NJSOM Fall Meeting

Update on Everything Oncology in D.C. and Beyond

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Executive Director
October 6, 2022

What's Happening in DC in General?

- Congress last week passed a short-term spending bill to avert a government shutdown till after the elections
- All eyes now on the elections
  - Democrats pointing to wins on inflation reduction and lowering drug prices, and focusing on the Supreme Court and red state state abortion rulings
  - Republicans pointing to record inflation, immigration, and general lawlessness
- Congressional Republicans still looking forward to taking the majority in the House (likely not a big flip) and less likely the Senate
- Democrats more optimistic about possibly keeping the House and feeling good about the Senate
- Senator Manchin gave his party a big win in passing the Inflation Reduction Act
  - But overplayed his hand and came up dry in passing some energy transfer measures for WV
    - Ironic that both progressive Democrats and Republicans lined up against Manchin

What's Happening in DC Oncology Related?

- Inflation Reduction Act (IRA) empowers Medicare to negotiate drug prices
- Pressure ramping up on hospitals, especially with 340B
  - Hospitals marking up cancer & other expensive drugs
    - COA released an updated study oh 340B hospital drug mark-ups (5X)
    - Studies also report on over-charges on services
  - Pharma company restrictions on use of multiple contract pharmacies in the courts
  - FTC looking at impact of hospital consolidation on patient care (and increasing costs)
  - Increased media coverage on high hospital costs and 340B bad behaviors
  - But with all this, CMS proposing to increase drug reimbursement to 340B hospitals
- State and Federal pressure ramping up on PBM bad behaviors
  - Democrats have stepped out on admitting PBMs have a hand in fueling drug prices higher
  - State pressure, and legislation, continues to mount
- Enhancing Oncology Model (EOM) announced as the follow-up to the Oncology Care Model (OCM)
  - COA received an extension for applications till 10/10
    - Apply even if you are unsure of participating

IRA Drug Pricing Provisions

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ness by reason of such requirements before final action on such application.

SEC. 138521. TERMINATION OF EMPLOYER CREDIT FOR PAID FAMILY AND MEDICAL LEAVE.

Section 45S(i) is amended by striking "December 31, 2025" and inserting "December 31, 2023".

Subtitle I—Drug Pricing

PART 1—LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION

SEC. 139001. PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.

(a) PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e–3) the following new part:

"PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

"SEC. 1191. ESTABLISHMENT OF PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

"(1) publish a list of negotiation-eligible drugs and selected drugs in accordance with section 1192;

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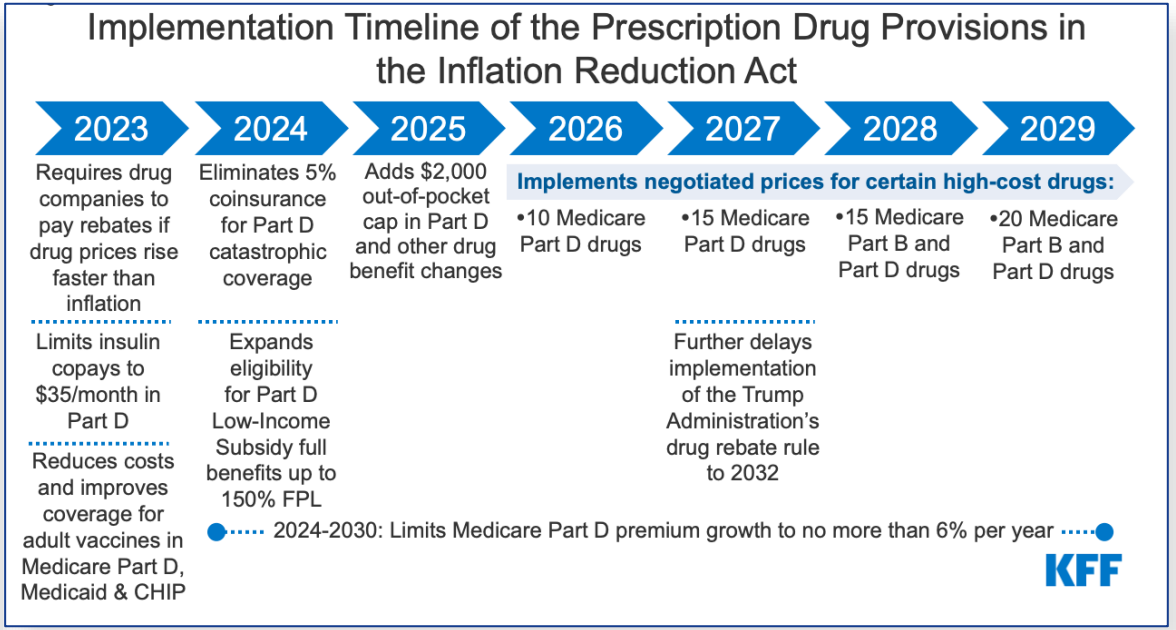
November 3, 2021 (12:14 p.m.)



Target Drugs: Cimzia, Eylea, Keytruda, Opdivo, Prolia/Xgeva, Soliris, Entyvio, Sandostatin Lar Depot, Simponi / Aria, and Tyvaso / Orenitram ER

Next Steps and How This Plays Out

- CMS ramping up hiring to staff the "negotiation" arm
  - $3 billion allocated for 10 years
- Lots of time and lots of things will happen before 2028
  - CMS has no experience "negotiating" drug prices
    - Steep learning curve
    - The wheels of government turn slowly
  - If Republicans take the House, they will drag CMS up to the Hill every chance possible
  - This will end up in the courts when at least one company will not "negotiate"
    - Possibly end up in the Supreme Court over constitutional issues
  - The outcome of the 2024 election for President will absolutely impact this if a Republican is elected
- We have spent a lot of time with the White House and Congress trying to get providers out of the middle of "negotiations"
- ***Good news is biosimilars reimbursed at ASP + 8%!***

CMS "Negotiation" Structure

Proposed

 # FTEs: 95

 # Vacancies: 95

Medicare Drug Rebate and Negotiations Group (Admin Code TBD) 7 FTEs
1 Director, ES-0340-00 1 Deputy Director (Policy), GS-0107-15 1 Deputy Director (Operations), GS-0107-15
1 Pharmacist, GS-0660-15 1 HIS (TA), GS-0107-15 1 Operations Spec, GS-0301-09 1 HIS (SA), GS-0107-14

Division of Contract Support (Admin Code TBD) 12 FTEs	Division of Manufacturer Compliance and Oversight (Admin Code TBD) 13 FTEs	Division of Manufacturer Data and Inflation Rebate Operations (Admin Code TBD) 15 FTEs
1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14
3 Contracting Officer Rep, GS-1101-12/13 2 HIS (Program Contractor Mgmt), GS-0107-12/13 1 Budget Analyst, GS-0560-12/13 2 Financial Mgmt Analyst, GS-0501-12/13 2 Mgmt & Prog Analyst, GS-0343-12/13	1 HIS (Program Contractor Mgmt), GS-0107-12/13 4 HIS (Program Policy), GS-0107-12/13 4 HIS (Program Oversight), GS-0107-12/13 2 Mgmt & Prog Analyst, GS-0343-12/13	1 HIS (TA), GS-0107-14 2 HIS (Program Contractor Mgmt), GS-0107-12/13 4 HIS (Program Policy), GS-0107-12/13 2 Mgmt & Prog Analyst, GS-0343-12/13 3 IT Spec (Data Mgmt), GS-2210-12/13 1 Pharmacist, GS-0660-12/13

* FTEs displayed are vacant

KEY:

New Group/Division

CMS "Negotiation" Structure (continued)

Proposed

 # FTEs: 95

 # Vacancies: 95

Division of Data Assessment and Analytics (Admin Code TBD) 16 FTEs	Division of Rebate Agreements & Drug Price Negotiations (Admin Code TBD) 16 FTEs	Division of Policy (Admin Code TBD) 16 FTEs
1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14
2 HIS (TA), GS-0107-14 2 Pharmaeconomist, GS-0660-12/13 1 Economist, GS-0110-12/13 3 HIS (Program Policy), GS-0107-12/13 4 Social Sci Research Analyst, GS-0101-12/13 1 Data Scientist, GS-1560-12/13 1 Pharmacist, GS-0660-12/13	2 HIS (TA), GS-0107-14 2 Economist, GS-0110-12/13 5 HIS (Program Policy), GS-0107-12/13 1 Mgmt & Prog Analyst, GS-0343-12/13 2 Pharmacist, GS-0660-12/13 2 Social Sci Research Analyst, GS-0101-12/13	2 HIS (TA), GS-0107-14 1 Economist, GS-0110-12/13 6 HIS (Program Policy), GS-0107-12/13 1 Mgmt & Prog Analyst, GS-0343-12/13 2 Pharmacist, GS-0660-12/13 2 Social Sci Research Analyst, GS-0101-12/13

* FTEs displayed are vacant

KEY:

New Group/Division

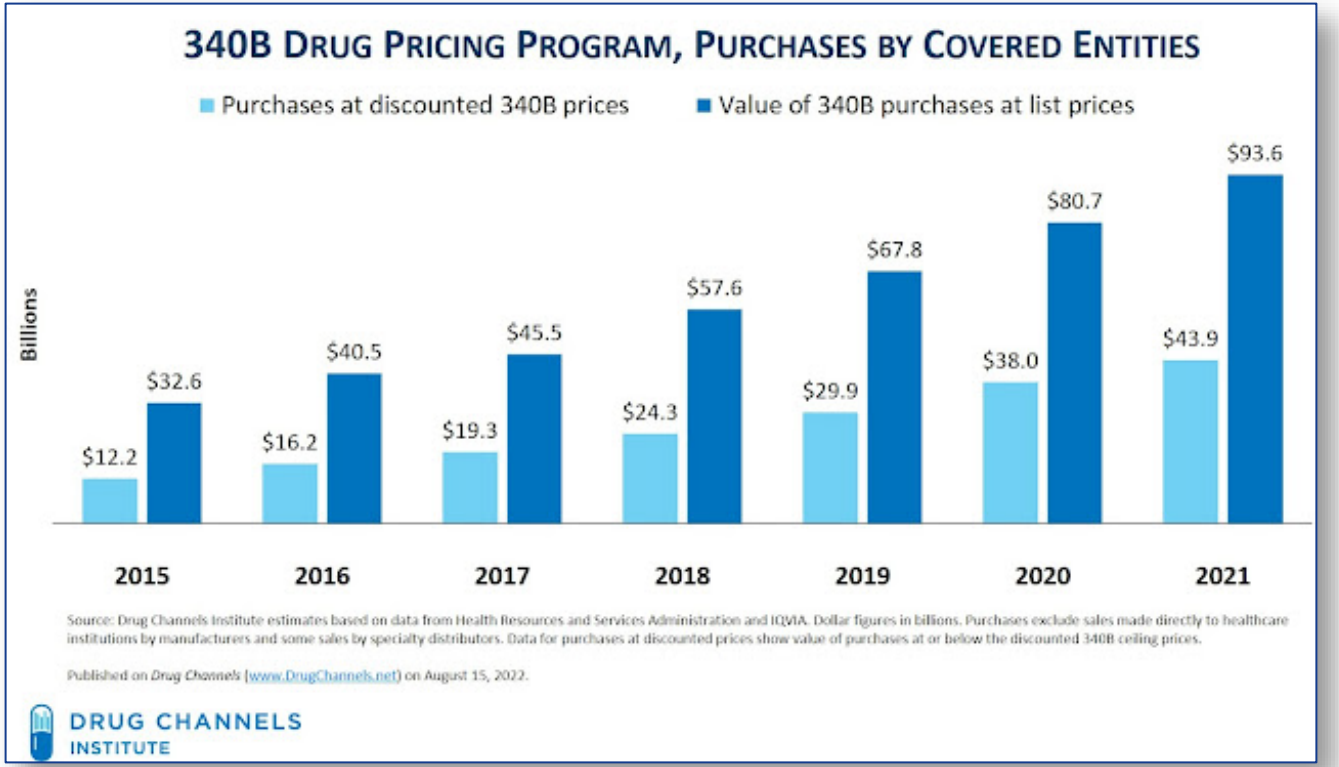
What's All Wrong with Medicare "Negotiating" Prices

- This is targeted at 60 million Medicare beneficiaries
  - Leaves 250 million Americans with commercial insurance or no insurance swinging in the wind
    - Prices likely increased to compensate with Medicare "negotiated" prices
- Launch prices will likely be increased
  - Pharma will protect products that may end up facing "negotiations" and from inflation caps
- Won't stop hospitals, especially large 340B hospitals, from marking up prices to patients with commercial insurance or no insurance
- The courts may well kill this and weaken CMS
- We are all over this in getting practices out of the middle of "negotiations"
  - Developed legislative language
  - Multiple calls with the White House and Congress
  - Possible "marker" bill introduced even this year

Background on the 340B Drug Pricing Program

- **340B is a CRITICAL safety net program, especially for patients with cancer who are uninsured or underinsured**
- However, the program has expanded from a handful of safety net providers to 50+% of all U.S. hospitals *(Source: Berkeley Research Group)*
  - WAC list price value of 340B drug purchases reached $93.6 billion in 2021 *(Source: IQVIA)*
    - 14% of the total U.S. pharmaceutical market
- 340B generated $40 billion in profits for participants *(Source: Masia/Columbia University & SSR Health)*
- One estimate is that by 2026 340B will be the largest federal drug program, surpassing both Medicare and Medicaid drug programs *(Source: Berkeley Research Group)*

340B Growth Continues

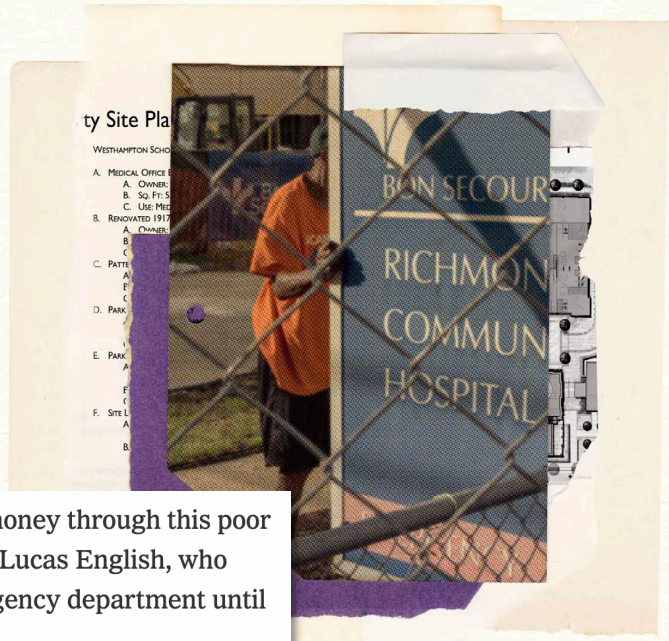


340B Hospitals in the Media Crosshairs

PROFITS OVER PATIENTS

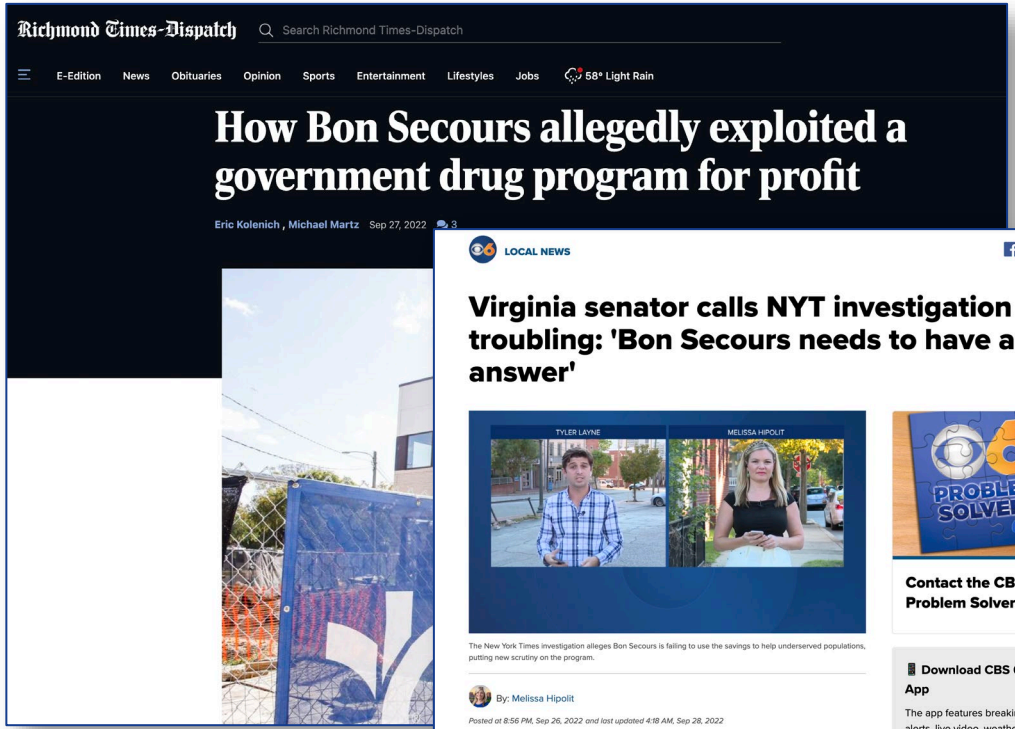
How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits

Bon Secours Mercy Health, a major nonprofit health system, used the poverty of Richmond Community Hospital's patients to tap into a lucrative federal drug program.



"Bon Secours was basically laundering money through this poor hospital to its wealthy outposts," said Dr. Lucas English, who worked in Richmond Community's emergency department until 2018. "It was all about profits."

Creating a 340B Firestorm



Impact of the Supreme Court Decision on 340B

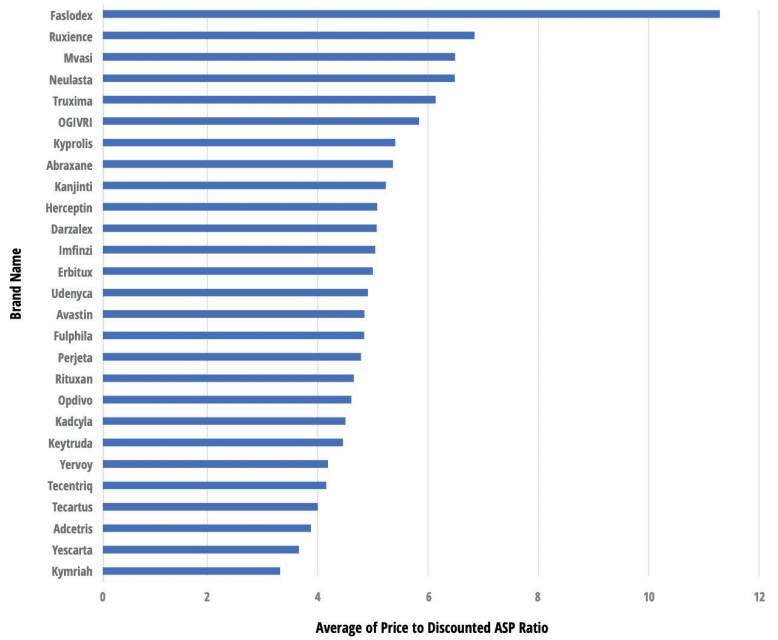
- Very narrow decision basically saying HHS/CMS has to use hospital survey data to change 340B hospital Medicare reimbursement
- Just pertains to 2018 & 2019
- Litigation still pending for 2020, 2021 & 2022
- CMS now has hospital survey data that would actually lower reimbursement from ASP – 22.5% to ASP – 28.7%
- CMS released proposed 2023 HOPPS rule stating likely to increase reimbursement to 340B hospitals by 37% (ASP + 6%)
- D.C. Court just ruled that CMS can wait till 2023 and must change reimbursement NOW
- *In short, this is a real mess!*

What's COA Doing?

- Published hospital drug mark-up study 2.0
  - Looks at top 340B hospitals' reported data
- Wrote 340B legislation that would ensure discounts go to patients in need, not to hospitals
  - In effect, the 340B discounts would "follow the patient"
  - Would apply to 340B DSH hospitals and independent practices
- Filed *amicus briefs* relating to both the Lilly and AZ versus HHS lawsuits over 340B restricting sales to 340B contract pharmacies
- Working with the media
- Looking at legal options to stop CMS from increasing reimbursement to 340B hospitals

340B Hospital Drug Markups – COA Study 2.0

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



340B hospitals' own self-reported pricing data reveals that they price the top oncology drugs at **4.9 times their 340B acquisition costs**, assuming a 34.7 percent discount, which is a conservative estimate.

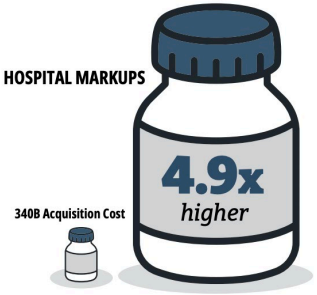


Exhibit 5.

Herceptin Markups Across Settings and Payers

(one year of therapy)

Community Practice or non-340B Hospital Treating a Medicare Patient

Purchased for	$66,107
Reimbursed at	$70,073
Margin	**$3,966**

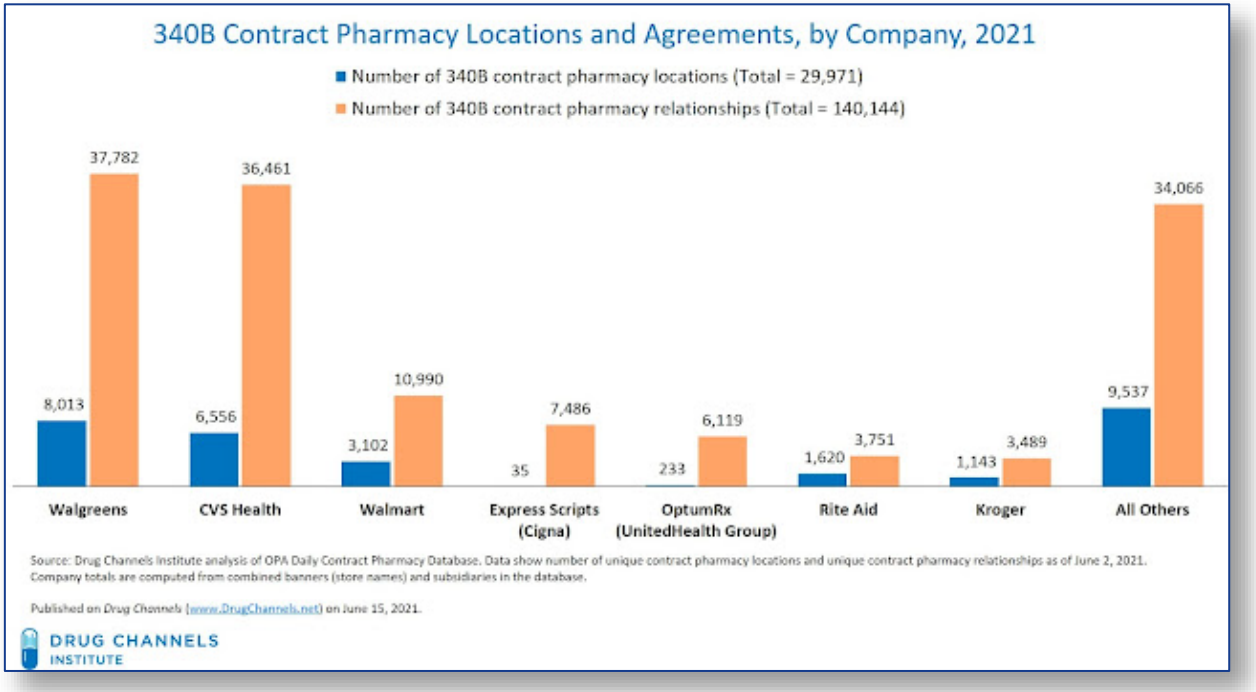
340B Hospital Treating a Medicare Patient

Purchased for	$43,168
Reimbursed at	$70,073
Margin	**$26,905**

340B Hospital Treating a Commercial Patient

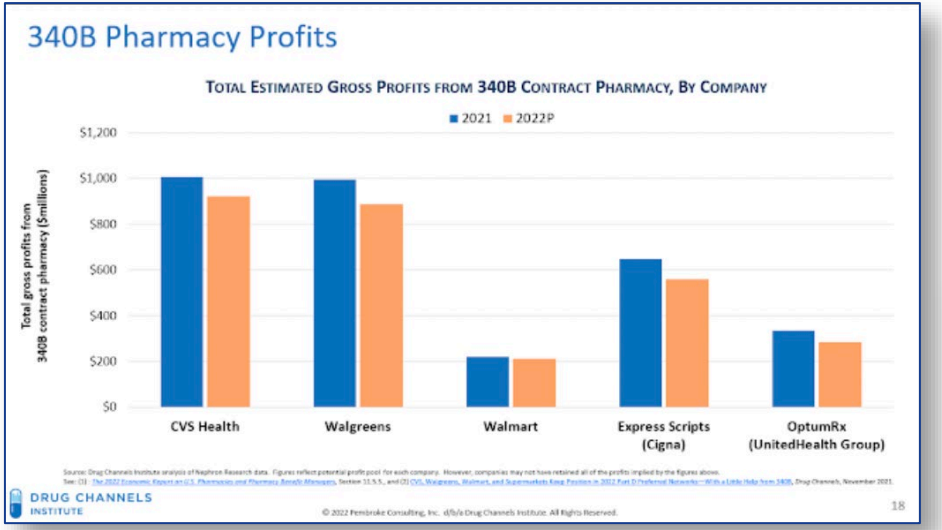
Purchased for	$43,168
Insurer Charged	$217,122
Margin	**$173,954**

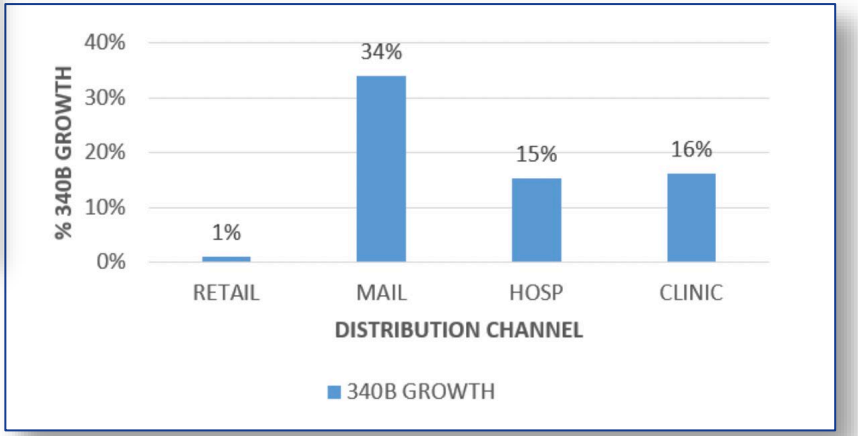
PBMs Now Major Players in 340B



Top 3 PBM non-retail pharmacies now account for 18% of 340B pharmacy relationships *(Source: Drug Channels)*

PBMs Making Huge Profits on 340B





Source: https://www.iqvia.com/locations/united-states/blogs/2022/04/340b-program-continues-to-grow-while-contract-pharmacy-restrictions-take-effect

Implications of PBMs' Intrusion in 340B

- Ask yourselves why insurers and their PBMs want to white bag injectables and fill orals from their specialty/mail order pharmacies?
  - *Because they are 340B contract pharmacies!*
    - And there is no oversight of contract pharmacies in terms of what they can and can't do
- Ultimately, the PBM/insurer complex wants to control what treatment is provided and who provides it and where!

Moreover, Specialist agrees, with respect to all chronic biotherapies administered in Specialist's office to Members, to order the necessary specialty medications from a Participating specialty pharmacy provider. With respect to Members diagnosed with either Crohn's Disease or Immunodeficiency Syndrome or Infused Medications for Psoriasis and needing specialty medications for their conditions, Specialist shall in accordance with a Member's plan and unless prohibited by law, coordinate with Member's Participating specialty pharmacy provider to transition the drug and service authorization, drug distribution, **clinical oversight** and billing management of the specialty medications treating these conditions to the participating specialty pharmacy.

What's New on the PBM Front

- Pretty intense state activity and more to come when legislative sessions start back up in 2023
- More federal activity as the Democrats have started to target PBMs
  - Senate Commerce Committee on PBMs
  - Senators' Cantwell and Grassley bill on PBM transparency
  - Much more to come next year
- More media coverage on PBM bad behaviors
- Latest PBM-related issue is TRICARE letting Express Scripts do whatever it wants

State Developments: 2022 By the Numbers

46 States in Session

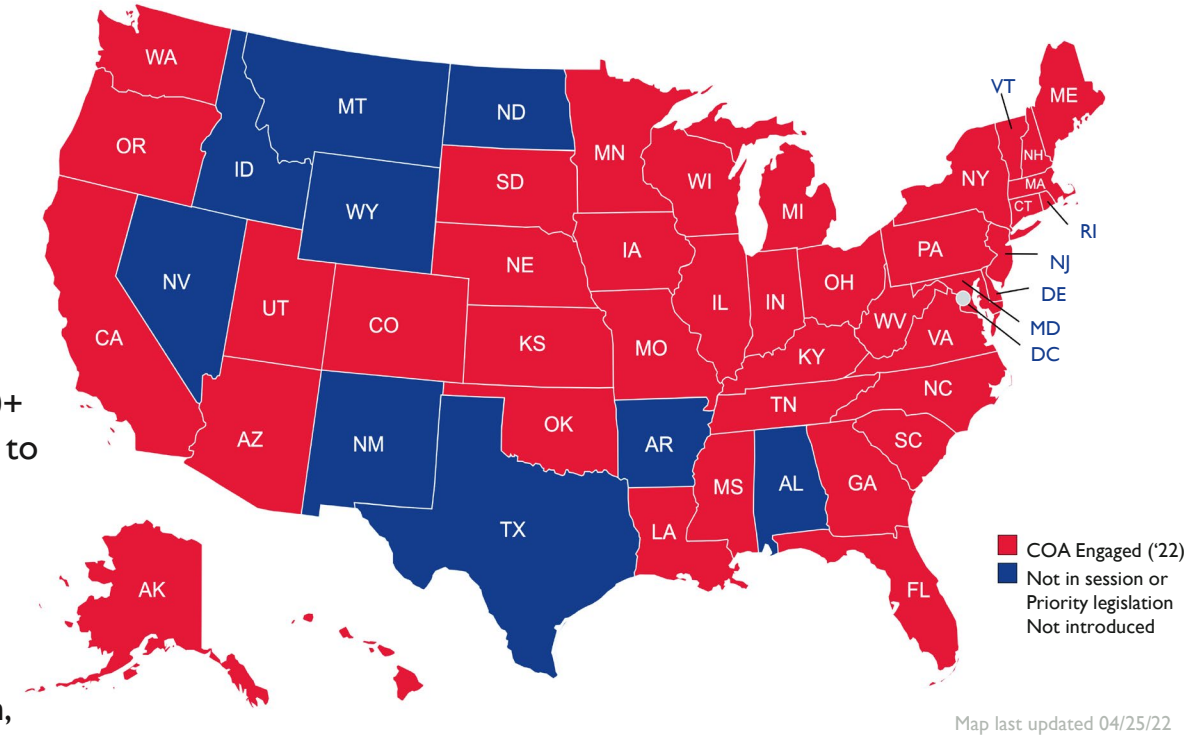
In 2022 41 states introduced bills of relevance to oncology and pharmacy benefit managers.

350+ Industry Bills

300+ bills were introduced with the intention of reforming pharmacy benefit manager practices, while an additional 50+ concerned additional topics of relevance to oncology.

61 Bills Passed

17% of all bills filed were passed in 2022. Total passed is reflective of consolidation, not rate of success.



Map last updated 04/25/22

2022 State Developments: Top Performers

Massachusetts

- 29 Bills Filed

Issues:

- PBM Transparency
- Anti-steerage
- Maximum Allowable Cost
- Rebate Passthrough
- Accumulator Adjustment Programs

New Jersey

- 28 Bills Filed

Issues:

- PBM Licensure
- PBM Transparency
- Prior Authorization
- Step Therapy
- Accumulator Adjustment Programs

Oklahoma

- 23 Bills Filed

Issues:

- PBM Licensure
- PBM Transparency
- Step Therapy
- Prior Authorization
- Maximum Allowable Cost Lists

Minnesota

- 20 Bills Filed

Issues:

- PBM Licensure
- PBM Transparency
- Anti-steerage
- Maximum Allowable Cost
- Rebate Passthrough

2022 Trending State Reforms

PBM Licensure

Licensure bills require pharmacy benefit managers to apply for a license to operate in a state. Licensure bills may require a PBM to follow specific requirements and guidelines in order to obtain a license and may institute fees and penalties for PBMs. Licensure bills may also establish revolving funds to continue oversight.

PBM Transparency

Transparency bills vary widely. Some require pharmacy benefit managers to report to a state agency or other regulatory body on an annual or biannual basis, disclosing information concerning rebates, formulary changes, pharmacy ownership information, and contract information. Other bills prohibit PBMs from imposing gag clauses on pharmacists.

Accumulator Adjustment Program Bans

AAP bills require PBMs to recognize copay assistance programs, waivers, and third-party payments for prescriptions as part of a patient's deductible and annual out-of-pocket costs.

Enhancing Oncology Model Purpose & Timeline

"The purpose of the new EOM is to drive transformation in oncology care by preserving or enhancing the quality of care furnished to beneficiaries undergoing treatment for cancer while reducing program spending under Medicare fee-for-service (FFS)."

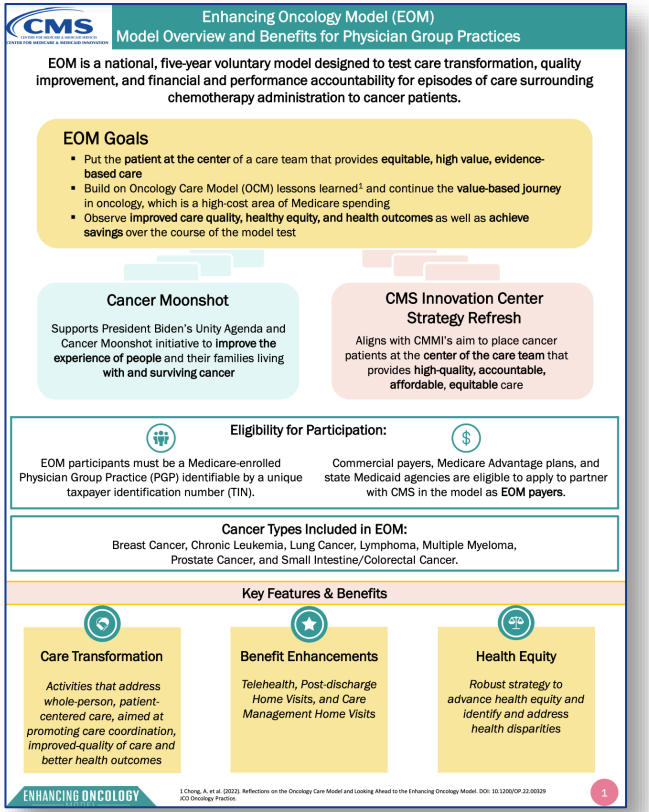
"Under EOM, participants will be incentivized to consider the whole patient and engage with them proactively, during and between appointments."

- Application period now open and runs through October 10, 2022
  - Non-binding application
  - CMS reviews each application and acceptance notification late 2022 or early 2023
- Model starts on July 1, 2023 and runs for five years until June 30, 2028

Enhancing Oncology Model Overview

- Builds off of the Oncology Care Model (OCM)
  - Like the OCM the Enhancing Oncology Model (EOM) is a voluntary model
  - Like the OCM the EOM has two methods of payment
    - Per beneficiary, per month Monthly Enhanced Oncology Services (MEOS) payment
    - Reward payment for saving Medicare money based on performance (Performance-Based Payment or PBP)
- But significant differences from the OCM
  - Open to Physician Group Practices (PGPs) only
    - Must have at least one oncologist
    - Can participate in other CMMI models (e.g., Maryland Total Cost of Care Model)
  - Only 7 cancer types
  - Focused on addressing health inequities in cancer treatment
  - Requires practices to do more but be paid less
    - Screen for health-related social needs
    - Implement ePROs
  - Requires practices to assume risk from the start
    - Two options of less risk and more risk
  - *"cancer-type specific approach to calculating benchmarks"*

CMS Enhancing Oncology Model Summary



Enhancing Oncology Model (EOM)
Model Overview and Benefits for Physician Group Practices

EOM is a national, five-year voluntary model designed to test care transformation, quality improvement, and financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients.

EOM Goals

- Put the **patient at the center** of a care team that provides **equitable, high value, evidence-based care**
- Build on Oncology Care Model (OCM) lessons learned[1] and continue the **value-based journey** in oncology, which is a high-cost area of Medicare spending
- Observe **improved care quality, healthy equity, and health outcomes** as well as **achieve savings** over the course of the model test

Cancer Moonshot

Supports President Biden's Unity Agenda and Cancer Moonshot initiative to **improve the experience of people** and their families living **with and surviving cancer**

CMS Innovation Center Strategy Refresh

Aligns with CMMI's aim to place cancer patients at the **center of the care team** that provides **high-quality, accountable, affordable, equitable** care

Eligibility for Participation:

EOM participants must be a Medicare-enrolled Physician Group Practice (PGP) identifiable by a unique taxpayer identification number (TIN).

Commercial payers, Medicare Advantage plans, and state Medicaid agencies are eligible to apply to partner with CMS in the model as **EOM payers**.

Cancer Types Included in EOM:
Breast Cancer, Chronic Leukemia, Lung Cancer, Lymphoma, Multiple Myeloma, Prostate Cancer, and Small Intestine/Colorectal Cancer.

Key Features & Benefits

Care Transformation

Activities that address whole-person, patient-centered care, aimed at promoting care coordination, improved-quality of care and better health outcomes

Benefit Enhancements

Telehealth, Post-discharge Home Visits, and Care Management Home Visits

Health Equity

Robust strategy to advance health equity and identify and address health disparities

ENHANCING ONCOLOGY

1 Chong, A. et al. (2022). Reflections on the Oncology Care Model and Looking Ahead to the Enhancing Oncology Model. DOI: 10.1200/OP.22.00329 JCO Oncology Practice.

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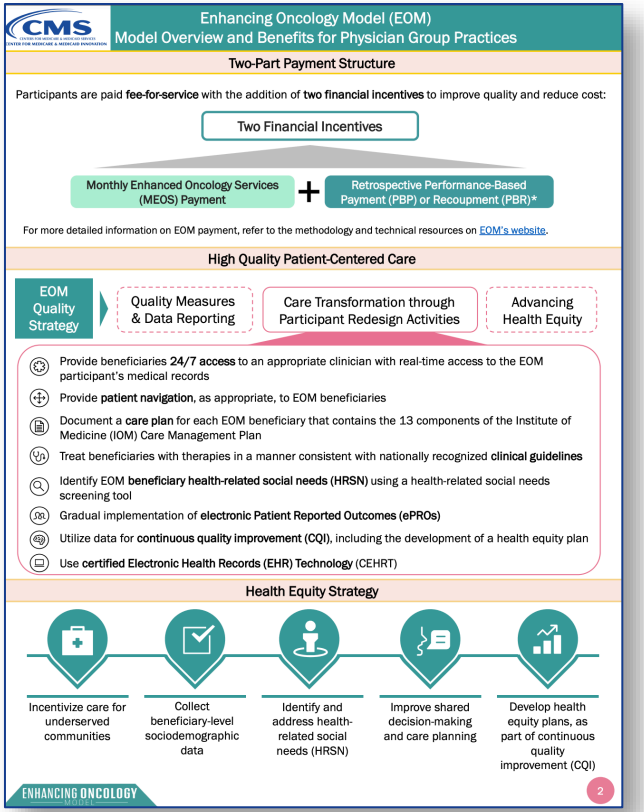


Enhancing Oncology Model (EOM)
Model Overview and Benefits for Physician Group Practices

Two-Part Payment Structure

Participants are paid **fee-for-service** with the addition of **two financial incentives** to improve quality and reduce cost:

Two Financial Incentives

Monthly Enhanced Oncology Services (MEOS) Payment + Retrospective Performance-Based Payment (PBP) or Recoupment (PBR)*

For more detailed information on EOM payment, refer to the methodology and technical resources on EOM's website.

High Quality Patient-Centered Care

EOM Quality Strategy: Quality Measures & Data Reporting; Care Transformation through Participant Redesign Activities; Advancing Health Equity

- Provide beneficiaries **24/7 access** to an appropriate clinician with real-time access to the EOM participant's medical records
- Provide **patient navigation**, as appropriate, to EOM beneficiaries
- Document a **care plan** for each EOM beneficiary that contains the 13 components of the Institute of Medicine (IOM) Care Management Plan
- Treat beneficiaries with therapies in a manner consistent with nationally recognized **clinical guidelines**
- Identify EOM **beneficiary health-related social needs (HRSN)** using a health-related social needs screening tool
- Gradual implementation of **electronic Patient Reported Outcomes (ePROs)**
- Utilize data for **continuous quality improvement (CQI)**, including the development of a health equity plan
- Use **certified Electronic Health Records (EHR) Technology** (CEHRT)

Health Equity Strategy

- Incentivize care for underserved communities
- Collect beneficiary-level sociodemographic data
- Identify and address health-related social needs (HRSN)
- Improve shared decision-making and care planning
- Develop health equity plans, as part of continuous quality improvement (CQI)

ENHANCING ONCOLOGY

2

CMS Enhancing Oncology Model Summary

Enhancing Oncology Model
Model Overview and Benefits for Physician Group Practices

Increased Access to and Use of Data

Data Sharing

CMS will make various data available, upon request, to EOM participants, such as:

- **Quarterly** feedback reports and dashboards
- **Semiannual** reconciliation reports, attribution lists, and episode-level files
- As often as **Monthly** claims Data

Data Collection[2]

EOM participants will be required to submit data to CMS while in the model, such as:

Quality Measure Data

EOM quality measures will focus on domains such as management of symptoms toxicity and management of psychosocial health.

Clinical Data

CMS will require collection and reporting of clinical data elements that are not available in claims or captured in the quality measures.

Sociodemographic Data

Feedback reports will stratify aggregate de-identified data by sociodemographic variables. Examples of sociodemographic data CMS may require EOM participants to collect and report, if available, include but are not limited to: race, ethnicity, language preference, sexual orientation and gender identity.

For more detailed information on EOM data strategy, refer to the EOM Request for Applications (RFA) on EOM's website.

2 Quality measures, clinical and sociodemographic data elements for EOM will be released in Summer/Fall 2022.

ENHANCING ONCOLOGY MODEL

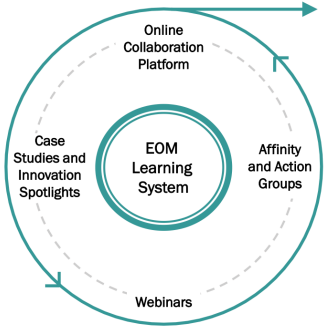
3

Enhancing Oncology Model
Model Overview and Benefits for Physician Group Practices

Supportive Environment for Care Transformation and Moving Forward in Value-Based Care

EOM Learning System

The EOM Learning System will **facilitate** the achievement of EOM's strategic goals, helping to **drive improvement in areas of cost and quality.** The Learning System is a structured approach to identifying, sharing, and spreading best practices and quality improvement strategies to support achieving the model aim.



The **EOM Learning System** will support participants in the achievement of the model's strategic goals through:

1. Leveraging CMS and EOM participant and payer data to identify **best practices and new knowledge**
2. Sharing and spreading best practices and new knowledge through **learning communities and networks**
3. Information and work will be shared through **three communication channels:**
   - From participant to participant
   - From CMS to participants
   - From participants to CMS
4. The EOM Learning System will be based on novel aspects of EOM and will also build upon pertinent learnings from OCM. It will include resources such as **online collaboration platform, case studies and innovation spotlights, peer-to-peer learning groups, and webinars**

Additional Information

EOM Website:
https://innovation.cms.gov/innovation-models/enhancing-oncology-model

Request for Applications:
https://innovation.cms.gov/media/document/eom-rfa
All EOM applications must be submitted by 11:59 pm Eastern Daylight Time on September 30, 2022

EOM Helpdesk
EOM@cms.hhs.gov
Phone: 1-888-734-6433 option 3

ENHANCING ONCOLOGY MODEL

4

Comparison of the OCM vs. EOM

Provision	Oncology Care Model	Enhancing Oncology Model
Medicare Beneficiary Population	Medicare beneficiaries with a cancer diagnosis who are receiving chemotherapy (including hormonal therapies)	Medicare beneficiaries with one of seven cancer types: breast, lung, lymphoma, multiple myeloma, small intestine/colorectal, prostate, and chronic leukemia receiving systemic chemotherapy (not including exclusively hormonal therapies)
Required Practice Redesign Activities	Six cross-cutting requirements providing for broad improvements in cancer care, including documenting a care plan that includes the 13 elements of the Institute of Medicine (IOM) Care Management Plan	Same as OCM with addition of two practice redesign activities: gradual implementation of electronic Patient Reported Outcomes (ePROs) and screening for “health-related social needs” (HRSNs) using an HRSN tool.
Data Sharing & Collection	No collection of sociodemographic data. CMS did not stratify data based on sociodemographic factors within feedback reports or reconciliation reports	Sociodemographic data required, if available, as a part of EOM health equity focus. CMS may share with EOM participants certain aggregated, de-identified data; for example, aggregate utilization data, stratified by sociodemographic metrics (e.g., dual status, LIS eligibility, and race and ethnicity).

Six Practice Redesign Activities + Two EOM Additions

1. Provide beneficiaries 24/7 access to an appropriate clinician with real-time access to the EOM participant's medical records.
2. Provide patient navigation, as appropriate, to EOM beneficiaries.
3. Document a care plan for each EOM beneficiary that contains the 13 components of the IOM Care Management Plan, as applicable to the EOM beneficiary.
4. Treat beneficiaries with therapies in a manner consistent with nationally recognized clinical guidelines.
5. Utilize data for continuous quality improvement (CQI).
6. Use Certified EHR Technology (CEHRT) as specified in 42 CFR § 414.1415(a).
7. *Identify EOM beneficiary health-related social needs using a HRSN tool.*
8. *Gradual implementation of electronic Patient Reported Outcomes (ePROs).*

Comparison of the OCM vs. EOM (continued)

Provision	Oncology Care Model	Enhancing Oncology Model
Per Beneficiary/Per Month (PBPM) Payment	Monthly Enhanced Oncology Services (MEOS) payment amount of $160 PBPM for each OCM beneficiary. The entire $160 is included as episode expenditures	MEOS payment amount of $70 PBPM but increased to $100 PBPM for dual-eligible beneficiaries dually of which $70 will be included as episode expenditures in reconciliation calculation
Drug Payment	No change from Medicare fee-for-service of ASP + 6% (ASP + 4.3% with sequester). Total cost of care responsibility that includes Part B drug payment and certain Part D expenditures	Same as the OCM
Attribution Methodology for MEOS and Performance-Based Payment	E&M claims with a cancer diagnosis on the service line during a six-month episode	Attribute to the eligible oncology provider with the first qualifying E&M service after initiating chemotherapy, provided that the provider has at least 25% of the cancer-related E&M services during the episode. If the initiating oncology provider does not bill at least 25% of cancer-related E&M services during the episode, then attribute based on plurality of cancer-related E&M services at an oncology PGP.

Comparison of the OCM vs. EOM (continued)

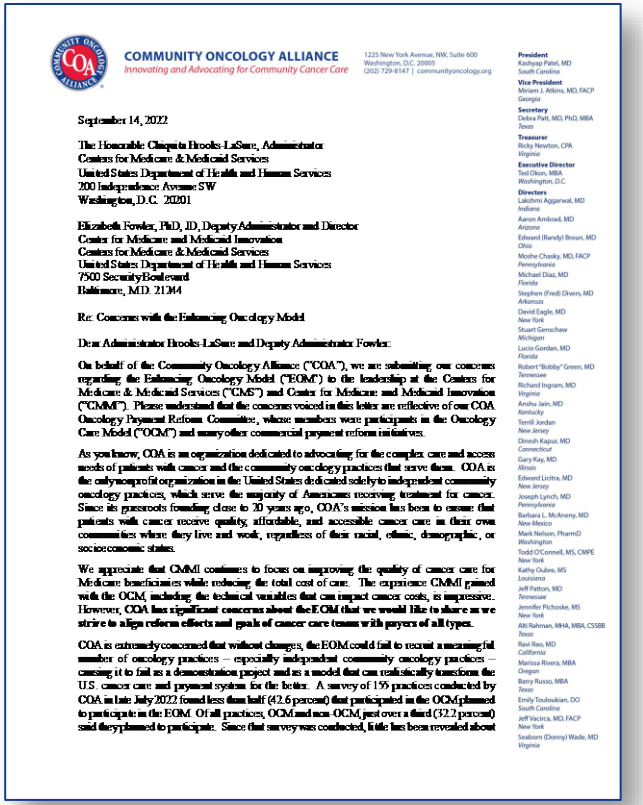
Provision	Oncology Care Model	Enhancing Oncology Model
Novel Therapies Adjustment for Performance-Based Payment	Calculated in aggregate across all cancer types	Calculated separately for each of the seven included cancer types
Risk Adjustment for Performance-Based Payment	All cancer types included in one price prediction model. Clinical data used in final five performance periods, where participating practice-reported metastatic status is included in risk adjustment	Included cancer type-specific price prediction models. A more robust use of EOM participant reported clinical and staging data in risk adjustment, to include metastatic status and HER2 status
Risk Arrangements for Performance-Based Payment	One-sided risk in performance period (PP) 1, followed by the option for one-sided or two-sided risk in PP2 to PP7. Participants earning a performance-based payment by the initial reconciliation of PP4 have the option to stay in one-sided risk from PP8 to PP11. Other participants must either accept two-sided risk in PP8 to PP11 or be terminated from the model.	Two mandatory downside risk arrangement options. Option 1 is less aggressive two-sided risk with minimal downside risk. Option 2 is more aggressive two-sided risk.

Comparison of the OCM vs. EOM (continued)

Provision	Oncology Care Model	Enhancing Oncology Model
Risk Arrangements for Performance-Based Payment (continued)	**Original Risk Arrangement** Discount: 2.7% of benchmark amount Stop-gain/stop-loss: 20% of benchmark amount **Alternative Risk Arrangement** Discount: 2.5% of benchmark amount Minimum threshold for recoupment: 2.5% of benchmark amount Stop-gain: 16% of total Part B revenue for the practice Stop-loss: 8% of total Part B revenue for the practice.	**Risk Arrangement 1 (RA1)** EOM discount: 4% of the benchmark amount Target amount: 96% of the benchmark amount Downside risk (stop-loss): 2% of the benchmark amount Upside risk (stop-gain): 4% of the benchmark amount **Risk Arrangement 2 (RA2)** EOM discount: 3% of the benchmark amount Target amount: 97% of the benchmark amount Downside risk (stop-loss): 6% of the benchmark amount Upside risk (stop-gain): 12% of the benchmark amount

EOM Problems: What COA is Doing

- Like the OCM, the EOM is too prescriptive
  - Government telling physicians how to practice
    - Worse yet, telling them they are not practicing correctly
- Requires practices to do more but will pay almost half as much in the OCM
  - Puts more onus on oncologists
  - Prohibits billing for Chronic Care Management Services
- CMS doesn't understand the use of ePROs
- Immediately mandating 2-sided risk
- Nearly impossible to qualify as an Alternative Payment Model (APM) because of the limitation to only 7 cancer types
  - Will mean MIPS reporting
- Benchmarks not available until after the model starts
- No indication that CMS has the ability to provide timely, understandable feedback



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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September 14, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Elizabeth Fowler, PhD, JD, Deputy Administrator and Director
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Concerns with the Enhancing Oncology Model

Dear Administrator Brooks-LaSure and Deputy Administrator Fowler:

On behalf of the Community Oncology Alliance ("COA"), we are submitting our concerns regarding the Enhancing Oncology Model ("EOM") to the leadership at the Centers for Medicare & Medicaid Services ("CMS") and Center for Medicare and Medicaid Innovation ("CMMI"). Please understand that the concerns voiced in this letter are reflective of our COA Oncology Payment Reform Committee, whose members were participants in the Oncology Care Model ("OCM") and many other commercial payment reform initiatives.

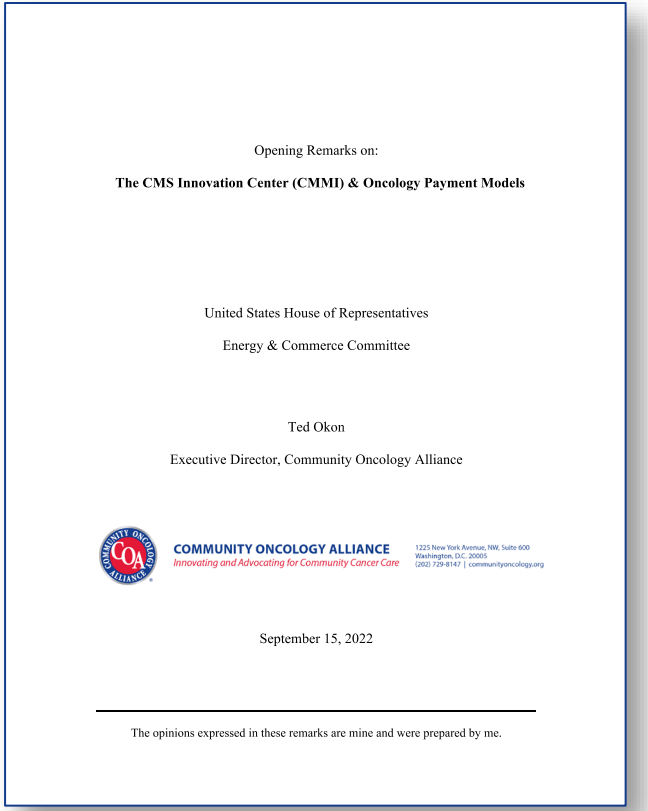
As you know, COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding close to 20 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

We appreciate that CMMI continues to focus on improving the quality of cancer care for Medicare beneficiaries while reducing the total cost of care. The experience CMMI gained with the OCM, including the technical variables that can impact cancer costs, is impressive. However, COA has significant concerns about the EOM that we would like to share as we strive to align reform efforts and goals of cancer care teams with payers of all types.

COA is extremely concerned that without changes, the EOM could fail to recruit a meaningful number of oncology practices – especially independent community oncology practices – causing it to fail as a demonstration project and as a model that can realistically transform the U.S. cancer care and payment system for the better. A survey of 155 practices conducted by COA in late July 2022 found less than half (42.6 percent) that participated in the OCM planned to participate in the EOM. Of all practices, OCM and non-OCM, just over a third (32.2 percent) said they planned to participate. Since that survey was conducted, little has been revealed about

Briefing Congress on the Oncology Model Debacle

- Briefed Republicans on the Energy & Commerce Committee on the oncology model "debacle"
- First oncology model was the COME HOME model
  - CMMI spent $19 million on a successful model
  - Model was over and put to rest
- Next up was the OCM
- While the OCM was going on CMMI tried three times to launch national models to end-run Congress on drug pricing reform
- Fall of 2019, CMMI released a concept paper on the Oncology First Model
  - Never heard another thing about it
- OCM was extended a year due to COVID
- EOM released in June 2022
- OCM ended at the end of June 2022
  - So, one year gap between the OCM end and the EOM start



Opening Remarks on:

The CMS Innovation Center (CMMI) & Oncology Payment Models

United States House of Representatives

Energy & Commerce Committee

Ted Okon

Executive Director, Community Oncology Alliance

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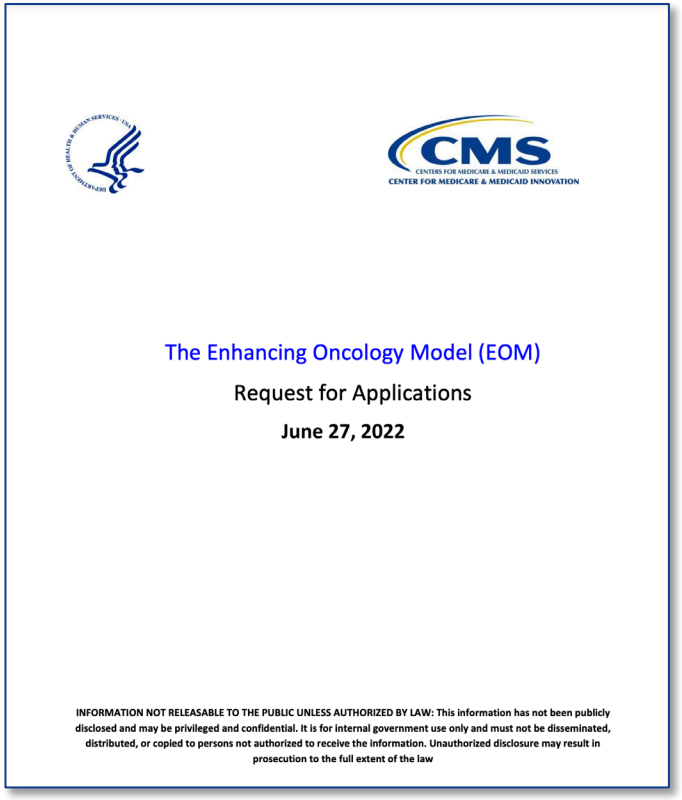
September 15, 2022

The opinions expressed in these remarks are mine and were prepared by me.

What You Need to Do if Interested in the EOM

- Go to the EOM website to fill out an application
  - https://innovation.cms.gov/media/document/eom-rfa
  - https://app.innovation.cms.gov/EOM/IDMLogin?ec=302&startURL=%2FEOM%2Fs%2F
  - Remember, it's non-binding
  - Do it tomorrow, if interested, because not easy and the clock is running out
  - CMMI listened to us and extended the application deadline till October 10th
- Join with other practices to share information
  - COA EOM cooperative group
    - Contact Bo Gamble at bgamble@COAcancer.org

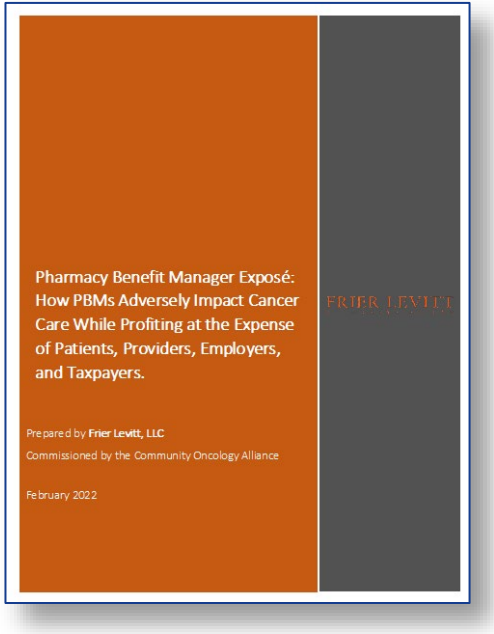


COA's Current Focus & Top Priorities

- PBMs, PBMs, PBMs
  - Working on the TRICARE issue as an immediate priority
  - DIR fees, DIR fees, DIR fees
    - Worked with Congress to hold a hearing/forum on PBMs
      - Talking to Congress about the next hearing/forum in 2023
    - Ongoing communications with CMS and the FTC
      - Submitted written comments to the FTC in May
    - Working on new legislation to stop sham DIR "quality" programs
  - Stopping "fail first" step therapy edits
    - Iron therapy most recent example with UnitedHealth Care
  - Major push to curb/stop prior authorizations
    - Working on "gold card" legislation
  - Stop white bagging initiatives
    - White bagging "legal" letter for practices
    - Working with payers, where possible

Focus & Priorities (continued)

- PBMs, PBMs, PBMs (continued)
  - Steering to PBM-affiliated pharmacies & delaying patients' oral drugs
    - "72-hour" bill
    - Congressional action
  - Major PBM whitepaper/exposé released by Frier Levitt for COA
- 340B reform
  - Discount "follows the patient" – *wherever the patient is treated* – to benefit patients in need, not hospital systems
  - Working closely with major media
  - Exploring legal options to stop CMS from increasing drug reimbursement to 340B hospitals
- Working with CMMI to make changes in the EOM
- Ramping up initiatives on health disparities



Thanks!

Ted Okon

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Twitter: @TedOkonCOA

PLEASE email me with any questions!