TxSCO Update

Oct. 13, 2022

Overview: Notable Updates

Federal

- Provider reimbursement
  - Bill to Prevent Pay Cut Introduced in the House
  - White Bagging update
- 340B
  - Recent scrutiny
- CMMI EOM
  - The Latest

State

- Select Committee on Health Care Reform
- Texas Palliative Care Interdisciplinary Advisory Council Recommendations
- Adoption of a Texas Medicaid Advance Care Planning (ACP) Benefit

Federal Update

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Provider Payment

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Bill to Prevent Pay Cut Introduced in the House

September 13, 2022. Rep. Larry Bucshon (R-IN) and Rep. Ami Bera (D-CA) introduced the H.R. 8800, the "Supporting Medicare Providers Act of 2022" which would prevent a 4.42% Medicare physician fee payment cut from taking effect on January 1, 2023.

The Supporting Medicare Providers Act of 2022

- **Prevents a 4.42% Medicare Physician Fee Payment cut from taking effect on January 1, 2023**
- The bill is sponsored by Rep. Ami Bera (D-CA) and currently has 49 bipartisan cosponsors
- Further actions to increase physician reimbursements are still being discussed among members
- On 9/15 a bipartisan group of eight lawmakers asked health providers, advocates, and experts to give any input on how Congress should change Medicare payments

"The AMA commends Reps. Bera and Bucshon for acknowledging the disparity between what it costs to run a physician practice and what these cuts will mean for patient care in the Medicare program. Our patients are counting on Congress to agree to a solution, and the clock is ticking,"

AMA

"The ACS strongly supports the Supporting Medicare Providers Act of 2022, which would stop the 4.42% cuts in Medicare payments that surgeons and other providers are facing on January 1st "

ACS

"The AAFP continues to advocate for payment reforms that appropriately invest in primary care and ensure physicians have the resources and flexibility they need to care for all their patients."

AAFP

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Sources: Rep. Bera (link), POLITICO (link)

Physician Payment Cuts

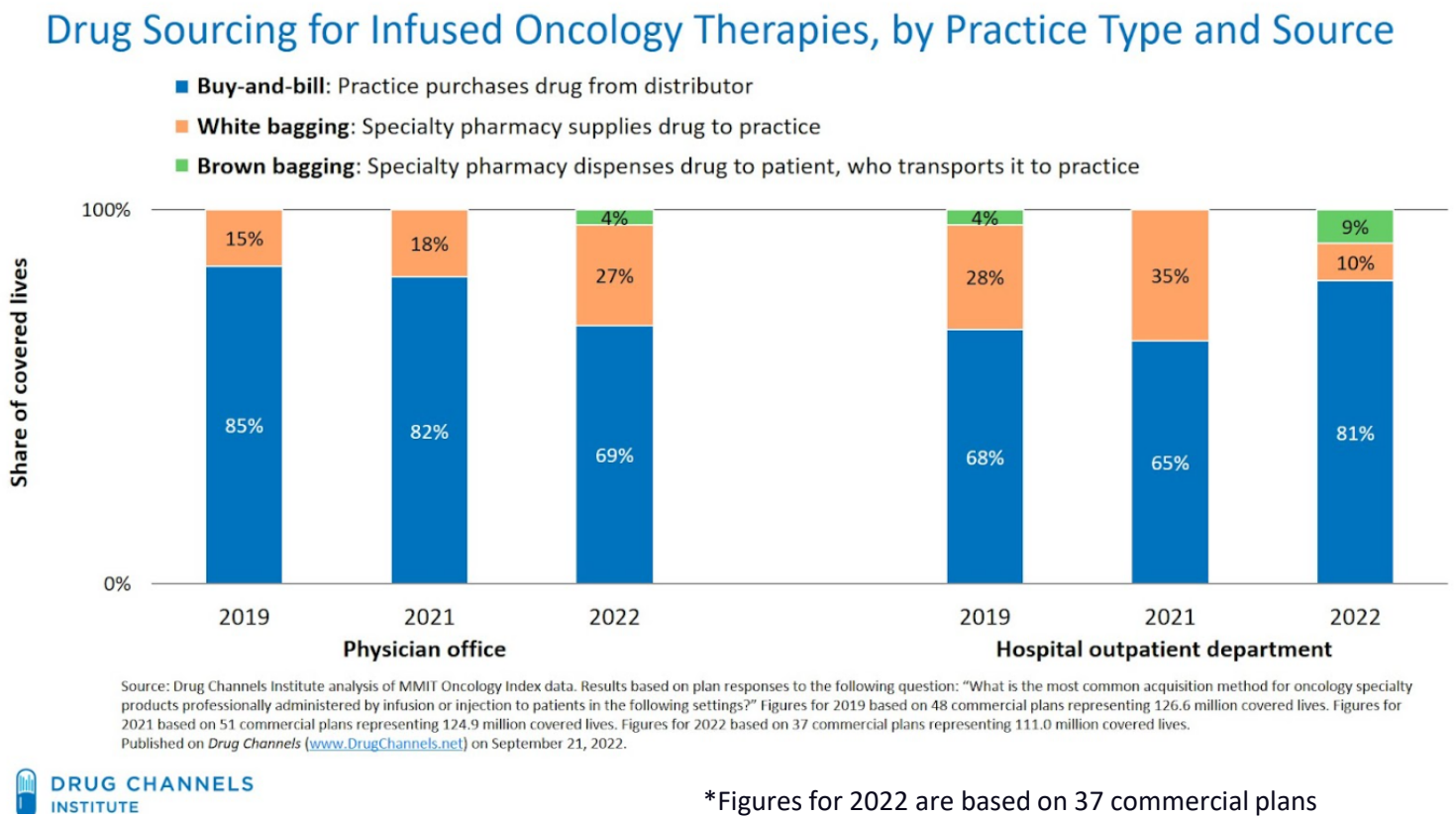
Payment Cuts Supposed to take Effect Jan 1, 2022	Protecting Medicare & Farmers from Sequester Cuts Act	Payment Cuts Expected Jan 1, 2023
• 3.7% E/M budget neutrality cuts • 2% sequester cut • 4% estimated PAYGO cuts from American Rescue Plan • 0% update	• 3% E/M budget neutrality relief • Sequester phase-in (2% starting 7/1/22) • 4% PAYGO postponed 1 year	• 3% budget neutrality cut • 1.5% additional budget neutrality cut in the PFS conversion factor • 2% sequester • 4% PAYGO cut • 0% update until 2026 • MIPS penalties up to -9%

- AMA is working on several proposals to address budget neutrality including:
  - Look-back period to account for incorrect utilization projections and return money to the PFS
  - Raising the threshold that triggers budget neutrality adjustments ($20M has been in place since 1992)
- AMA also working on an annual inflation adjustment for PFS, but recognize that the CBO score will be high

White Bagging: 2022 Utilization Increased for Community Practices, Decreased for HOPD

2022 Trends

- Buy-and-Bill has rebounded substantially in 2022
  - "At hospitals, buy-and-bill appears to have rebounded substantially. For 2022, health plans representing 81% of covered lives reported that buy-and-bill was hospital outpatient departments' most common method for sourcing provider-administered oncology drugs. This figure is significantly higher than the figures from 2019 and 2021."
- For physician offices, white bagging continues to increase, up to 27% in 2022 compared to 18% in 2021
- For 2022, Brown Bagging was reported to be the most common acquisition method for a minority of plans' covered lives



*Figures for 2022 are based on 37 commercial plans representing 111.0 million covered lives

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Source: Sept. 21, 2022. Drug Channels Analysis

340B

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Court Orders HHS to Immediately Pay 340B Hospitals the "Full" Part B Payment Rate for Remainder of CY2022

Background

- CMS has issued differential payment for 340B and non-340B hospitals within the OPPS payment system since CY2018
  - The Medicare statute allows HHS to set reimbursement for outpatient drugs based on two formulas, via survey of acquisition costs or "average price" set by statute at 106% of ASP
- In 2018 and 2019, Trump Administration did not conduct a survey but set reimbursement at ASP-22.5% for 340B hospitals*
  - In 2020 the Trump Administration conducted a hospital survey (link) on acquisition costs
- Various hospital groups sued HHS over the payment policy
- The Biden Administration's CY2022 OPPS Final Rule continued 340B payment rate policy

SCOTUS Ruling

June 15, 2022

- Unanimous US Supreme Court ruling that the 2018 and 2019 340B reimbursement cuts were unlawful because HHS did not perform an acquisition cost survey
- The case was sent back to the US District Court for the District of Columbia for a decision on a remedy

District Court Ruling

September 28, 2022

- US District Court vacates the prospective drug reimbursement rate for 340B hospitals for the remainder of 2022 (link)
  - *"The Court is troubled that HHS appears to rely on budget neutrality as a license "to continue violating the law for the remainder of the year and make up for it later."*
  - *"HHS should not be allowed to continue its unlawful 340B reimbursements for the remainder of the year just because it promises to fix the problem later."*
  - *The Court recognizes that HHS's budget will be unbalanced if it must immediately start to pay 340B hospitals their proper due for the remainder of 2022. But that disruption would be minimal, because HHS admits that vacating the 340B reimbursement rate for the remainder of 2022 would account for "only [ ] a small sliver of the overall time periods challenged in this action."*

What's Next?

- It's unclear if the government will appeal this decision or how quickly the higher payments will begin
- The court has not ruled on the questions of remedies for past 2018-2022 underpayments
- As indicated in the proposed rule, CMS is expected to finalize the CY2023 OPPS reimbursement at ASP+6% for both 340B and non-340B facilities
- In the CY2023 Proposed Rule, CMS sought comment on solutions to budget neutrality concerns for previous years' payments

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* For non-pass-through drugs at most 340B hospitals

NYT 340B Investigation: "How a Hospital Chain Used A Poor Neighborhood to Turn Huge Profits"

The New York Times

Sept. 24, 2022: The New York Times ran a piece titled "How a Hospital Chain Used A Poor Neighborhood to Turn Huge Profits" detailing how Bon Secours Mercy Health System, a major nonprofit health system based in Cincinnati, used Richard Community Hospital, which serves lower income patients, to tap into 340B revenues.

"A Lucrative Drug Program"

- "Big hospital chains figured out how to supercharge the [340B] program. The basic idea: Build clinics in wealthier neighborhoods, where patients with generous private insurance could receive expensive drugs, but on paper make the clinics extensions of poor hospitals to take advantage of 340B"
- Since 2013, Bon Secours has "opened up nine satellite clinics in the wealthier parts of the Richmond area . . . **Even though the outposts are miles from Richmond Community, they are legally structured as subsidiaries of the hospital, which entitles them to buy drugs at the discounted rate"**
- **Richmond Community hospital can buy a vial of Keytruda at a discounted price of $3,444, the hospital then charges a private insurer, Blue Cross Blue Shield, seven times that price, $25,425. "That is nearly $22,000 profit on a single vial. Adults need two vials per treatment course."**

Ben Secours Spending

- **"Bon Secours . . . has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods according to more than 20 former executives, doctors, and nurses"**
  - Richmond Community Hospital was forced to close its ICU in 2017 and continually runs short on supplies
  - "In 2012, the city agreed to lease land to Bon Secours at far below market value on the condition that the chain expand Richmond Community's facilities. Instead, Bon Secours focused on building a luxury apartment and office complex. The hospital system waited a decade to build the promised medical offices next to Richmond Community"
  - "In December, Bon Secours kicked off a $108 million construction project at St. Francis to expand its I.C.U. and maternity ward. Not long before that, Bon Secours broke ground on a free-standing emergency room that would be an extension of St. Francis in suburban Chesterfield County"

"Bon Secours was basically laundering money through this poor hospital to its wealthy outposts"-Lucas English, a former Richmond Community ER Doctor

BON SECOURS MERCY HEALTH

The way hospitals use the 340B program is "nakedly capitalizing on programs that are intended to help poor people"-Dr. Peter B. Bach

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340B Hospitals Drug Markups: 4.9x Acquisition Cost

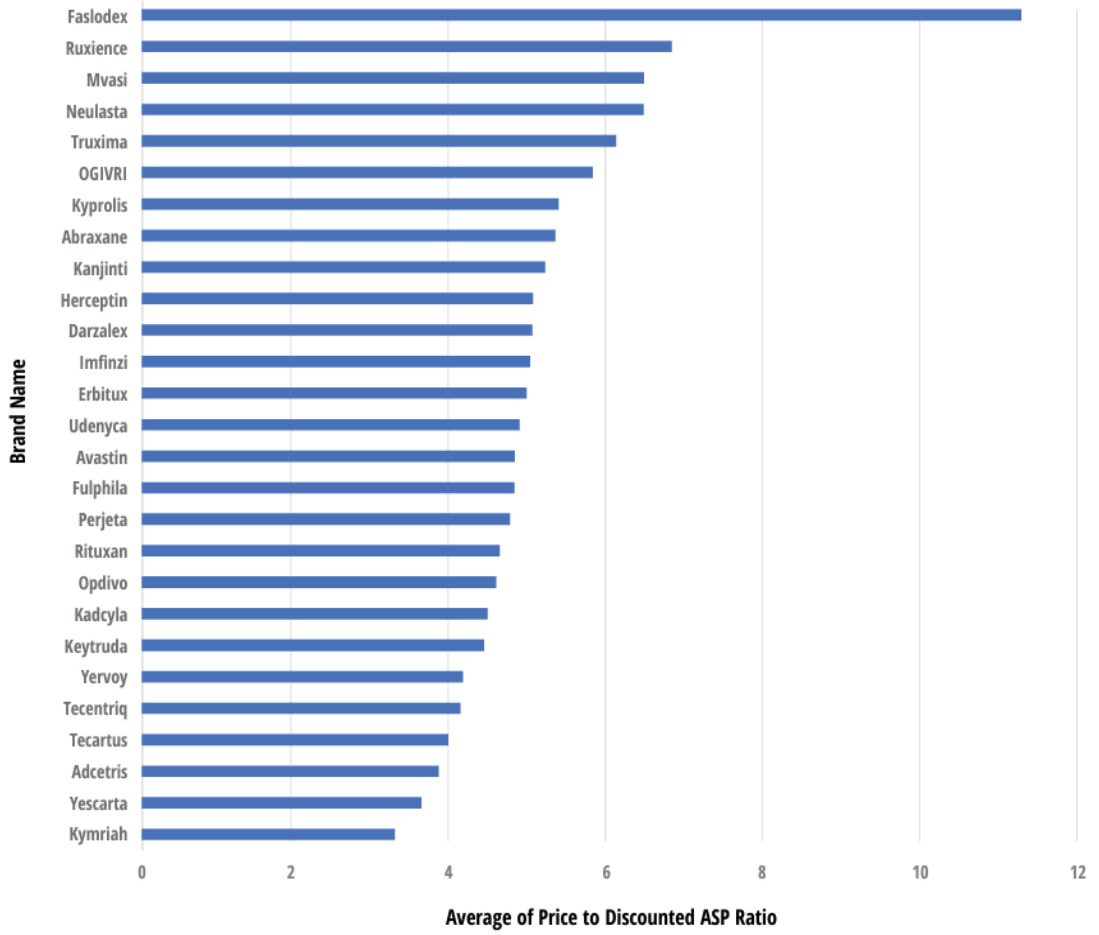
Methodology

- COA examined pricing data for the top 49 acute care disproportionate hospitals (DSH) participating in 340B
- DSH hospitals represent 78% of 340B purchases

Key Findings

- 340B DSH hospitals:
  - **Price drugs at a median of 4.9 times their 340B acquisition costs**
  - Charge commercially insured patients 7.4 times higher prices compared to Medicare patients
  - Remain slow to adopt biosimilars, with only 20% carrying all biosimilar studied
  - Charge cash-paying patients, such as the uninsured, similar prices compared to commercial insured patients
- There is a large spread in negotiated prices between hospitals and between payers in the same hospital
  - Ex: Prices for Keytruda ranged from 2.6 times to over 7 times 340B acquisition costs within the same hospital

Exhibit 3. **Average 340B Hospital Markup vs. 340B Hospital Discounted Acquisition Cost**

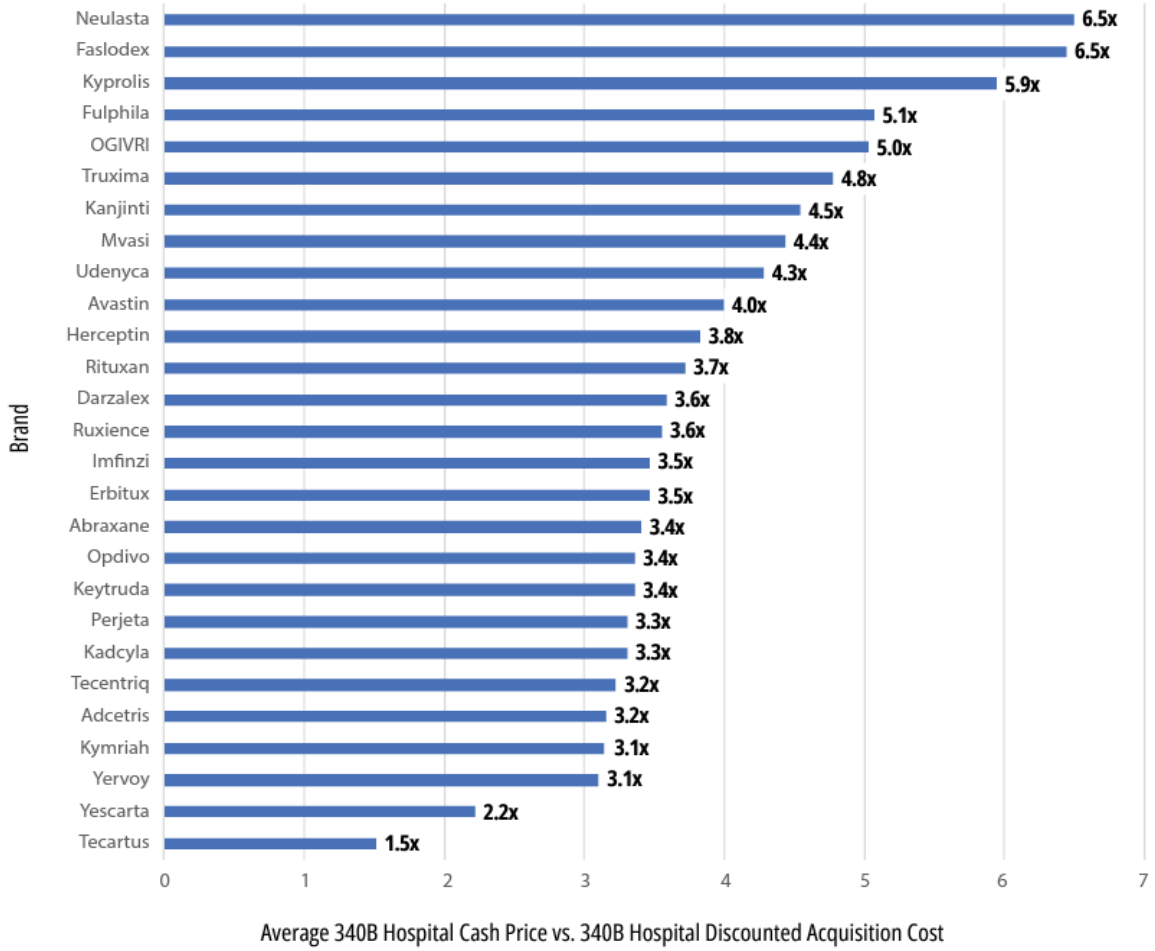


COA, Examining 340B Hospital Price Transparency, Drug Profits, and Incentives (Sept. 13, 2022)

340 Hospitals Drug Markups: Cash Paying Patients Do Not Receive Significant Drug Discounts

Hospitals charge 3.2 times ASP for commercial plans and charge cash-paying patients, such as the uninsured, 3.0 times ASP

Exhibit 10. **Comparison of Average Cash Price vs. 340B Hospital Discounted Acquisition Cost**



COA, Examining 340B Hospital Price Transparency, Drug Profits, and Incentives (Sept. 13, 2022)

CMMI Enhancing Oncology Model (EOM):

Non-Binding Applications Deadline Extended to Oct. 10 (previously Sept. 30)

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Who Will Apply to Participate in the EOM? Application Deadline was Extended Only 10 Days

Still TBD (and may not be made public)

- ADVI believes non-OCM participants are less likely will have a difficult time with infrastructure requirements and mandatory two-sided risk on Day 1
- COA conducted a survey in July 2022 (see next two slides)
- Recent COA/ACCC/ASCO webinar, Bo Gamble (COA Director of Quality and Value) referenced the non-binding nature of applications as a means to 'apply now, decide later':

> *"Think of it as you're applying for college. Submit your application, then study over it for the next three or four months and see if you're ready. You'll probably get asked to commit sometime in February, March, or April, but it gives you some time to try to model it yourself and look at all the aspects of it."*

Two days before the non-binding application deadline, CMMI extended deadline on Sept. 28 to Oct. 10 and issued updated 13-page FAQ (link), which notes CMS seeks "sufficient participation":

> Q. Is there a cap on the number of PGP applicants that CMS will accept?
> A. Currently, there is no cap on the number of applications for EOM participation. **CMS notes that sufficient participation in the model by EOM participants will be necessary in order for CMS to be able to detect a meaningful change in Medicare's expenditures as a result of the model test**.

Notable Oncology Provider Announcement

Oct. 3, 2022: OneOncology announced that 100% of its 14 practices submitting non-binding applications

TENNESSEE ONCOLOGY · NEW YORK CANCER & BLOOD SPECIALISTS · WEST CANCER CENTER & RESEARCH INSTITUTE · ARIZONA BLOOD & CANCER SPECIALISTS · ECHO · THE CENTERTX · LOSANGELES CANCERNETWORK · Astera CANCER CARE · PENNSYLVANIA CANCER SPECIALISTS Research Institute · PIEDMONT CANCER INSTITUTE · UCBC UNIVERSITY CANCER & BLOOD CENTER · MARY BIRD PERKINS CANCER CENTER · MOASD Medical Oncology Associates of San Diego · CANCER & HEMATOLOGY CENTERS OF WESTERN MICHIGAN

726	260+	421,000+
Total providers	Total sites of care	Total patients seen in 2021

"With large and diverse patient populations combined with OneOncology's analytics and value-based care expertise, our practice partners will have the data and insights to help them successfully participate in the EOM… We're proud that all OneOncology practices have applied to participate, and we look forward to working with them to them to drive high-quality, patient-centered outcomes in Medicare's value-based oncology model."

[On Health Equity]: "Having 14 of 14 OneOncology practices apply for EOM is an important indication of our practice partners' commitment to promote health equity. It also underscores the important contribution of the oncology community to improve access to high-quality cancer care for underserved populations." - Dr. Davey Daniel, MD, CMO, OneOncology

"CMMI made important updates to OCM risk adjustment methodology and modification of risk arrangements in response to the COVID-19 pandemic. So, we remain optimistic about opportunities to engage CMMI to promote improvements to EOM that will make the program more conducive to community oncology practices' participation."

COA Letter to CMMI on EOM Concerns

Care Management

- Limiting EOM to 7 cancer types creates inequities for patients
- EOM is too prescriptive
  - Mandated requirements ignore unique practice culture
- Billing should be allowed for Chronic Care Management
  - $70 MEOS payment is insufficient to cover these services and creates 2 systems of care
- Requiring EOM participants to aid with Health-Related Social Needs (HRSN) without additional resources is overly burdensome

Social Determinants of Health and ePROs

- SDOH data collection is burdensome to community practices and may damage patient trust
- ePRO effectiveness has not been studied in the community
  - Requires high implementation costs
- Assessing outcomes at every office visit is redundant
  - Creates an overload of information
- Frequency of Patient Reported Outcome Measures (PROMs) is unnecessary

Payment Methodology

- EOM must provide participants clear expectations in care and financial goals
- EOM is overly focused on reducing cost, instead of balancing with other goals
- Immediately mandating 2-sided risk may limit participation
- Payment methodology is too complex
  - Cannot easily be emulated or audited

Qualification of the EOM for AAPM and QPP

- With fewer qualifying cancer patients, it will be nearly impossible for practices to achieve QPP AAPM status
  - Cancer teams treating other types of patients would be required to comply with MIPS and EOM criteria
- Many practices in the OCM accepted risk because they could achieve QPP status and AAPM bonus payments
  - Without this incentive, practices will be unwilling to take on risks in the EOM

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Source: Sept. 14, 2022: COA "Formal Comments to CMS on Enhancing Oncology Model Concerns" (link)

COA Letter to CMMI on EOM Concerns: Shares Survey Results and Recommendations

Expected EOM Provider Participation (Late-July 2022 Survey*)

- 42.6% of practices that participated in OCM plan to participate in EOM
- 32.2% of practices plan to participate in EOM
- Only 8% of non-OCM participants are interested in the EOM

Recommendations
1. Provide more financial information, including care-team specific benchmarks for the first performance period
2. Implement a minimum of 2 full years or either an upside or no risk option
3. All participants should be allowed to exit the EOM with a minimum of 30 days notice
4. Increase the MEOS payment, particularly in the initial phases of the EOM, to cover additional costs
5. Provide timely, clear, and useful information back to EOM participants
6. Include all cancer types to ensure all patients receive high-quality care and increase the likelihood that participants can qualify as an AAPM

"Without changes, we are concerned that the EOM will fail as a demonstration project and as a model that can realistically transform the U.S. cancer care and payment system for the better."

*COA notes since the survey, "little has been revealed about the EOM that would lead COA to believe that many practices will change their mind about joining without some of the changes and suggestions outlined in this letter taking effect."
Source: Sept. 14, 2022: COA "Formal Comments to CMS on Enhancing Oncology Model Concerns" (link)

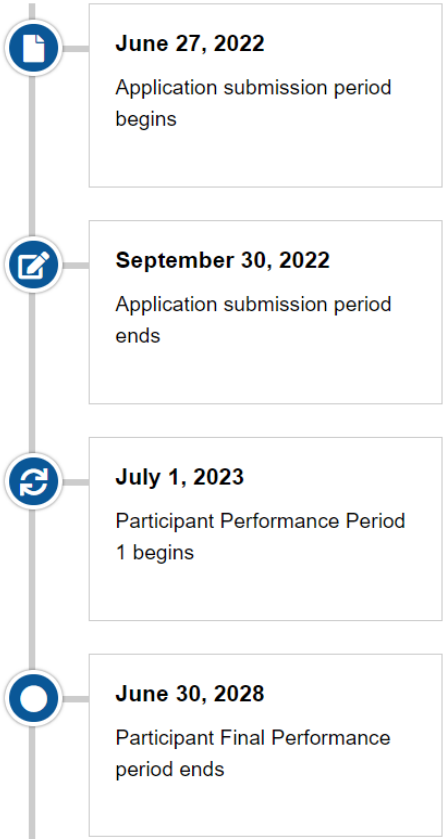
Recap: EOM Announced for July 2023 (1 year gap from the OCM sunset)

On June 27, 2022, CMMI issued a replacement for the Oncology Care Model (OCM), the voluntary, 5-year Enhancing Oncology Model (EOM) (link) with provider Request for Applications (RFA) with accompanying fact sheet (link) and FAQ (link). CMMI hosted an EOM Overview Webinar on June 30 (slides and recording).

- **CMMI draws on key aspects of the OCM (e.g., MEOS payment (albeit lower rate) with PBP, chemotherapy trigger, 6-month total cost of care) with new elements:**
  - Health equity focus (e.g., screening for health-related social needs, developing a health equity plan)
  - Gradual requirement to use ePROs
  - Risk: Mandatory downside risk to all providers at the model start with 2 options for provider participants

- **Like OCM, Part B/D drugs will continue to be reimbursed per current policy.**

- **Like OCM, no model-specific drug preferencing**
  - "Further, EOM does not dictate which drugs or services practitioners must provide. Participating practices are expected to use shared decision-making techniques to work with beneficiaries in the model to develop the most appropriate course of treatment for each patient."
    - Thus the value of novel and costly therapies will continue to be judged by providers based on their contribution to total cost of care
  - "Value-based payment models like OCM have motivated clinicians to focus on supportive care therapies, and high-value prescribing, such as the adoption of biosimilars, as increasing numbers of biosimilars have come to market. For example, the increased adoption of biosimilars in an OCM practice led to a significant reduction in typical drug costs."



Recap: EOM Top 7 Takeaways

Overall, similar to OCM

- EOM largely continues OCM with a few changes, continuing as a total cost of care model with a chemotherapy trigger
  - Change: MEOS payment is significantly reduced
- Narrower scope
  - Includes only 7 tumor types and no hormonal therapy
- Manufacturer impact does not change from OCM
- ADVI Advisor:
  - Similar to OCM, but "CMMI changed the model to increase the likelihood that it generates savings and there are clear efforts to include equity considerations. The ePROs are an interesting twist."

Drug payment

- Like OCM, no change to Part B or Part D drug reimbursement
- Providers continue to be incentivized to make value judgement on treatments as they are judged on the total cost of care
- Note: CMMI drug pricing reforms still loom
  - If Congress fails to enact significant drug pricing reforms before the midterm election, the Biden administration will be pressured to act unilaterally and pursue Medicare-specific reforms, like government negotiation, through CMMI

Provider participation and risk

- Provider participation is voluntary, like OCM
- Downside risk is required from the start, unlike OCM

Provider payment

- EOM continues OCM's MEOS (lower) plus PBP
  - $70 for non-duals
  - $100 for dual eligibles
- Low MEOS compounded by fewer patients:
  - 7 tumor types
  - No hormonal therapy
- PBP calculated based on target price based on historical claims and adjusted for trend, novel therapies, clinical case adjustments (like OCM)
  - Targets determined on a cancer-specific basis, addressing a major criticism of the OCM
- Note: Novel Therapies Adjustment (NTA) for PBP will be calculated separately for the 7 included cancer types
  - Change from OCM: NTA calculated in aggregate across all cancer types

Participant redesign activities

- PRAs similar to OCM, with two new requirements and an explicit focus on health equity
- Two new requirements:
  - Assessment of social determinants of health needs
  - Gradual implementation of ePROs
- Practices required to submit "health equity plans" to CMMI

Quality measures

- CMS releasing specific measures this Summer/Fall
- CMS "will continue to explore opportunities to update the quality measure set over time in alignment with the principles and domains outlined above as new measures emerge, including those that promote equity."

Timing

- Providers have short window to apply (i.e., 2 months)
  - OCM participants the most likely to apply, although practices need to decide whether the extra administrative burden outweighs the lower MEOS for fewer patients
- One year gap after OCM
  - Oncologists in OCM must wait another full year before the EOM begins
  - Patient navigator role 'unfunded' for current OCM practices for a year, as this role is required again in EOM
- No public comment opportunity with this model

Recap: Implications from Unique Perspectives

Provider Perspective

- No change in drug reimbursement
- MEOS decrease will be substantial
  - Providers will need to consider whether the effort is worth the lower MEOS
  - Fewer eligible patients, due to only 7* tumor types in EOM scope and exclusively hormonal therapy excluded
  - Estimate: ~75% cut overall in MEOS
- Non-OCM providers face costly ramp up to meet EOM criteria
  - Unlikely a practice not currently in OCM will choose to participate
  - "For practices, the MEOS decrease will be substantial (as much as 75% decrease) and they will need to consider whether the effort is worth it. There is no way a non-OCM practice will choose to participate."
- OCM participants must determine how to resource Patient Navigators in one-year gap

Patient Perspective

- Fewer patients will be eligible, due to only 7 tumor types and exclusively hormonal therapy excluded in EOM scope
- No cost-sharing for Enhancing Services in MEOS
- Patients in OCM were generally happy with enhanced services
  - Felt they were getting higher quality care

Manufacturer Perspective

- Little to no change from OCM:
  - The value of novel, costly therapies will continue to be judged by providers, as with OCM, based on their contribution to total cost of care
- Like OCM, EOM does not dictate drug choice
  - "Value-based payment models like OCM have motivated clinicians to focus on supportive care therapies, and high-value prescribing, such as the adoption of biosimilars, as increasing numbers of biosimilars have come to market. For example, the increased adoption of biosimilars in an OCM practice led to a significant reduction in typical drug costs."

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*7 in-scope tumor types: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer (hormonal therapy in breast and prostate cancer are excluded (i.e., not included as episode triggers))

State Update

Select Committee on Health Care Reform

- Earlier this month, the House Select Committee on Health Care Reform met in their last scheduled hearing of the interim.
- The committee heard testimony on their interim charge "*to examine the potential impact of delayed care on the state's health care delivery system, health care costs, and patient health outcomes, as well as best practices for getting patients with foregone or delayed health interventions back into the health care system. The study should consider patient delays in obtaining preventative and primary health services, such as well-child care, prenatal care, screenings for cancer and chronic disease, behavioral health, and immunizations, in addition to delays in seeking urgent care or care for chronic disease.*"
- Debra Patt, M.D. spoke to the challenges of Texas patients related to lack of access to cancer screening due to lack of health insurance coverage; insurer delays including prior authorization; workforce shortages; and the harm of white bagging mandates.

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Texas Palliative Care Interdisciplinary Advisory Council

- The Texas Palliative Care Interdisciplinary Advisory Council (PCIAC) recently issued its official recommendations to the 88th Texas Legislature, which include the following policy issues:
  - Supportive palliative care regulatory standards for home health agencies;
  - Adoption of a Texas Medicaid Advance Care Planning (ACP) benefit;
  - Child Life Specialists are essential members of the supportive palliative care team;
  - Promote health care provider and health care professional continuing education opportunities;
  - Establishment of a Supportive Palliative Care Awareness Day; and
  - Expanding the Medicaid hospice benefit into the prenatal period to improve care for children with a terminal and/or life-limiting illness

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Adoption of a Texas Medicaid ACP Benefit

- The PCIAC recommends that a Texas Medicaid ACP benefit:
  - provide reimbursement for vital, and ongoing crucial ACP discussions to be provided in-person and/or via telehealth;
  - for individuals of all ages with a serious illness who have at least one of the following eight conditions: chronic kidney disease, heart failure/ischemic heart disease, diabetes, COPD, advanced liver disease, Alzheimer's disease or senile dementia, stroke, and/or cancer.
- Additionally, the Texas SPC benefit should include the following services:
  - Supportive palliative care assessment and consultation;
  - Advance care planning;
  - Plan of care/goals of care;
  - Interdisciplinary palliative care team;
  - Care coordination;
  - Pain and symptoms management;
  - Mental health and medical social services;
  - Training and respite services for family caregivers; and
  - Telehealth services

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Elections in Less Than a Month

- Depending on the poll, statewide Republican candidates are leading their Democratic opponents by 7-11 points with Patrick showing the biggest lead followed by Abbott then Paxton
  - When certainty of voting is taken into account the numbers increase to 8-12 with Abbott showing the biggest differential
  - These numbers have been fairly level over the last month and despite millions pouring into ad buys on both sides especially for the final 30 day stretch, the numbers aren't expected to shift much
  - Still a lot of time left for something to blow up
- Democrats leaning on social issues while Republicans focusing on border security and public safety
  - Economy also a big issue for the right and it will resonate despite it being more of a federal issue
- Both Abbott and O'Rourke are reporting around $25M in contributions over the last three months
  - Total contribs in the Gov race are close to $175M

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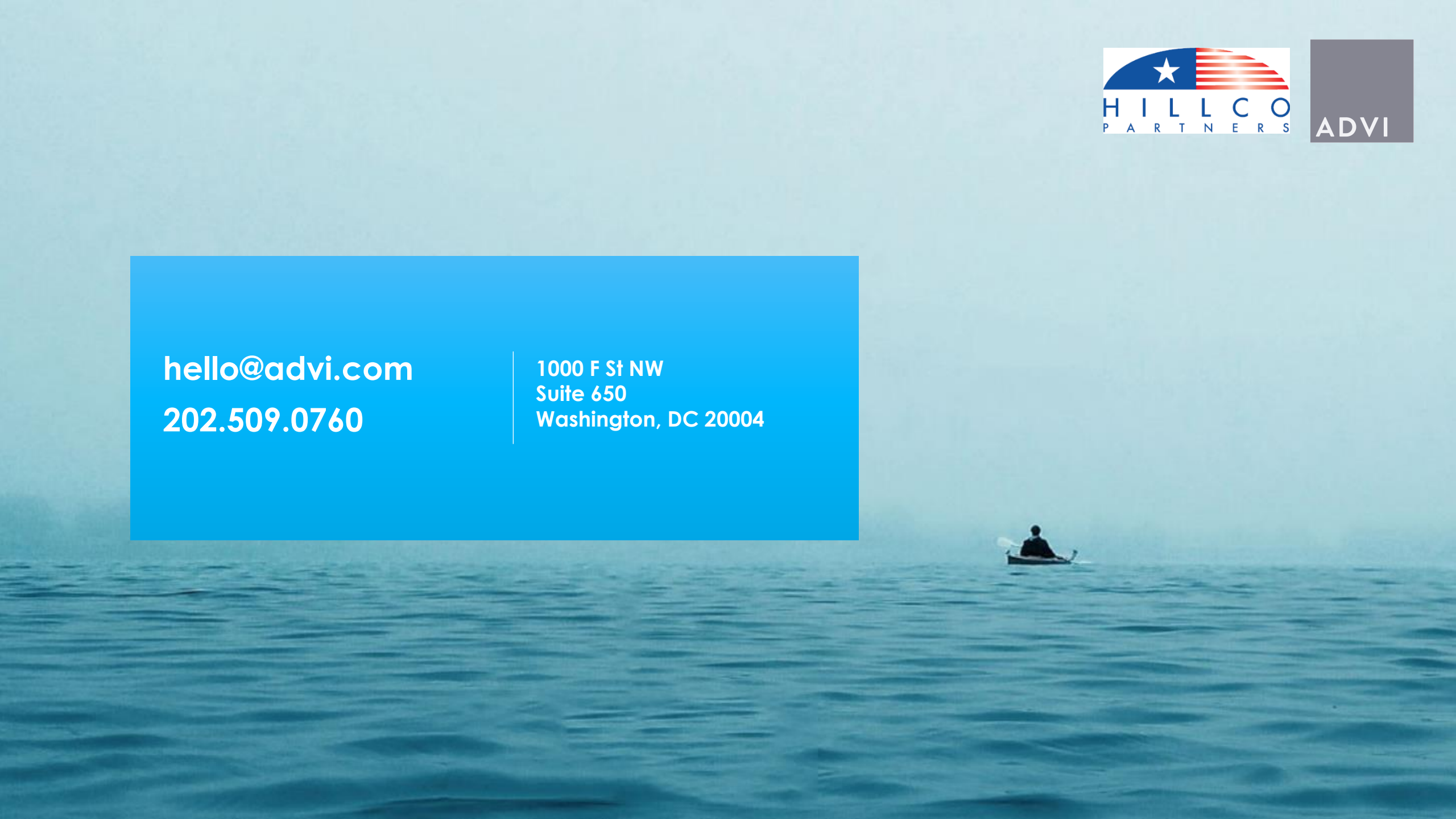

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