



TxSCO Update

July 13, 2023

Overview: Notable Updates

Federal

- EOM participants announced
- Site neutral payments
- 340B Proposed Rule
- Appendix
 - PBM reforms
 - Biden Administration's "Persistent Poverty Initiative" to Combat Cancer Inequities
 - Oncology drug shortages
 - EOM: additional context

State

- Special Session Update
- Update on Texas Abortion Ban



Federal Update

EOM Timeline

Oct. 10, 2022

 Applications due to CMMI (nonbinding)

May 19, 2023

- Practices received data
- "Data is out, but not what was expected to make decisions."

June 27, 2023

- CMMI announced 67 practices will participate
- Multiple reports of CMMI inaccuracy



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April 12, 2023

- Providers received agreements
- Raises new questions, as practices expected to use the data from CMMI to inform their decision
- Clarification that EOM practices can leave during EOM with (undefined) penalties
- Provider Insight: "There is some confusion over how this works; we've reached out to CMMI for clarity"

June 1, 2023

- Deadline: **Participant** agreement due to CMMI (list not public)
- Provider Insight: "We had been told the deadline would be July 1st, so this is unfortunate"

July 1, 2023

5-year model begins with mandatory 2-sided risk on Day

EOM Participating Practices Announced However, errors raised as practices counted multiple times and practices that withdrew are reflected on the list (AJMC, Link)

On June 27th, CMS announced information about practices who have committed to participating in the Enhancing Oncology Model (EOM) launching July 1, 2023.

Per CMMI, 67 practices will participate in EOM

- Participating practices span across 37 states, including 600 sites of care and 3,000 unique practitioners
- ~15% of participating practices are in rural/small town areas





Of important note, ~50% of practices that will participate in **EOM did not participate in the Oncology Care Model (OCM)**

New practices may have a steeper learning curve as they adjust to the mandatory two-sided risk model

"Not only has CMMI ignored all of COA's efforts to collaborate and suggestions to strengthen the EOM to attract participants, but it has also failed to respond to a serious flaw our analysts recently identified in the EOM methodology dealing with breast cancer treatment. This has left practices that want to participate in the EOM struggling with a decision that could be detrimental to patient care and possibly damaging to practice survival...The EOM should have been a successful oncology model attracting all participants from the prior CMMI OCM but instead unfortunately looks to be a failure from the start".



Southern Cancer Center	University of Alabama Health Services Foundation	Mercy Clinic Fort Smith Communities	Arizona Oncology Associates	HonorHealth Ambulatory	Compassionate Cancer Care Medical Group	PMK Medical Group	Sierra Hematology & Oncology, Medical Center	The Oncology Institute CA	The Oncology Institute FL
The Oncology Institute TX	Torrance Health Association	Rocky Mountain Cancer Centers	Starling Physicians	American Oncology Partners	Cancer Care Centers of Brevard Cancer Specialists		Cleveland Clinic - Martin Memorial Health Center	Cleveland Clinic Florida	Indian River Health Services
Mount Sinai Medical Center	Stuart Oncology Associates	Woodlands Medical Specialists	The Longstreet Clinic	Illinois Cancer Specialists	Appalachian Regional Healthcare	Sidney Kimmel Comprehensive Cancer Center	Cancer and Hematology Centers of Western Michigan	Trinity Health IHA Medical Group Hematology Oncology	Minnesota Oncology Hematology
Mercy Clinic Joplin	Bozeman Health Deaconess Hospital	Vidant Medical Group	Capital Health System, Inc Sole MB	Comprehensive Cancer and Hematology Specialists	Hackensack Meridian Health Medical Group Specialty Care	Noah Lindenberg PC	Regional Cancer Care Associates	Christus St. Vincent Hospital	New Mexico Oncology Hematology Consultants
Tri-County Hematology and Oncology Associates	TriHealth H	Oncology Associates of Oregon	Allegheny Clinical Medical Oncology	Alliance Cancer Specialists	Bryn Mawr Medical Specialists	Cancer Care Associates of York	MUSC Community Physicians	Prisma Health dba Prisma Health University Medical Group	Self Medical Group
University Medical Associates of the Medical University of South Carolina	Ballad Health	Tennessee Oncology	West Clinic	Oncology Hematology Consultants, PA dba The Center for Cancer and Blood Disorders	South Texas Hematology and Oncology	Texas Oncology	Oncology & Hematology Assoc. of Southwest Virginia	Shenandoah Oncology	Virginia Cancer Specialists
		Virginia (Assoc		of Vermont Northwe Specialist	Northwe	Edw st Medical Comprehen cialties Center@	sive Cancer		

Site Neutral Payment Update: House E&W Comm. Advance Bipartisan Healthcare Package



On July 12, 2023, the House Education and Workforce advanced transparency-related bills to the House floor

Bill	Topics Addressed	Bill Summary
H.R. 4509, Transparency in Billing Act	Transparency Site-Neutral Payment	 Prohibits group health plans from paying hospitals for items and services provided at an off-campus outpatient department unless the submitted claim includes a separate unique health identifier indicating the department where the services were furnished. Prohibits hospitals from submitting claims without a separate unique health identifier. HHS may issue penalties to hospitals for noncompliance: \$5,500/day for hospitals with more than 30 beds, \$300/day for hospitals with less than 30 beds.
H.R. 4527, Health DATA Act	Transparency	 Amends ERISA to ensure that plan fiduciaries can access de-identified claims, including information related to cost and quality. Applies to contracts with group health plans and other entities, such as PBMS. Requires fiduciaries of group health plans to annually submit attestations to the HHS Secretary.
H.R. 4508, Hidden Fee Disclosure Act	Transparency PBMs	 Requires PBMs to disclose fee and compensation information to plan sponsors, including: Fees, rebates, alternative discounts, co-payment offsets, and other remuneration Amount of fees, discounts, and price concessions expected to be passed on to the plan sponsor or beneficiaries Compensation received (1) as a result of paying less for a drug than patient cost-sharing, (2) due to spread pricing, (3) from drug manufacturers/ third parties in exchange for certain activities Requires to PBMs to submit annual reports to plan fiduciaries including above information and total drug spending, clawbacks.





On July 7, 2023, CMS released a Hospital OPPS Proposed Rule (340B Program) and an accompanying fact sheet (link).

Background

- •CMS responds to the Supreme Court's (June 15, 2022) ruling on American Hospital Association v. Becerra regarding 340B OPPS payment rates:
- •The reimbursement change for 340B drugs was unlawful because HHS failed to conduct a survey of hospitals' drug acquisition costs under the relevant statute
- •CMS Proposes:
- •A one-time lump sum remedy payment to affected 340B covered entity hospitals, inclusive of foregone beneficiary copayment amounts.
- •A corresponding offset for nondrug items and services, by decreasing the OPPS conversion factor to all OPPS providers except new providers by 0.5%..

Lump Sum Payments to Affected Providers for 340B-Acquired Drugs

- •Some CY2022 340B drug claims have already been reprocessed at ASP +6%, those providers have already received \$1.5 billion of the \$10.5 billion.
- •CMS proposes a one-time lump sum of the remaining \$9.0 billion to affected providers within 60 days of receipt of MAC instruction.

Beneficiary Copayments

- •The \$9.0 billion payment includes \$1.8 billion attributable to what the affected covered entities would have collected from beneficiaries, if the 340B payments were subject to beneficiary copayments.
- •CMS emphasizes that 340B covered entity hospitals may not bill beneficiaries for coinsurance on remedy payments, regardless of the adjustment.

Prospective Offset for Higher Payments for Non-Drug Items and Services from CY 2018-2022

- •CMS estimates that hospitals were paid \$7.8 billion more for these non-drug items and services between CY 2018-2022
- •To reduce future payments by decreasing the OPPS conversion factor to all OPPS providers except new providers by 0.5% starting in CY 2025, until the until full \$7.8 billion is offset

New Providers

- •To exclude providers that did not enroll in Medicare until after January 1, 2018, from the proposed prospective rate reduction.
- "New providers" did not fully benefit from the increased payment for non-drug items and services from CY 2018-2022
- Approximately 300 of the 3,900 OPPS providers will meet this definition
- •CMS is soliciting comments on its proposed definition of "new provider"

ADVI Source: ADVI Instant (link)

State Update



Special Session Update

- The legislature was called into an immediate special session after the regular session adjourned
- The goal was to address property tax relief which wasn't provided during the regular session
- After a first special session ended in failure the Governor called a second special session for the same purpose
- Earlier this week both chambers announced an agreement and that they would be working this week to pass the relief package.
- The \$18B package will accomplish the following:
 - Provide about \$0.10 in ISD M&O rate compression reducing tax rates across the state
 - Provide an increase in the residential homestead exemption from \$40k to \$100k
 - Establish a 20% pilot program for three years ensuring non-homestead residential properties and all commercial properties valued below \$5M will not be taxed on appraisal increases of more than 20%; the \$5M threshold will be indexed to inflation
 - Increase the franchise tax exemption from \$1M to \$2.47M
- The chambers are expected to send te package to the Governor's desk today and adjourn.
- Another special session is expected to be called upon completion of the Senate's Paxton trial to address school choice and other school finance-related issues



Update on Texas Abortion Ban

- In the most recent legislative session, Rep. Ann Johnson (D-Houston) and Sen. Bryan Hughes (R-Mineola) quietly passed House Bill 3058.
- HB 3058 provides a partial solution to the grey area surrounding situations when doctors can provide services to pregnant women who are experiencing life-threatening conditions.
- The bill provides legal protections for doctors in two situations:
 - Ectopic pregnancies, and
 - Premature rupture of membranes, or when a mother's water breaks early in the pregnancy



Appendix

2023 Federal Scrutiny of PBMs



Jan. - Feb.

March

April

May

June

- 1/31: Sens. Cantwell (D-WA) and Grassley (R-IA) reintroduced <u>S. 127</u>, "PBM Transparency Act"
- 1/31: Sen. Grassley (with Cantwell, others) introduced <u>S</u>. <u>113</u>, "Prescription Pricing for the People Act"
- 2/16: Senate Commerce hearing, "Bringing Transparency and Accountability to Pharmacy Benefit Managers"

- 3/1: House Oversight Comm. launched a PBM investigation
- Chairman Comer (R-KY) sent letters to <u>OPM</u>, <u>CMS</u>, and the <u>TRICARE</u> seeking "documents and communications to determine the extent PBMs' tactics impact healthcare programs administered by the federal government."
- 3/17: Rep. Carter (D-GA) introduced H.R. 317, "The Drug Price Transparency in Medicaid Act" to ban PBM spread pricing with Medicaid MCOs
- 3/30: Senate Finance hearing, "PBMs and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers"

- 4/13: Express Scripts

 announced new transparency efforts and
 "Copay Assurance Program"
- 4/20: Senate Finance
 Committee release <u>framework</u>
 for PBM legislation
- 4/26: House E&C Committee
 hearing, "Lowering
 Unaffordable Costs: Legislative
 Solutions to Increase
 Transparency and Competition
 in Health Care"
- 4/27: Rep. Spanberger (D-VA introduced <u>H.R. 2816</u>, "PBM Sunshine and Accountability Act" to increase reporting requirements for PBMs

- 5/10: Senate HELP hearing,

 "The Need to Make Insulin
 Affordable for All Americans"
- 5/11: Senate HELP <u>advanced</u> several PBM and Rx bills to Senate Floor
- 5/11: State Insurance
 Commissioners <u>seek</u> meeting with FTC on PBM investigation
- **5/17: FTC** widens its PBM investigation to include group purchasing organizations.
- 5/23: House Oversight
 Committee hearing, "The Role
 of Pharmacy Benefit Managers
 in Prescription Drug Markets
 Part I: Self-Interest or Health
 Care?"
- 5/24: House E&C Committee advanced PBM and Rx bills to House floor
- 5/25: House Oversight
 Committee Chair Comer (R-KY)
 states
 that he plans to work
 with E&C committee to pass
 PBM reforms
- 5/31: CVS executive states that company will find ways to

- 6/21: House Education and Workforce HELP Subcommittee hearing, "Competition and Transparency: The Pathway Forward for a Stronger Health Care Market"
- 6/22: Sens Menendez (D-NJ) and Lankford (R-OK) introduced S.2129, the "Ensuring Access to Lower-Cost Medicines for Seniors Act". While the bill applies to MA-PDs and PDPs, the sponsors frame the goal of the bill as combatting PBM practices.

PBM Reforms At-a-Glance: Pending Legislation Transparency efforts have highest likelihood for enactment

В	ill	Market	Prohibits Spread Pricing	Requires 100% Pass-Through of Rebates to Plans	Requires Disclosure to Plans	Requires Disclosure to HHS	Mandates Report/ Study	Prohibits Certain Clawbacks	Regulates PBM Fees (besides transparency)	Delinks PBM Compensation from Drug Prices/Rebates	Regulates Formulary Practices	Last Updated	Next Step	Likelihood of Enactment
Benefit	Pharmacy Manager rm Act	Commercial	x	Х	Х	Х	Х		х			June 22, 2023 Placed on Senate calendar	Senate Floor	Low
Manager T	macy Benefit ransparency act	All	X	X*	X*	Х	Х	X	X			March 22, 2023 Committee markup, APPROVED	Senate Floor	Low
Pricing for	escription the People act	NA					Х					March 1, 2023 Placed on Senate calendar	Senate Floor	High
	ate Finance posal	TBD	X**		X**	X**				X**		April 20, 2023 Framework released by committee	Release bill text	TBD
	H.R.2679, PBM Accountabi lity Act	Commercial			х	Х	Х					May 24, 2023 Committee markup, APPROVED	House Floor	High
H.R.3561	H.R.1613, Drug Price Transparen cy in Medicaid Act	Medicaid	X	X		X (upon request)	Х		X			May 24, 2023 Committee markup, APPROVED	House Floor	Moderate to Low

^{*}Excepts PBMs that pass through 100% of rebates to plans and disclose certain information.

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^{**}Senate Finance Framework only contains potential proposals, details of future legislation unclear.

PBM Reforms At-a-Glance: Pending Legislation Transparency efforts have highest likelihood for enactment

Bill	Market	Prohibits Spread Pricing	Requires 100% Pass-Through of Rebates to Plans	Requires Disclosure to Plans	Requires Disclosure to HHS	Mandates Report/ Study	Prohibits Certain Clawbacks	Regulates PBM Fees (besides transparency)	Delinks PBM Compensation from Drug Prices/Rebates	Regulates Formulary Practices	Last Updated	Next Step	Likelihood of Enactment
H.R.2816, PBM Sunshine and Accountability Act	Part D Individual Employer			Х	Х	X					April 25, 2023 Referred to E&C and W&M	Markup TBD	High
S.1967, Patients Before Middlemen Act	Part D							Х	X		June 14, 2023 Referred to Finance	Markup TBD	Moderate
S.2129, Ensuring Access to Lower-Cost Medicines for Seniors Act	Part D									X***	June 22, 2023 Referred to Finance	Markup TBD	Moderate
S, Medicare PBM Accountability Act	Part D			Х	Х	Х					July 12, 2023 Discussion Draft Released	Seeking Commen t	High
H.R.4508, Hidden Fee Disclosure Act	Employer			Х							July 12, 2023 Committee markup, APPROVED	House Floor	



Biden Administration Launches "Persistent Poverty Initiative" to Combat Cancer Inequities

On June 26, 2023, the Biden Administration announced \$50 million in awards as part of the new Persistent Poverty Initiative, which aims to address the structural and institutional factors of persistent poverty in the context of cancer.

Goals

- Coordinated by the National Cancer Institute (NCI), the Persistent Poverty Initiative aims to "alleviate the cumulative effects of persistent poverty on cancer outcomes" by:
 - Building research capacity
 - Fostering cancer prevention research
 - Promoting the implementation of community-based programs

Program Overview

- NCI awarded \$50 million to five new "Centers for Cancer Control Research in Persistent Poverty Areas"
- Each center is located in a "persistent poverty area", defined as an area where 20% or more of the population have lived below the poverty line for the last 30 years.

Each center will:

- Work with targeted low-income communities to implement and measure the effectiveness of structural interventions for cancer control and prevention, follow-up care, and survivorship.
- Conduct research in areas such as reducing obesity, improving nutrition, increasing physical activity, helping people quit smoking, and improving living conditions through supplemental income.
- Train a pipeline of early-career investigators to work with underserved communities.

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Source: NIH (6/26/23, link)

Biden Administration Launches "Persistent Poverty Initiative" to Combat Cancer Inequities

Center	Leading Organization	Populations the Center will Work With		Functions
Acres Homes Cancer Prevention Collaboration	University of Texas MD Anderson Cancer Center, Houston	Black/African American and Hispanic communities in northwest Houston	•	Evaluate interventions in nutrition and physical activity to help prevent obesity and obesity-related cancer
The Center for Cancer Control in Persistent Poverty Areas	University of Alabama at Birmingham	Black/African American communities in Jefferson County, Alabama	•	Evaluate interventions aimed at reducing cancer disparities by improving living environments and promoting healthy activities. Test diet and exercise interventions for cancer survivors.
The Upstream Center	Stanford University, Palo Alto	Hispanic and Asian American communities in Santa Clara and Yolo Counties in northern California	•	Assess how state programs for guaranteed basic income affect cancer outcomes. Test whether the earned income tax credit promotes the adoption of healthy behaviors related to reducing colorectal cancer risk.
The Center for Social Capital	Weill Cornell Medicine and Columbia University, New York City	Black/African American, Caribbean American, and Hispanic communities in the South Bronx, north- central Brooklyn, Washington Heights, and Western Queens in New York City	•	Test the effectiveness of cancer education and tobacco cessation programs in promoting multigenerational health.
HOPE & CAIRHE 2gether	University of Utah, Salt Lake City	Hispanic communities in Utah and American Indian communities in rural areas of Montana, Oregon, South Dakota, and Wisconsin	•	Test interventions for commercial tobacco cessation and obesity prevention.

Source: NIH (6/26/23, <u>link</u>)

Oncology Drug Shortages: Recent FDA and Congressional Activity

June 2

FDA <u>announced</u> that it will allow temporary importation of cisplatin from China-based Qilu Pharmaceuticals, which is not currently approved to distribute in the US

FDA will also allow Intas
 Pharmaceuticals to
 resume distribution
 under a strict verification
 process.

FDA Authority

- Throughout the shortages, FDA has also asked Congress for additional authority to require:
- Manufacturers to report increases in demand
- Companies include the original manufacturer of a product's active pharmaceutical ingredient on its label

June 6 June 12

- In a <u>statement</u>, Ranking Member Pallone (D-NJ) noted that his disappointment that E&C Republicans have not included Democratic bills focused on alleviating shortages in the Pandemic and All-Hazards Preparedness (PAHPA) Act reauthorization. These include:
- H.R. 3008, Drug Shortage Prevention Act of 2023
- H.R. 2500, Protecting Americans from Unsafe Drugs Act of 2023
- H.R. 3810, Drug Origin
 Transparency Act of 2023
- H.R. 3793, Ensuring Access to Lifesaving Drugs Act of 2023
- H.R. 3807, Medical Device Shortage Reduction Act of 2023

June 15

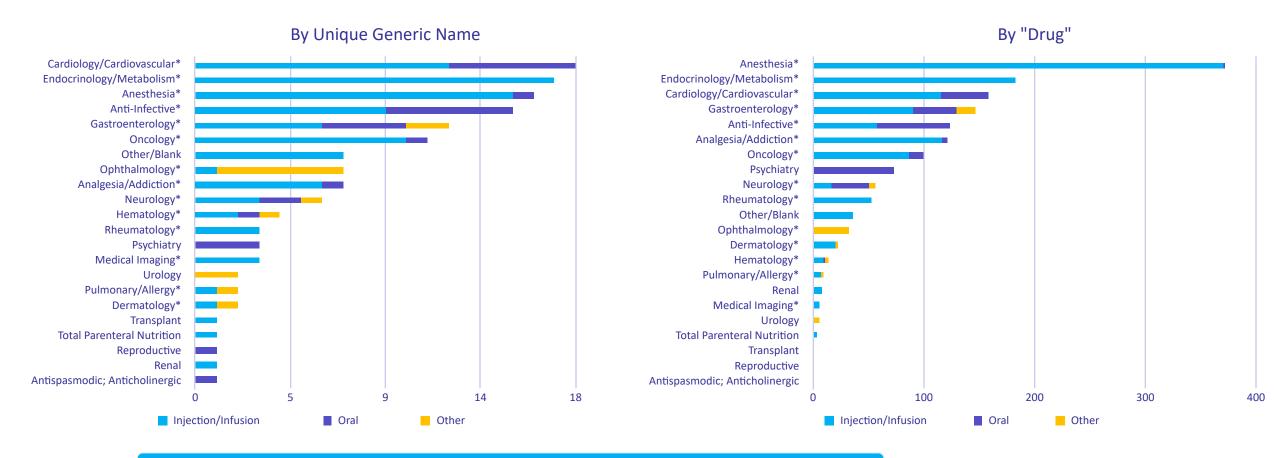
 Republican leadership issued a <u>request for</u> <u>information</u> from all stakeholders on the shortages and potential solutions.

- Sens. Peters (D-MI) and Ernst (R-IA) introduce S.1961, the Pharmaceutical Supply Chain Risk Assessment Act
- The bill would require HHS, DoD, DHS, and the White House Office of Pandemic Preparedness and Response to conduct a risk assessment of the pharmaceutical supply chain to determine how potential shortages can impact national security and broader public health

June 26

- Ranking Member Pallone
 (D-NJ) issues another
 statement pushing E&C
 Republicans to include
 bills addressing drug
 shortages in PAHPA,
 calling it the "only
 realistic pathway for
 Congress to swiftly
 address drug shortages."
- E&C Chair Rep. McMorris Rodgers (R-WA) has said she intends for the committee to address drug shortages outside of PAHPA.

Current Drug Shortages by Therapeutic Area



Takeaways

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- •Confirms claims that drug shortages are less of a problem for oral/small molecule drugs, as they account for a little less than 20% of current shortages
- In oncology, oral drugs account for closer to 10% of current shortages

Current Oncology Drug Shortages

- Capecitabine Tablets
- Amifostine Injection
- Azacitidine for Injection
- Carboplatin Injection
- Cisplatin Injection
- Cytarabine Injection
- Dacarbazine Injection
- Fludarabine Phosphate Injection
- Leucovorin Calcium Injection
- Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection
- Streptozocin (Zanosar) Sterile Powder

- Capecitabine tablets
- Amifostine injection
- Azacitidine injection
- Carboplatin injection
- Cisplatin injection
- Cytarabine injection
- Dacarbazine injection
- Fludarabine phosphate injection
- Leucovorin calcium lyophilized powder for injection
- Lutetium Lu 177 vipivotide tetraxetan (Pluvicto) injection
- Streptozocin (Zanosar) sterile powder
- Dexamethasone sodium phosphate injection
- Hydrocortisone sodium succinate injection
- Methotrexate injection
- Pentostatin injection



The ACS list includes four additional drugs in shortage (all injectable) The ACS list appears to be based on ASHP shortage

- The ACS list appears to be based on ASHP shortage list, which as different parameters than that of the FDA
- Differences on the FDA v.
 ASHP shortage parameters
 are detailed on the ASHP
 website (link)

Additional Resources

- NCCN recently surveyed their members on the impact of shortages
 - NCCN Statement
 - NCCN Survey Results

■ Injection/Infusion ■ Oral ■ Other

EOM Participation

EOM Participating Practices Announced – Updated July 12th

On June 27th, CMS announced information about practices who have committed to participating in the Enhancing Oncology Model (EOM) launching July 1, 2023 After the initial participant list was released, many practices commented publicly that they were no longer participating. CMS released an updated list on July 12th.

44 practices will participate in EOM

- Participating practices span across 26 states
- The original list of practices had:
 - 67 practices (-34%)
 - 37 states (-30%)

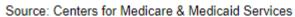




Of important note, ~34% of practices that will participate in EOM did not participate in the Oncology Care Model (OCM)

New practices may have a steeper learning curve as they adjust to the mandatory two-sided risk model





Practices who participated in the Oncology Care Model

University	of A	labama
OTHIVEISIC		abaiia

Arizona Oncology Associates

HonorHealth Ambulatory

PMK Medical Group

Sierra Hematology & Oncology Medical Center

Rocky Mountain Cancer Centers

Starling Physicians

American Oncology Partners

Cancer Specialists

Longstreet Clinic

Illinois Cancer Specialists

Cancer and Hematology Centers of Western Michigan

Comprehensive Cancer and Hematology Specialists

Regional Cancer Care Associates

Christus St. Vincent Hospital

Oncology Associates of Oregon

Bryn Mawr Medical Specialists

Prisma Health University Medical Group

Tennessee Oncology
West Clinic

Texas Oncology

Oncology & Hematology Associates of Southwest Virginia

Shenandoah Oncology

Virginia Cancer Specialists

Virginia Oncology Associates

Northwest Cancer Specialists/Compass
Oncology

Northwest Medical Specialists

Edwards Comprehensive Cancer Center

Practices who DID NOT participate in the Oncology Care Model

Mercy Clinic Fort Smith Communities

The Oncology Institute CA

The Oncology Institute FL

The Oncology Institute TX

Torrance Health Association

University Medical Associates of the Medical University of South Carolina

Appalachian Regional Healthcare

Trinity Health IHA Medical Group
HemOnc

Minnesota Oncology Hematology

Mercy Clinic Joplin

Bozeman Health Deaconess Hospital

Vidant Medical Group

Capital Health System

Tri-County Hematology and Oncology
Associates

MUSC Community Physicians

Self Medical Group

US Oncology Practices in EOM

Arizona Oncology Associates

Rocky Mountain Cancer Centers

Illinois Cancer Specialists

Regional Cancer Care Associates

Texas Oncology

Shenandoah Oncology

Virginia Cancer Specialists

Virginia Oncology Associates

Minnesota Oncology Hematology

Northwest Cancer Specialists/Compass Oncology

Note: All 10 US Oncology practices participated in OCM

OneOncology Practices in EOM

Cancer and Hematology Centers of Western Michigan

Tennessee Oncology

West Clinic

Note: All 3 OneOncology practices participated in OCM



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