternity admissions.

Sources: HPC analysis of CHIA APCD v7.0, 2015-2017. Out of state and non-acute care hospitals excluded.

Overall Market Trends Were Mixed



The percentage of hospitalized patients discharged to institutional post-acute care fell again in 2018, from 18.5% to 17.8%, while use of home health care increased.



Commercial membership under alternative payment arrangements fell from 45% to 42.8% in Massachusetts from 2016 to 2018.



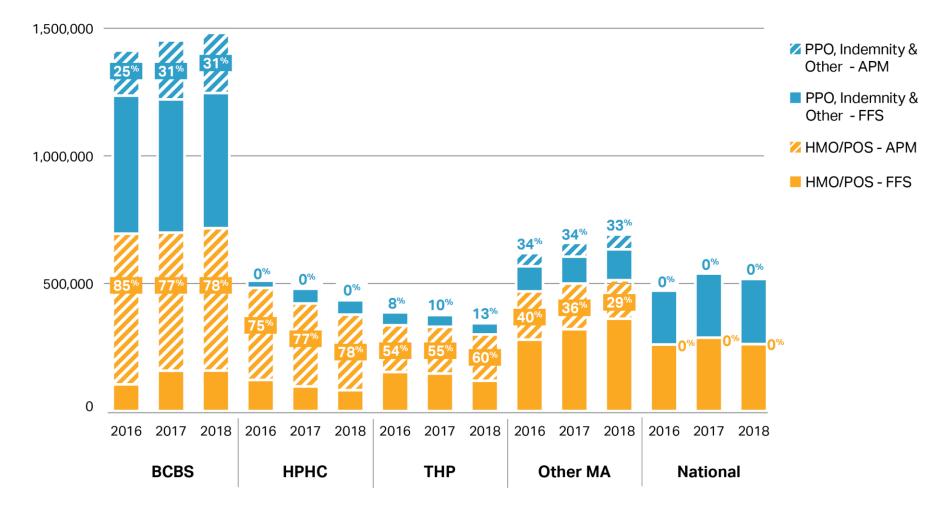
Massachusetts had the **second-highest Medicare hospital readmission rate** in 2017.



Commercial

While overall APM adoption was stagnant in 2018, there is variation among Massachusetts insurers for their HMO and PPO members.

Commercial membership under alternative payment method (APM) and fee-for-service (FFS) contracts by payer, 2016-2018. Labels indicate percentage under an APM by product category.



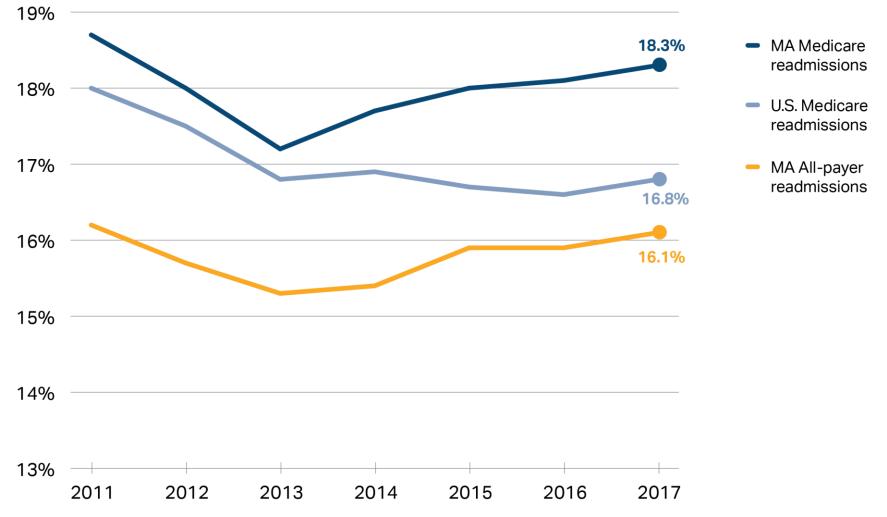


Notes: Aetna was excluded from this analysis due to data anomalies. Other MA includes AllWays, Fallon, HNE, BMCHP, THPP, HPI, and Unicare. National payers includes United and Cigna.

Source: HPC analysis of Center for Health Information and Analysis Annual Report APM Databooks (2016-2018).

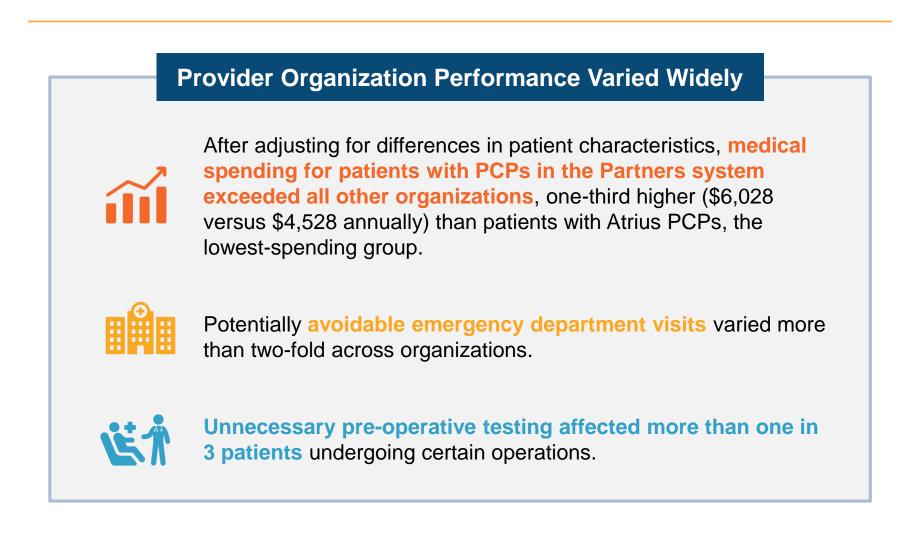
Massachusetts readmission rates continue to increase and significantly exceed the U.S. average.

Thirty-day readmission rates, Massachusetts and the U.S., 2011-2017



НРС

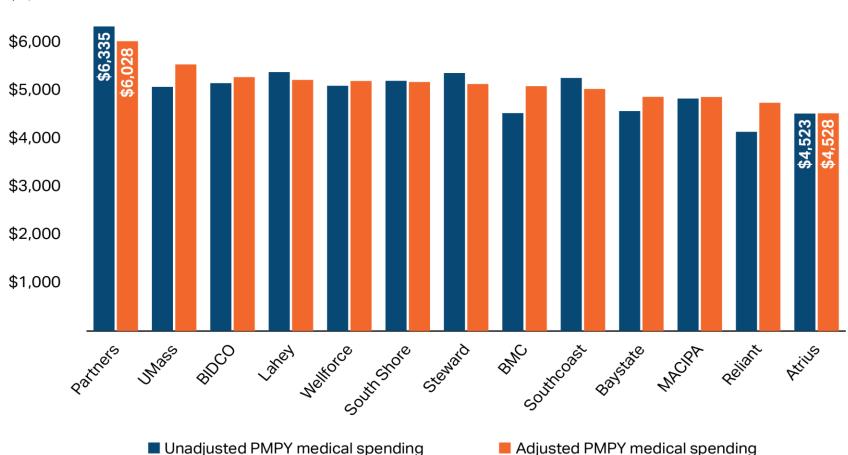
Notes: Massachusetts Medicare and U.S. Medicare readmission rates are for Medicare beneficiaries aged 65 and over Sources: Centers for Medicare and Medicaid Services (U.S. and Massachusetts Medicare Geographic Variation Public Use Files 2011-2017); Center for Health Information and Analysis (MA All-payer 2011-2018).





Annual risk-adjusted medical spending was \$1,500 (33%) higher for patients attributed to Partners PCPs than for patients with Atrius PCPs.

Annual medical spending per attributed member by provider organization, 2017



\$7,000

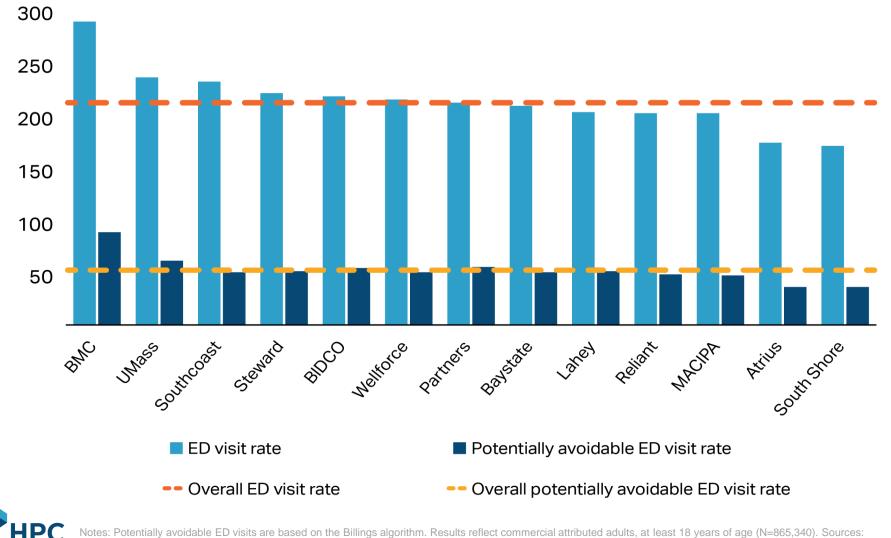


Notes: PMPY = per member per year. Prescription drug spending and non-claims-based spending excluded. Spending results are for commercial attributed adults (N=865,340). Adjusted results are adjusted for differences in age, sex, health status, and community-level variables related to education and socioeconomic status. See technical appendix for more details.

Sources: HPC analysis of Massachusetts All-Payer Claims Database, 2017.

Potentially avoidable emergency department visits varied two-fold by provider group.

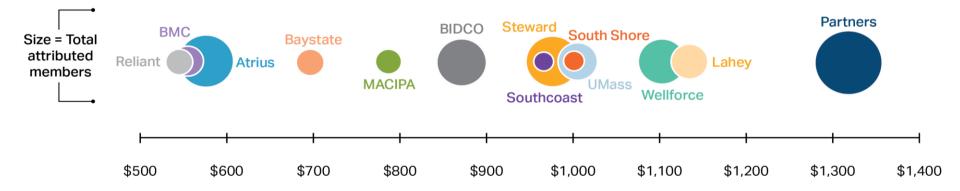
Adjusted visits per 1,000 attributed commercial patients, 2017



Notes: Potentially avoidable ED visits are based on the Billings algorithm. Results reflect commercial attributed adults, at least 18 years of age (N=865,340). Sources: HPC analysis of Massachusetts All-Payer Claims Database, 2017

Total per-member spending on 7 low value care measures varied more than two-fold across provider groups.

Low value tests and procedures per 100 eligible commercial patients, 2017



Spending for low value services per 100 attributed patients



Notes: Low value spending across all seven measures was summed by provided organization and then divided by the total number of commercial adult attributed members and reported as a rate per 100 members.

Source: HPC analysis of Massachusetts All-Payer Claims Database, 2017

The HPC has developed **15** policy recommendations for market participants, policymakers, and government agencies.

Throughout these recommendations, the term "the Commonwealth" is intended to be broadly inclusive of all relevant stakeholders, both public and private, that influence the delivery and payment of health care in Massachusetts and whose commitment to action is necessary for advancing the recommended policy changes.

New recommendations

Revised and refreshed recommendations featured in past Cost Trends Reports



2019 Cost Trends Report: Summary of Recommendations for Discussion

New Recommendations

- 1. Primary and Behavioral Health Care: Payers and providers should increase spending devoted to primary care and behavioral health while adhering to the cost growth benchmark. Policymakers, payers, and providers should support advancements to develop and utilize technology, such as telehealth, that improves access to primary and behavioral health care. Lawmakers should amend scope of practice laws that are not evidence-based and should continue to strengthen the health care workforce with roles designed to meet the needs of the communities and patient populations they serve.
- 2. Ambulatory Care: The Commonwealth should closely scrutinize how care is delivered and paid for in different ambulatory settings, including urgent care and hospital main campus and off-campus sites. Regulators, payers, and other stakeholders should also examine provider plans for outpatient service expansions and critically consider how new projects are likely to impact cost, quality, access, and competition in the provider market.
- 3. Coding Intensity: The Commonwealth should take action to mitigate impacts of improved clinical documentation on spending and performance measurement. Specific areas of action include more frequent updates to software programs to better align payments with actual resource use, mechanisms to offset coding-related spending impacts, and continued development of alternative risk adjustment methods and performance metrics less sensitive to coding-based acuity.



2019 Cost Trends Report: Summary of Recommendations for Discussion

New Recommendations

- 4. Pharmaceutical Spending: The Commonwealth should take action to reduce drug spending growth and implement policies to increase oversight and transparency for the full drug distribution train, such as by authorizing the expansion of the HPC's review to include drugs with a financial impact on the commercial market in Massachusetts and increasing state oversight of pharmacy benefit managers' (PBMs) pricing practices. Payers and providers should pursue strategies to maximize value and enhance access by using risk-based contracts and value-based benchmarks when negotiating prices, distributing clinical decision tools, monitoring prescribing patterns, and developing plan designs that minimize financial barriers to high-value drugs.
- 5. Accountability Under the Cost Growth Benchmark: The Commonwealth should strengthen its ability to hold health care entities responsible for their spending growth. Policymakers should improve the annual performance improvement plan (PIP) process by allowing the Center for Health Information and Analysis (CHIA) to use metrics beyond health status adjusted total medical expenses when identifying entities and strengthen the HPC's ability to hold entities accountable for spending that impacts the health care cost growth benchmark by enhancing financial penalties for above-benchmark performance and non-compliance.
- 6. Employer Engagement and Consumer Choice: The Massachusetts business community should increase its coordinated engagement to drive changes in health care. Employers should collaborate with payers, providers, and other stakeholders to influence changes in spending and affordability, care delivery, and the promotion of a value-based market. Specific levers include lowering premium contributions for plans favoring efficient providers, promoting the use of two-sided risk contracts, and offering coverage through Health Connector for Business if eligible. To further support these strategies, policymakers should take action to broaden employer access to a wide range of insurance products for their employees and to ensure that payers make affordable, high-value products available.



2019 Cost Trends Report: Summary of Recommendations for Discussion

Revised and Refreshed Recommendations

- 7. Administrative Complexity: The Commonwealth should take action to identify and address areas of administrative complexity that add cost to the health care system without improving the value of care. Specific areas of focus should include requiring greater standardization of common administrative tasks across payers and facilitating efforts between government, payers, providers, and patients to identify and reduce other drivers of valueless administrative complexity.
- 8. Facility Fees: Policymakers should take action to require site-neutral payment for common ambulatory services and limit the cases in which both newly licensed and existing sites can bill as hospital outpatient departments. Additionally, outpatient sites that charge facility fees should be required to conspicuously and clearly disclose this fact to patients, prior to delivering care.
- **9. Out-of-Network Billing:** Policymakers should enact a comprehensive law to address out-ofnetwork billing. Specific provisions should include requirements for advance patient notification when a provider may be out-of-network, protections for consumers from out-of-network bills in emergency and "surprise" billing scenarios, and the establishment of a reasonable and fair reimbursement rate for out-of-network services through a statutory or regulatory process. Any such process should avoid using provider charges or list prices as a benchmark in determining payment.



2019 Cost Trends Report: Summary of Recommendations for Discussion

Revised and Refreshed Recommendations

- **10.** Alternative Payment Methods: The Commonwealth should continue to promote the increased adoption and effectiveness of APMs, especially in the commercial market where expansion has stalled. Specific areas of focus should include increased use of APMs for preferred provider organization (PPO) populations, alignment across payers and improvement of APM features including shifting to two-sided risk models, and adoption of bundled payments for common and costly episodes of care by payers and providers.
- 11. Health Disparities: The Commonwealth should seek to understand and address inequities in the opportunities and resources available to enable health and well-being for all citizens. Specific areas of focus should include policies to encourage downstream collaborations between health care providers and social service organizations to identify and address patients' health-related social needs (HRSN), and promotion of upstream cross-sector collaborations to understand the causes of health inequity in communities and leverage resources to address those inequities.
- 12. Investing in Innovation, Learning, and Dissemination: The Commonwealth should continue to support targeted investments to promote innovation, learning, and dissemination of promising care models. Specific opportunities for investment include longitudinal care models to support individuals and families experiencing the effects of substance use disorder, alternatives to traditional hospital-based clinical care, telehealth as a strategy to increase access to high-need services such as behavioral health, care models that promote care coordination and integration, and maternal health—particularly among populations for which there are significant disparities in outcomes.



2019 Cost Trends Report: Summary of Recommendations for Discussion

Revised and Refreshed Recommendations

- **13. Low Value Care:** The Commonwealth should act to reduce the provision of health care that does not provide value to patients. Payers, providers, and purchasers should collaborate on strategies to reduce low value care through measurement, reporting, and appropriate financial incentives and support the incorporation of evidence-based guidelines into practice. The Commonwealth should encourage information campaigns like *Choosing Wisely*® that disseminate research findings about low-value care to engage patients in their care and ensure they are informed about clinical value before they seek services.
- 14. Provider Price Variation: The Commonwealth should take action to reduce unwarranted variation in provider prices. Policymakers should advance specific, data-driven interventions to address the pressing issue of persistent provider price variation, particularly given new findings indicating that savings from shifts from inpatient to outpatient care may be lost due to hospital price differentials.
- **15. Affordability:** Health care affordability must remain a central focus of the Commonwealth's health care agenda. The Commonwealth should continue to examine and address the factors impacting premium and out-of-pocket cost growth and their disproportionate impact on lower-to-middle income residents and small businesses.





VOTE: 2019 Health Care Cost Trends Report

MOTION: That, pursuant to section 8(g) of chapter 6D of the Massachusetts General Laws, the Commission hereby authorizes the issuance of the annual report on cost trends as presented.



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Drug Pricing Review

Overview

Chapter 41 of the Acts of 2019 (the "Budget") was signed by Governor Baker on July 31, 2019.

Statutory Authority

(1) Section 46 gives the Executive Office of Health and Human Services (EOHHS) authority to negotiate a supplemental rebate agreement (SRA) directly with pharmaceutical drug manufacturers for MassHealth. If EOHHS is unable to successfully negotiate an SRA, they may refer the manufacturer to the Health Policy Commission (HPC).

(2) Upon referral from EOHHS, Section 6 gives the HPC the authority to propose a *supplemental rebate... based on a proposed value of the drug.* The commission may request records from the manufacturer, with sanctions for non-compliance. Finally, the Commission will issue a determination on whether the manufacturer's pricing of a drug is *unreasonable or excessive in relation to the commission's proposed value of the drug.*



The MassHealth Process



MassHealth negotiates directly with a drug manufacturer for a supplemental rebate.

If negotiations fail for high cost drugs, MassHealth may propose a value for the drug and solicit public input on the proposed value for the drug.

MassHealth updates its proposed value for the drug as necessary and solicits further negotiations with the manufacturer.

If negotiations with the manufacturer fail, MassHealth may refer the manufacturer to the HPC for review.

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The HPC Process

The HPC Process



HPC notifies the manufacturer that it has been referred by MassHealth for review and requests information, including completion of the Standard Reporting Form.

HPC reviews information submitted by the manufacturer.

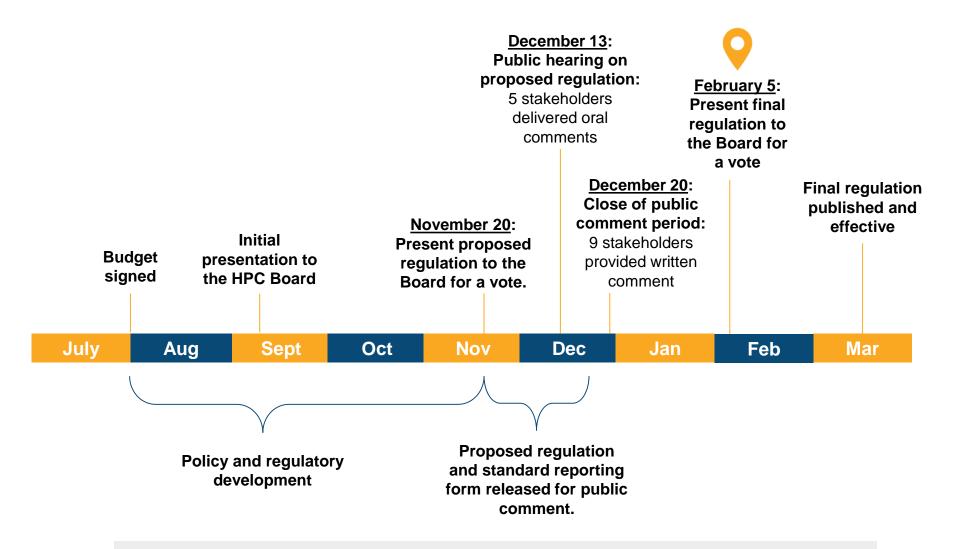
HPC may:

- Identify a proposed value for the drug;
- In consultation with MassHealth, propose a supplemental rebate for the drug;
- Determine that the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug; or
- Close its review of the drug.

- HPC determines that a manufacturer's pricing is potentially unreasonable or excessive
- Notifies the manufacturer, and requests additional information.
- HPC solicits information from stakeholders.
 - Within 60 days of receiving completed information from the manufacturer, HPC issues a determination on whether the manufacturer's pricing of the drug is unreasonable or excessive in relation to HPC's proposed value for the drug.

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Regulatory Development Timeline





The HPC plans to finalize the Standard Reporting Form over the coming weeks and look forward to continue working with stakeholders throughout this process.

Purpose of Regulation, Standard Reporting Form, and Framework



Details the **process** for conducting our reviews

Broad descriptions of factors we consider and information we plan to collect reflect feedback from Commissioners and other experts as well as stakeholders

Requires a Commission vote to promulgate or change.

Standard Reporting Form

Details standardized information we expect to collect from all manufacturers

Content and format of form will be developed and refined based on ongoing feedback from manufacturers and other stakeholders

Form is expected to change and be refined over time. Released as **sub-regulatory guidance** on our website with advance notice of changes to manufacturers

Framework

Describes how we expect to evaluate different data sources for assessing value and pricing

Data sources and methods will be developed in concert with experts, including Commissioners, and reflect feedback from stakeholders

Will be **discussed publicly** at Board and Committee meetings and expected to change over time as new issues arise and new data sources become available.



Public Comment

The HPC held a public hearing and a one-month public comment period on the regulation and standard reporting form.

Comments and testimony submitted by 11 organizations:

- 1. Biotechnology Innovation Organization (BIO)
- 2. Blue Cross Blue Shield of Massachusetts
- 3. Disability Policy Consortium Representing 8 additional disability advocacy organizations[^]
- 4. Greater Boston Interfaith Organization^
- 5. Health Care for All and the Prescription Drug Affordability Coalition Representing 13 additional organizations^
- 6. Jewish Alliance for Law and Social Action*
- 7. Massachusetts Association of Health Plans
- 8. Massachusetts Biotechnology Council (MassBIO)
- 9. Mental Health Legal Advisors Committee*
- 10. Partnership to Improve Patient Care and 6 disease-specific advocacy groups
- 11. Pharmaceutical Research and Manufacturers of America (PhRMA)

*These groups presented oral testimony at the public hearing, but did not submit written testimony ^ these groups presented oral testimony at the public hearing and submitted written testimony



Торіс	Comment	Recommendation
	Industry groups voiced concern that certain data requested are confidential and proprietary, and asked that certain processes and safeguards be specified in the regulation.	Add to 12.12 to specify that the HPC "shall develop protocols to protect the confidentiality of records received from EOHHS or disclosed by the Referred Manufacturer."
Information submitted by the manufacturer	Industry groups expressed concern that some of the information requested from Referred Manufacturers is vague and that it would be difficult to determine what constitutes a complete response, including the requirement that manufacturers submit an assessment of the value of the drug.	Clarify in 12.04 (1) that the Referred Manufacturer must provide its own estimation of value of the Drug with supporting information, such as existing analyses.
	Industry groups wanted to ensure that they have the opportunity to provide input on the Standard Reporting Form (SRF).	Updated language in 12.04 (2) that the Standard Reporting Form will be developed and updated with advanced notice to and input from Manufacturers and other interested stakeholders.



Торіс	Comment	Recommendation
Information submitted by the manufacturer	Industry groups generally objected to the requirement that the SRF include pricing information (both national and international) and financial information on an aggregate and per-drug basis. In addition, they had concerns that the information may not be available in the format specified in the draft SRF.	Update language in 12.04 (3)(c)-(f) to allow for more flexibility in development of the standard reporting form and to allow the Referred Manufacturer to submit drug-specific financial information using the best information available. The HPC will continue to work with stakeholders and experts on the information requested and the format in which it is submitted on the Standard Reporting Form.
	Industry groups were concerned that 30 days would not be enough time for Referred Manufacturers to respond to information requests.	Add to 12.04 (1) and 12.09 (2) that another timeframe may be agreed upon, in writing, between the Referred Manufacturer and the HPC, through the Executive Director.



Торіс	Comment	Recommendation
Public notice, public summary, and stakeholder input	Patient and disability advocates and industry groups requested that the HPC have a clear process for considering input from stakeholders, including patients, caregivers, and clinical experts, in identifying a proposed value for the Drug.	 Add a section, 12.05, which specifies: Following notice to a Referred Manufacturer, the HPC shall post a notice on its website. Interested stakeholders may provide data or information they consider pertinent to the HPC's review of a Referred Manufacturer's pricing and factors for identifying a proposed value for the Drug. Clarification throughout the regulation that the HPC will consider information submitted by interested stakeholders.
	Patient and disability advocates requested transparency on the rationale for determining that a Referred Manufacturer's pricing is potentially unreasonable or excessive and the sources of information used in making its determination.	Add to 12.08 that the HPC "shall publicly post a summary of the rationale for determining that the Referred Manufacturer's pricing of the Drug is potentially unreasonable or excessive in relation to the value of the Drug and a list of any third-party cost- effectiveness analysis relied upon in identifying the proposed value."
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Торіс	Comment	Recommendation
Public notice, public summary, and stakeholder input	Patient groups supported the proposed regulation's requirement that following a determination the pricing of a Drug is unreasonable or excessive, the HPC post its proposed value of the drug; however, industry groups opposed publication of a proposed value in the proposed regulation.	We recommend no change to the regulation given differing comments received from stakeholders.
Factors in identifying a proposed value	Disability advocates requested that the HPC consider both clinical efficacy (performance under research conditions) <i>and effectiveness</i> (performance under "real world" conditions) in its process.	Update and align language in 12.04 (3)(a) and 12.06 (2)(a) to include "clinical efficacy, effectiveness, and outcomes" in the information requested in the Standard Reporting Form and in the factors for identifying a proposed value.
	Industry groups and payers recommended the HPC consider therapeutic equivalents, rather than pharmaceutical equivalents, of a Drug in identifying a proposed value for the Drug.	In 12.06 (2)(f), replace "pharmaceutical" with "therapeutic."



Торіс	Comment	Recommendation
Factors in identifying a proposed value	Disability advocates and industry groups requested clarification on how the HPC will consider the clinical importance of the Drug to patients and recommended including outcomes important to patients and families, such as the ability of patients to work and the impact on caregivers; the impact of treatment on future medical care; if the treatment addresses an unmet medical need; the effectiveness in comparison with standard care; disease severity and prevalence; benefits and risks of treatment; and the impact on subpopulations.	 Update 12.06 (2)(c) to consider: "the extent to which the Drug addresses an unmet medical need or impacts patient subpopulations" Update 12.06 (2)(e) to consider: "the likelihood that the use of the Drug will reduce the need for other care or reduce caregiver burden, or enhance quality of life." Add 12.06 (2)(g): "characteristics of the Drug, including means and setting of administration, dosing frequency, duration of therapy, side effects, interactions and contraindications, and potential for misuse or abuse."
	Disability advocates and industry groups voiced concerns and recommended a prohibition on use of any cost-effectiveness analyses that use Quality-Adjusted Life Years (QALY) in identifying the proposed value of a Drug.	Add to 12.06 (2)(h): "provided that the Commission shall consider the methodologies and models underlying such analyses, any assumptions or limitations of research findings in the context of the results, and any outcomes for affected subpopulations that utilize the Drug, if applicable."

Торіс	Comment	Recommendation
Impact on access for individual patients	Disability advocates expressed concern that identifying the proposed value of a Drug could negatively impact patient access.	Add a section, 12.14, clarifying that: "A determination of the value of a Drug pursuant to 958 CMR 12.00 et seq. is not intended to be a determination of the value of a Drug for any individual patient"

The HPC also recommends some minor technical edits and updates to streamline language and to align with EOHHS's regulation, 101 CMR 801.



Proposed Vote and Next Steps

The Board is asked to approve the issuance of the final regulation 958 CMR 12.00, *Drug Pricing Review*.

If approved by the Board, the final regulation will be filed with the Secretary of State and is anticipated to become effective upon publication in the Massachusetts Register on March 6, 2020.





VOTE: Drug Pricing Review Regulation

MOTION: That the Commission hereby authorizes the issuance of the final regulation for 958 CMR 12.00, Drug Pricing Review, pursuant to M.G.L. c. 6D, § 8A and M.G.L. c. 118E, § 12A.



AGENDA

- Call to Order
- Approval of Minutes from November 20, 2019 Meeting
- Market Oversight and Transparency
- Executive Director's Report
- Executive Session: Performance Improvement Plans (VOTE)
- Schedule of Next Meeting (March 11, 2020)

2020 Hearing on the Health Care Cost Growth Benchmark

Wednesday, March 11 12:00 PM Massachusetts State House, Gardner Auditorium

Chapter 224 prescribes the formula that the HPC must use to establish the benchmark each year

"For calendar years 2018 through 2022, the health care cost growth benchmark <u>shall be equal to</u> the growth rate of potential gross state product...minus 0.5 per cent"

Since 2018, the HPC has had limited authority to modify the benchmark if an adjustment is "reasonably warranted"

"For calendar years 2018 through 2022, if the commission determines that an adjustment in the health care cost growth benchmark is reasonably warranted...the board of the commission may modify the health care cost growth benchmark..." between -0.5 and PGSP





HEARING ON THE POTENTIAL MODIFICATION OF THE

HEALTH CARE COST GROWTH BENCHMARK





Upcoming HPC Publications in 2020

2019 Cost Trends Report and Chartpack

Hard copies of the annual report on trends in health care spending and care delivery will be available at the Benchmark Hearing



CHART Playbook

Practical resource based on lessons learned from CHART program awardees for providers looking to address the needs of medically and socially complex patients.

Drug Coupon Study

Study on the utilization and impact of discount vouchers for prescription drugs in Massachusetts





High-level summary of each SHIFT-Care awardee initiative within two design tracks. *Track 1: Addressing Health-Related Social Needs Track 2: Increasing Access to Behavioral Health Care*

Market Retrospective Study

Report on provider market trends over the past five years, including updated analyses from the HPC's *Community Hospitals at a Crossroads* report.





Performance Improvement Plans in Massachusetts: Reflections on Five Years of Evaluating Payer and Provider Spending Performance

Overview of successes and challenges in the process for monitoring and enforcing payer and provider performance relative to the health care cost growth benchmark.

Nurse Practitioner Policy Brief

Policy brief examining trends in the Nurse Practitioner workforce in Massachusetts





Moving Massachusetts Upstream (MassUP) Investment Program

- A partnership across state agencies: DPH, MassHealth, AGO, EOEA, and HPC
- Goal: to engage in policy alignment activities and make investments to support health care system-community collaborations to more effectively address the "upstream" causes of poor health outcomes and health inequity



December 2019

- RFP issued 12/17/19
- Began collecting stakeholders' questions

January 2020

- Info Session webinar 1/9/20
- Regularly post FAQ responses to COMMBUYS

Feb./March 2020

- All respondent questions due by 3:00 PM on Feb. 7
- Proposals due by 5:00
 PM on Feb. 26
- Review and selection
 process through March

April 2020

- Present awards for HPC Board approval on April 1
- Begin contracting, with June 1 target date for program launch



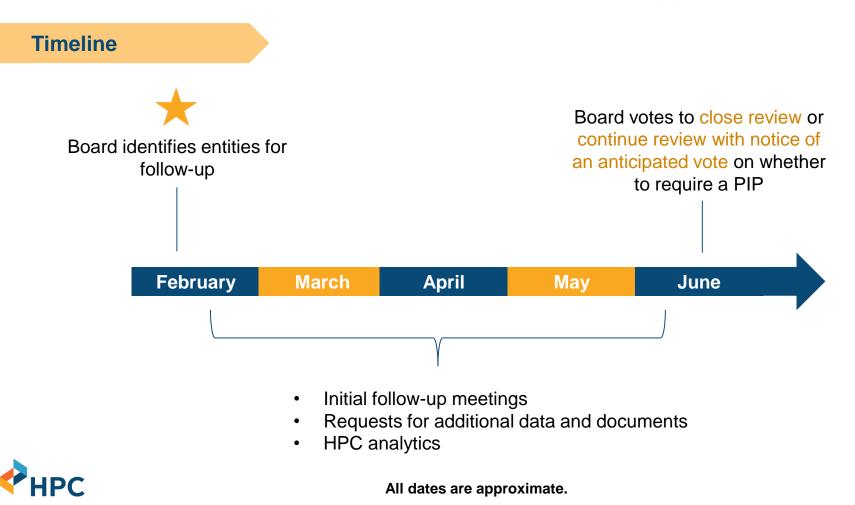
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Performance Improvement Plans

Executive Session

• The purpose of today's Executive Session is for the Board to consider the performance of select entities that were referred by CHIA based on their **2016-2017 spending growth.**





VOTE: Enter into Executive Session

MOTION:That, having first convened in open session at its February 5, 2020 board meeting and pursuant to M.G.L. c. 30A, § 21(a)(7), the Commission hereby approves going into executive session for the purpose of complying with M.G.L. c. 6D, § 10 and its associated regulation, 958 CMR 10.00, M.G.L. c. 6D, § 2A, and M.G.L. c. 12C, § 18, in discussions about whether to require performance improvement plans by entities confidentially identified to the Commission by the Center for Health Information and Analysis.

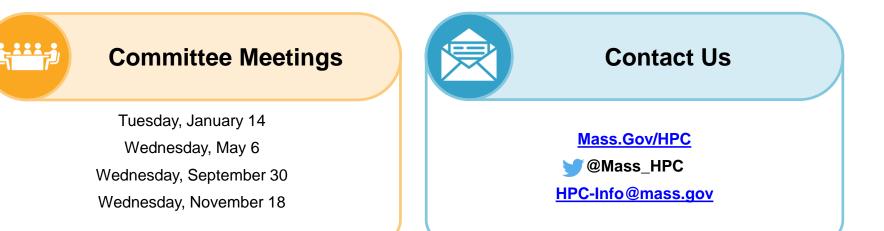


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Upcoming 2020 Meetings and Contact Information









APPENDIX

HPC Protection of Confidential Drug Pricing Information (CI)

- Confidential Information received from Manufacturers by the HPC is expressly exempted from release under the Massachusetts public records law and must be kept confidential by the HPC.
- Pursuant to its Written Information Security Program (WISP), the HPC has policies and procedures for receipt, protection and use of Drug Pricing CI:
 - CI will be transmitted to the HPC via the Commonwealth's secure, password-protected encrypted electronic data and file transfer platform, or via encrypted media
 - CI will be stored on at a password-permissioned location utilized by the HPC within the Commonwealth's Wide Area Computer network, within the IT security perimeter managed by EOTSS
 - Only HPC staff with a need to access the CI will be granted access, and only to the minimum amount of CI necessary
 - Authorized HPC staff will receive specialized privacy and security training and will execute CNDAs specifically applicable to the Drug Pricing CI
 - The HPC will require any HPC contractor(s) authorized to received CI to maintain privacy and security policies and procedures and will require the execution of CNDAs

