



ADVI

# TxSCO Update

April 13, 2023



# Overview: Notable Updates

## Federal

- EOM
  - July 1<sup>st</sup> Start Date Looms
- Bill introduced tying Physician Payment to Inflation
- PBMs
  - Latest Hearings, Bill Introductions
- Appendix
  - Site Neutrality Scrutiny
  - National Cancer Plan

## State

- Update on Clinician Administered Drug Legislation
- Update on Biomarker Testing Legislation
- Other Priority Bills

# Federal Update

# Current Status: What We Do and Don't Know

## What We Know

- Non-binding nature drove applicants, but ultimately may not participate on July 1
- Two-sided risk deterred applicants, especially non-OCM participants
- **Heard at COA (3/23-24):** Providers expressed concern with nearing launch on July 1 absent info from CMMI – running out of time to staff up
  - Hopeful for EOM delay or easing of 1-sided risk for first performance period
  - While able to bill care management codes for additional payment to supplement lower MEOS, EOM practices hesitant due documentation requirements and patient coinsurance obligation
  - ePRO requirements are concerning
    - Must determine which staff role is accountable
    - Expectation to further fuel staff burnout
    - Practices may leave EOM when ePROs required (although penalty for exit not defined yet)

## What We Don't Know

- Full list of practices that applied via RFA to CMMI, although several have issued press releases or otherwise shared that they've applied
- Practices are still waiting for target prices from CMMI, so cannot fully assess whether they'll participate on July 1
- Model design doesn't include a clear off-ramp, unlike OCM
- Whether oncologist CMMI engagement efforts have been successful in driving further change
  - Oncologists still 'hopeful'

# Recent Provider Reaction to EOM



March 13-24, 2023: Providers voiced the following reactions at COA's Annual Meeting and the [ACCC Annual Meeting](#) and Cancer Center Business Summit

"Darn near every practice that I've talked to at least doesn't know what they are going to do with EOM and it's March. This model starts in July"

"We've been reliant on retrospective data on our own from OCM, which I think gets us in the ballpark, but I don't think many practices know just yet exactly which risk track makes sense for them,"

"Even though it (the Monthly Enhanced Oncology Services (MEOS) payments) shows being \$70 versus \$160, which is may be 45ish percent, when you take the reduced opportunities as far as the number of patients, it's even less"

-Jeff Hunnicutt, CEO of Highlands Oncology Group, Northwest Arkansas

"We typically had about 700 OCM patients at any given month. Given the reduction to seven disease sites, we are currently looking at about 250 patients per month so now we're adding risk across a much smaller population"

-Barry Russo, CEO, Center for Cancer and Blood Disorders in Fort Worth, TX

"I think for us a large consideration is what we stand to gain compared to what we're already doing"

-Anne Marie Rainey, MSN, RN, CHC, compliance and quality control officer with Clearview Cancer Institute in Huntsville, AL

"...even now with the EOM, there's almost a step backwards. They're cutting out some of the episodes... It only applies to half of the patients, now what do we do with the other half of the patients? It's kind of maybe a slight step backwards in the spirit that we hopefully move forward.

With the EOM, we've been looking at our performance data in the OCM, we've been able to break it down to translate that data into the selected episodes of the EOM. But now that MEOS payments and the number of lives affected by this is less. That means less revenue coming in to support the program. We could live with that, but then the risk bands are changing....

We haven't made a firm decision yet as a group. I believe we will participate in the EOM, but there's going to be some doctors that are nervous about it, because the prospects for risk and some of the underwriting financial support that we had in the OCM is now diminished and we face some added chance that we could slip up and have a bad six months, and then the model isn't as favorable to us on an overall basis as the OCM was."

-Glenn Balasky, executive director of Rocky Mountain Cancer Centers

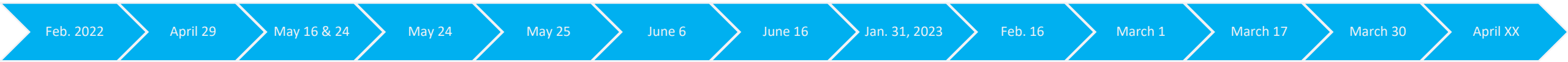
# Bipartisan House Bill Aims to Tie Physician Payment Rates to Inflation

## H.R. 2474, Strengthening Medicare for Patients and Providers Act

- April 3, 2023: Introduced by Rep. Ruiz, MD (D-CA)
- Bill aims to address concerns that Medicare payments to physicians have not kept pace with inflation
- The bill would transition to a single conversion factor equal to the percentage increase in the Medicare Economic Index, which is the impact of inflation on physician office costs and wage levels

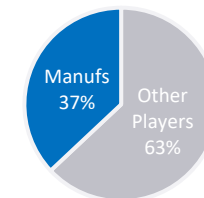
The American Medical Association (AMA) found that after adjusting for inflation in practice costs, Medicare payments to physicians have **declined 26%** from 2001 - 2023.

# Federal Scrutiny of PBMs



- 2/17: **FTC vote** on whether to launch a PBM study failed
- 2/24: **FTC RFI announced** an on PBM practices, comment period ends May 25
- CMS Part D Final Rule for 2023** requires all pharmacy price concessions be included in the definition of “negotiated price” (at the point of sale) beginning 2024
- Member letters to the FTC calling for a 6(b) study into PBM practices
- May 16: **Sens. Grassley (R-IA), Braun (R-IN) and Wyden (D-OR) letter**
- May 24: **Reps. Carter (R-GA) and Harshbarger (R-TN)**, both pharmacists, [letter](#)
- FTC transparency provisions
- Sens. Cantwell (D-WA) and Grassley (R-IA)** introduced [S. 4293](#), “PBM Transparency Act”
- PBM option of either:
  - Not engaging in pharmacy spread pricing or claw backs, or
  - Passing through 100% of rebates and concessions to the plan, and sharing cost data with the plan, as well as aggregate data on manuf rebates with the plan and any requesting federal agency
- FTC RFI comment period closed, 500+ stakeholders submitted including [105 Patient Groups](#) “to use all the power within its purview to help alleviate these harmful policies and practices that make access to prescription drugs out of reach for patients”
- FTC voted 5-0 to issue Section 6(b) orders and study PBM practices**
- Will “scrutinize the impact of vertically integrated PBMs on the access and affordability of prescription drugs.”
- Sent compulsory orders to CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc. Inc.
- FTC** issued an [enforcement policy statement](#) that targets rebates and fees which can prohibit competitors from targeting lower-cost drug alternatives
- FTC Chair Lina Khan: “Today’s action should put the entire prescription drug industry on notice: when we see illegal rebate practices that foreclose competition and raise prescription drug costs for families, we won’t hesitate to bring out full authorities to bear.”
- Sens. Cantwell (D-WA) and Grassley (R-IA)** re-introduced [S. 127](#), “PBM Transparency Act” to prohibit spread pricing and reduced reimbursement to offset Part D/Medicaid changes, and would authorize the FTC and states to enforce various mandates
- Sen. Grassley (with Cantwell, others)** introduced [S. 113](#), “Prescription Pricing for the People Act” directing the FTC to issue a report on PBMs within one-year
- Senate Commerce hearing, “Bringing Transparency and Accountability to Pharmacy Benefit Managers”**
- House Oversight Comm.** launched a [PBM investigation](#)
- Chairman Comer (R-KY) also sent letters to the [OPM](#), the [CMS](#), and the [TRICARE](#) seeking “documents and communications to determine the extent PBMs’ tactics impact healthcare programs administered by the federal government.”
- Rep. Carter (D-GA)** introduced [H.R. 317](#), “The Drug Price Transparency in Medicaid Act” to ban PBM spread pricing with Medicaid MCOs
- Senate Finance hearing**, “PBMs and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers”
- Senate HELP markup** of [yet-to-be-seen bill](#) that is expected to include PBM policy reforms was scheduled for April 19<sup>th</sup>; now postponed

Total Drug Spending: Where does the money go?



## Latest Data

- April 2021: The 3 largest PBMs – CVS Caremark, Express Scripts, OptumRx – enjoy roughly [80% market share](#)
- Jan. 2022: [Manufacturers retain 37%](#) of total spending on all drugs (branded and generic) and 49.5% for branded drugs
- Jan. 2022: [Net prices dropped](#) for branded drugs each year from 2018 through 2021
- March 2022: GTN bubble reached [\\$204B in 2021](#)
- March 2022: The 5 largest PBMs (CVS Caremark, Express Scripts, OptumRx, Humana, and Anthem’s IngenioRx) handled [\\$422B in gross drug revenues in 2021](#), with 90% of those revenues going to the 3 largest PBMs
- May 2022: The three largest PBMs [excluded 1,156 drugs](#) from their 2022 formularies, a 1,000% increase from 2014, with branded drugs without generic or biosimilar competition accounting for 47% of total exclusions

# Senate Finance Hearing: Impact of PBMs on Patients and Taxpayers

March 30, 2023: Senate Committee on Finance held a hearing ([link](#)) titled, “Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers.”

## Witnesses

• **Robin Feldman, JD**,  
University of California



• **Karen Van Nuys, Ph.D.**,  
Executive Director, Leonard  
D. Schaeffer Center for  
Health Policy, USC



• **Lawton Robert Burns, Ph.D.**,  
University of Pennsylvania



• **Matthew Gibbs, Pharm. D.**,  
President, Capital Rx



• **Jonathan E Levitt, JD**,  
Founding Partner, Frier  
Levitt Attorneys at Law



## PBM Impact

- Sen. Crapo (R-ID) noted that PBMs have played an important role in creating and protecting high-quality coverage options for seniors through Medicare Part D.
- Dr. Van Nuys (USC) discussed how PBMs provide important services to drug companies, insurers, employers, and patients, but their position in the middle of nearly every financial transaction allows them to suppress competition.
- Dr. Burns (UPenn) suggests that PBMs serve the interests of health plans and sponsors who utilize them, and they exert leverage over manufacturers to extract price concessions. He also notes that PBM business models have been changing over the last 5-10 years, and they no longer rely on rebates as much as they used to.

## Transparency

- Sen. Crapo (R-ID) acknowledged that the drug supply chain is often unclear and opaque, and that policymakers need more line of sight into drug pricing relationships and transactions, especially as they look to pursue reforms in the future.
- Dr. Van Nuys (USC) noted how the lack of transparency allows PBMs to raise drug costs and suppress competition, leading to outcomes where patients pay copays exceeding the cost of the drug on one in four prescriptions and plans paying on average 31% markups for generic scripts.

## Consolidation

- Mr. Levitt (Frier Levitt) stated that the six largest PBMs control 96% of the nation's prescription drug market and adversely impact all stakeholders in the drug supply chain, including patients, pharmacies, plan sponsors, and taxpayers.
- Dr. Gibbs (Capital Rx) remarked that PBMs have become consolidated and focus on rebate payments, which have created “a complex web of rebate payment definitions” that are difficult for employers and government entities to track.
- Dr. Van Nuys (USC) stated that with the top three PBMs handling 80% of all US prescription volume, this makes them more formidable when negotiating with drug manufacturers.
- Dr. Burns (UPenn) noted that consolidation is happening across healthcare. He mentioned that while there has been some consolidation in the PBM industry, it is still a competitive market.

## Biosimilars

- Sen. Crapo (R-ID) stated that misaligned incentives have constrained biosimilar uptake in Part D, driving manufacturers to launch products at multiple different price points, with PBMs sometimes preferencing the option with the higher sticker price.
- Dr. Feldman (UC) mentioned that biosimilars have the potential to lower drug prices and increase competition, but the current system makes it difficult for them to enter the market due to high costs and anti-competitive tactics by pharmaceutical companies and PBMs.

## Drug Pricing

- Sen. Wyden (D-OR) expressed concern that PBMs charge administrative fees to drug makers calculated as a percentage of a drug's list price, which creates perverse incentives that favor higher cost drugs.
- Dr. Feldman (UC) stated that while PBMs claim help health plans negotiate with drug companies for better prices, instead of prices coming down, the prices of many drugs have increased dramatically.
- Mr. Levitt (Frier Levitt) stated that growing gap between the list price of drugs and the actual net price is due to rebates that PBMs extract from manufacturers for preferential formulary placement.
- Dr. Burns (UPenn) argued that multiple factors, such as competition, transparency, and regulation, need to be addressed to effectively reduce prices.



# State Update

# Update on Clinician Administered Drugs Legislation

- House Bill 1647 by Rep. Cody Harris was heard in the House Insurance Committee on 3/28.
- As filed, the bill would prohibit health plans from requiring white-bagging clinician administered drug for a patient with a chronic, complex, rare, or life-threatening medical condition.
- As a result of negotiations with the bill author and the health plans, the following changes were made to a committee substitute that was voted out of committee on 4/4. The changes are as follows:
  - Limits to only those clinician administered drugs provided in a physician's office; hospital outpatient infusion centers and other clinician settings have been removed.
  - New language ensures that the prohibition on white bagging applies only if:
    - the patient's physician or health care provider determines that a delay of care would make disease progression probable; or
    - that the use of a health-plan required pharmacy would make death or patient harm probable, potentially cause a barrier to the patient's adherence to or compliance with the patient's plan of care; or timeliness of delivery concerns.

# Update on Biomarker Testing Legislation

- Senate Bill 989 by Sen. Joan Huffman was heard in the Senate Health and Human Services Committee on 3/29.
- The bill also establishes guidelines for health plans on coverage of biomarker testing, which is:
  - When the test is supported by medical and scientific evidence;
  - When the test provides clinical utility, which means the use of the test for the condition is evidence-based, scientifically valid, outcome-focused, and predominately addresses the acute issue for which the test is being ordered.
- The bill was voted out of committee on 4/3 and could be set for consideration by the full Senate this week

# Other Priority Bills

- House Bill 1, the state budget, includes two provisions:
  - \$10M for the Texas Colorectal Cancer Initiative, which would fund the treatment of colorectal cancer for uninsured and underinsured Texas residents with household incomes at or below 200 percent of the federal poverty level.
  - An increase in the income eligibility threshold for the Breast and Cervical Cancer Services program to 250 percent of the federal poverty level.
- House Bill 12 by Rep. Toni Rose, would provide 12 months of coverage for women post pregnancy. This bill is currently in House Calendars awaiting a day to be set for full debate.
- HB 173 by Rep. Stephanie Klick, which would provide for the licensing and regulation of genetic counselors, is also in House Calendars awaiting a day to be set for full debate.
- HB 389 by Rep. Nicole Collier and HB 1649 by Rep. Angie Chen Button, which would provide health benefit coverage for certain fertility preservation services, were both heard in the House Insurance committee on 4/4.
- HB 1283 by Rep. Oliverson, which relates to maintaining a single drug formulary under Medicaid, was heard in the House Select Committee on Health Care Reform on 4/6.

# APPENDIX

# Site Neutrality Scrutiny

## Moving to Site Neutrality in Commercial Insurance Payments

FEB 14, 2023 | HEALTH CARE



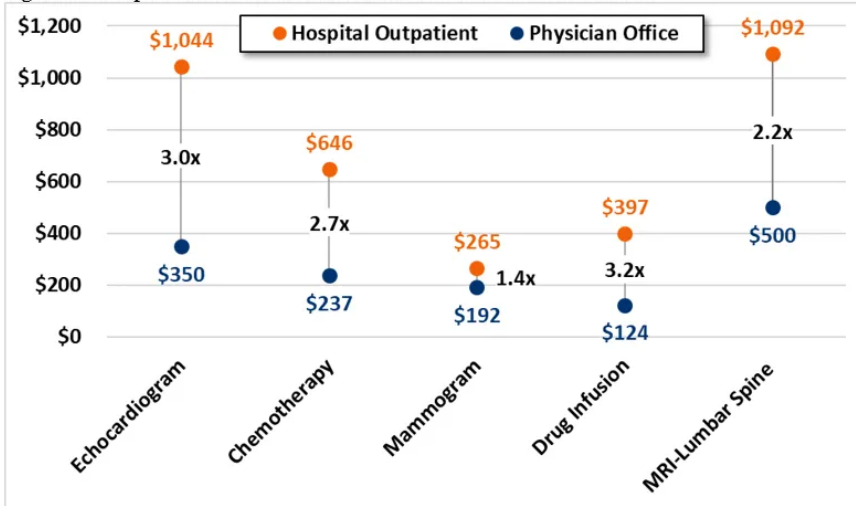
Committee for a Responsible Federal Budget

Over the next decade (2024-2033), policies that encourage site-neutral payments in the commercial insurance market could:

- Reduce total national health expenditures by \$458 billion
- Reduce commercial premiums by \$386 billion and patient cost sharing by \$73 billion
- Reduce the federal budget deficit by \$117 billion

These policies would also reduce incentives that drive consolidation and limit facility fee bills for patients.

Figure 1: Examples of Median Price Differentials Based on Site-of-Service



Source: Health Savers Initiative analysis of large- and small-group commercial claims data from 2019.  
 CPTs: Echocardiogram-Transthoracic; Chemotherapy Infusion-1 hr.; Mammogram-Bilateral Screening; IV Infusion-Single or First Drug; MRI-Lumbar Spine w/o Contrast.

## Time for Action To Reverse Hospital Consolidation

Jan 3, 2023 | 4 min read



Robert E. Moffit, Ph.D.

Senior Research Fellow, Center for Health and Welfare Policy  
 Moffit specializes in health care and entitlement programs, especially Medicare.

Second, Congress can make Medicare payment for medical services "site neutral." Today, Medicare routinely pays medical professionals more if a service is delivered in a hospital rather than a clinic or doctor's office. By paying the same for the same service, regardless of where it is delivered, Heritage Foundation analysts estimate a 10-year taxpayer savings of \$63.2 billion.

Because Medicare is the nation's largest health care payer, "site neutrality" payment would have a positive spillover effect in the private markets, intensifying provider competition and lowering patient costs. The policy has bipartisan potential. It is endorsed by liberal Brookings Institution scholars and conservative Health Policy Consensus Group and embodied in Transparency of Hospital Billing Act, also proposed by Rep. Spartz.

# Increasing Congressional Interest in Site Neutral Payments



*“Payment policies supporting higher reimbursement in the HOPD setting have led to a significant shift in the delivery of certain services from independent physician practices to the HOPD, and increased costs for patients, employers, and taxpayers. The Alliance has long supported reforms that would ensure Medicare reimburses—and beneficiaries pay—the same amount for the same service, regardless of the setting in which it was provided,”*

Statement in Support of House E&C Health Subcommittee Hearing on  
Transparency and Competition on March 28

# National Cancer Plan



# National Cancer Plan Overview

- On April 3, 2023, the Biden Administration released the National Cancer Plan establishing a roadmap to advance the National Cancer Program stemming from the National Cancer Act of 1971
- Goals for the National Cancer Plan are intended to:
  - Prevent Cancer
  - Reduce Mortality
  - Maximize Quality of Life for People Living with Cancer

## National Cancer Plan Goals

1. Prevent Cancer
2. Detect Cancers Early
3. Develop Effective Treatments
4. Eliminate Inequities
5. Deliver Optimal Care
6. Engage Every Person
7. Maximize Data Utility
8. Optimize the Workforce

## Goals 1 & 2

### Prevent Cancer

- All people and society adopt proven strategies that reduce the risk of cancer
- **STRATEGIES**
  - Understand cancer etiology and its relationship to genetic, behavioral, environment and SDOH
  - Pursue new cancer vaccines
  - Focus on cancer prevention clinical trials
  - Develop, test and evaluate interventions that promote cancer risk reducing behaviors
  - Prevent additional cancer among survivors
  - Develop and implement methods to eliminate tobacco exposure
  - Address obesity epidemic, esp in children

### Detect Cancer Early

- Cancers are detected and treated at early stages, enabling more effective treatment and reducing morbidity and mortality
- **STRATEGIES**
  - Develop new methods to detect cancers
  - Develop novel imaging technologies
  - Develop methods to identify pre-cancerous cells and eliminate them
  - Clinical trials to evaluate benefits and harms of novel cancer detection tests
  - Research partnerships to improve testing and adoption of effective cancer screening
  - Research to identify and overcome barriers to the treatment of early-stage cancers in communities with disparities, including financial toxicity and policies that limit effective system-level and community-sourced patient navigation services

# Goals 3 & 4

## Develop Effective Treatments

- Effective treatment, with minimal side effects, is accessible to all people with all cancers, including those with rare cancers, metastatic cancers, and treatment-resistant disease
- **STRATEGIES**
  - Pursue a greater understanding of the fundamental mechanisms of cancer biology with novel methods of visualizing and predicting tumor evolution
  - Use resources to identify biologically informed therapeutic targets
  - Focus on treating rare cancers, treatment resistant tumors and pediatric cancers
  - Expedite the timeline for new therapies from discovery to clinical trials
  - Collect population wide data on cancer recurrence and metastatic development linking characteristics to outcomes
  - Treatment prediction methods for response and LT outcomes

## Eliminate Inequities

- Disparities in cancer risk factors, incidence, treatment side effects, and mortality are eliminated through equitable access to prevention, screening, treatment, and survivorship care
- **STRATEGIES**
  - Study causes of disparities in cancer incidence and mortality
  - Pragmatic trial designs to overcome inequities that prevent successful outcomes in underserved populations
  - Ensure that all areas of cancer research address population-specific diversity in biological and societal factors that impede successful cancer diagnosis, prevention, treatment, and survivorship
  - Enhance cancer education to promote prevention and early detection
  - Develop culturally relevant education programs that increase community wellness
  - Increase representation of all populations in cancer research to ensure that everyone benefits from research and advancements

## Goals 5 & 6

### Deliver Optimal Care

- The health care system delivers to all people evidence-based, patient-centered care that prioritizes prevention, reduces cancer morbidity and mortality, and improves the lives of cancer survivors, including people living with cancer
- **STRATEGIES**
  - Advance research to inform improvements in cancer prevention, diagnosis, treatment and survivorship
  - Increase communication and collaboration between NCI and private orgs to maximize resources that facilitate cancer research
  - Promote cancer research results to decrease cancer mortality and improve survivor well-being
  - Identify and institute best practices for engagement, communication and health literacy in cancer risk, prevention, treatment and survivorship

### Engage Every Person

- Every person with cancer or at risk for cancer has an opportunity to participate in research or otherwise contribute to the collective knowledge base, and barriers to their participation are eliminated
- **STRATEGIES**
  - Enable every patient to contribute their health data and biospecimens to research for cancer research
  - Expand research infrastructure for studies to increase access to participation for all
  - Facilitate rapid referral, access, enrollment, accrual and retention of diverse populations in CTs
  - Integrate clinical research into routine clinical care
  - Ensure opportunities to participate in research are equitably distributed
  - Develop and implement methods to return research results to patients who participate in studies

## Goals 7 & 8

### Maximize Data Utility

- Secure sharing of privacy-protected health data is standard practice throughout research, and researchers share and use available data to achieve rapid progress against cancer
- **STRATEGIES**
  - Enable data sharing across all cancer research and develop tools that optimize data use and analysis to achieve rapid progress
  - Build a unified Cancer Research Data Ecosystem that enables data collection, integration, harmonization, distribution and reuse of data from a range of research studies
  - Develop data quality standards, metrics and methods to facilitate health care data as a research tool
  - Develop novel data visualization and analysis tools to be made available to researchers
  - Engage patients in data sharing while respecting their wishes for use
  - Enable access to research for communities and organization that face resource limitations

### Optimize the Workforce

- The cancer care and research workforce is diverse, reflects the communities served, and meets the needs of all people with cancer and those at risk for cancer, ensuring they live longer and healthier lives
- **STRATEGIES**
  - Engage and support diverse pool in cancer research/careers
  - Eliminate barriers for individuals historically excluded from or underrepresented in cancer research workforce
  - Initiative to address gaps and needs and increase the number of cancer researchers from underrepresented backgrounds
  - Research to understand and address needs and concerns of cancer researchers at all career stages
  - Develop new strategies and mechanism to support career development paths in life science industries and non-research, such as education, health policy and health journalism

# National Cancer Plan Reactions

# National Cancer Plan



Organization	Statement	Link
BIO	<p>“The Biden administration’s National Cancer Plan, released yesterday, seeks to coordinate government, research, and the biotech industry to cut cancer deaths in half by 2047-but we know looming price controls could stall new R&amp;D anyway”</p> <p>“We’re all for more support for cancer research, and the NIH and NCI are valued partners of the U.S. biopharmaceutical industry in our quest to bring new innovations to patients. But looming price controls could keep the cancer moonshot from ever taking off.”</p>	<a href="#">link</a>
ASCO	<p>“This plan represents the exact kind of roadmap the nation needs. Decades of past federal research investment are already paying off with promising new methods of early detection and new treatments. But research alone won’t get us to our goals, . . . we need a concerted and coordinated effort across the entire cancer community to make sure new discoveries and proven interventions reach our entire population of individuals with cancer and have a chance to benefit everyone. . . Getting better care—care that we know is effective—to the people who need it most is an urgent need in this country. . . Whether it’s reaching patients in rural areas who need to travel long distances to receive service or reaching people in urban areas who lack access, it’s critical to identify and fix the barriers to care and gaps in treatment as soon as possible”</p> <p>“From foundational biology to transformative scientific discoveries, from public policy to private sector partnerships, it’s going to take a significant, sweeping effort to reduce cancer incidence and deaths and the National Cancer Plan provides clear goals, strategies, and a call to action to achieve that goal. . . ASCO stands ready and eager to work with NCI and the entire cancer community to put this plan into action as soon as possible—we have to act now!”</p>	<a href="#">link</a>
ACS CAN	<p>“Ending cancer as we know it will take collaboration, cooperation, and integrated workplans that address the entire cancer continuum—from prevention, to detection, to treatment, cure and survivorship. We applaud the leadership of the Moonshot Initiative, and the comprehensive framework described yesterday by Dr. Bertagnolli. . . ACS is prepared to stand shoulder to shoulder with the NCI in accelerating the National Cancer Plan, leveraging our resources and sharing knowledge to accelerate progress and move us closer to the goal of ending cancer as we know it.”-Dr. Karen E. Knudsen, CEO of the American Cancer Society and ACS CAN</p>	<a href="#">link</a>





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