

ASCO Update: Cancer Care Under a New Administration

Melissa Dillmon, MD
Immediate Past President, Georgia Society of
Clinical Oncology
State Affiliate Council Chair, ASCO



The Environment



Your New Healthcare Team



President Donald
Trump



Tom Price
Secretary of HHS



Francis Collins
Director of NIH



Scott Gottlieb
FDA Commissioner



Seema Verma
CMS Administrator

Administration's Health Care Priorities

- Repeal and Replace the ACA
- Addressing Drug Pricing
- Reducing Regulatory Burdens
- Cutting Medicaid
- Reducing Medical Research Funding
- Trimming the Budgets of Healthcare Agencies

Executive Orders

“Minimizing the Economic Burden of the Patient Protection and Affordable Care Act”

- Agencies to use all discretion to remove financial burdens on states, individuals, families, providers and insurers. **Jan. 20, 2017**

“Reducing Regulation and Controlling Regulatory Costs”

- Includes requirement involving cost analyses that could fundamentally alter the process and content of regulations. **Jan. 30, 2017**

“Establishing the President’s Commission on Combating Drug Addiction and the Opioid Crisis” Mar 29, 2017



....drug pricing EO??

How ASCO Sets Policy Priorities

- Government Relations Committee considers
 - Input from ASCO members
 - Priorities from ASCO committees
 - Initiatives driven by policymakers
 - Assessment of political landscape
- Approved by ASCO Board of Directors

ASCO PRIORITIES: 2017-2018

GOAL 1: Pursue access to high quality, affordable care for every patient with cancer

Examples: Drug Price, Access to Care

GOAL 2: Advance policies and delivery system reform that supports oncology providers in their delivery of high quality, high value cancer care

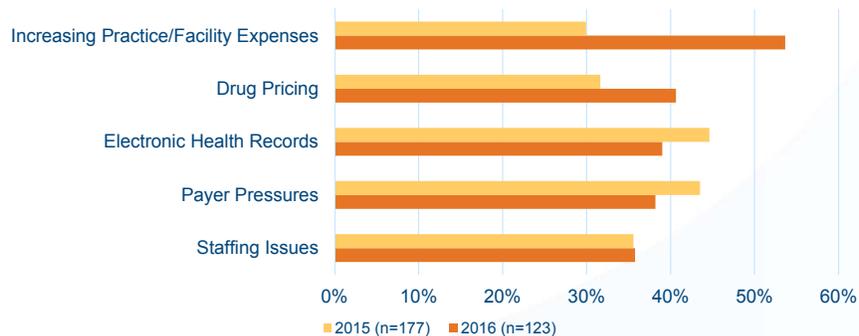
Examples: MACRA, Payment Reform

GOAL 3: Advocate for policies that support a robust federally funded cancer research, prevention, drug development and clinical trials system

Examples: Oppose Right to Try, Ensure Clinical Trials Coverage, Robust NIH Funding

ADVANCE AT FEDERAL AND STATE LEVELS

Top Practice Pressures, ASCO Oncology Practice Trends Survey (2015-2016)



Happenings on Capitol Hill



“Skinny Repeal” Fails



July 28, 2017

Health Reform or Taxes?



Senate Finance Chairman Orrin Hatch (R-Utah)

"We're not going back to health care.....I'm sick of it..."

Efforts to Revive Repeal Continue

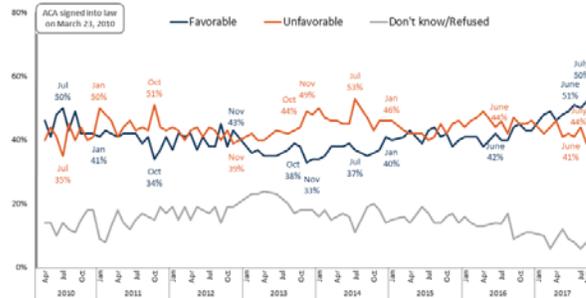
Problem Solvers Caucus

- bipartisan
- advancing temporary solution

Administrative Actions?

Figure 7
More of the Public Have Favorable Views than Unfavorable Views of ACA

As you may know a health reform bill was signed into law in 2010, known commonly as the Affordable Care Act or Obamacare. Given what you know about the health reform law, do you have a generally favorable or generally unfavorable opinion of it?



NOTE: Data not collected for Dec 2012, Jan 2013, May 2013, Jul 2013, Aug 2014, Feb 2015, May 2015, Jul 2015, May 2016, and Jan 2017.
SOURCE: Kaiser Family Foundation Health Tracking Polls

Next Steps Not Clear...ASCO's Position: *Ensure Access to Insurance Coverage*

- Coverage for those with pre-existing conditions
- Coverage for cancer patients regardless of income and health
- No lifetime coverage caps
- Guaranteed renewability
- Coverage of cancer screenings



Ensure Access to Affordable, High-quality Cancer Care

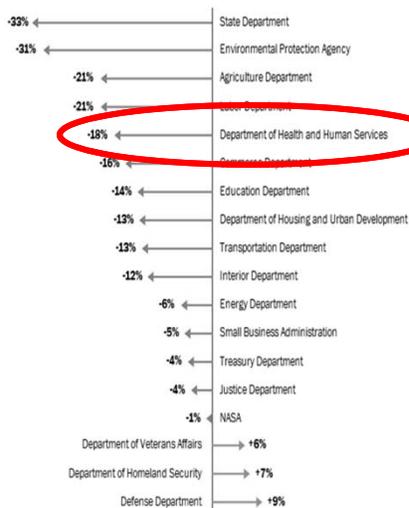
All individuals with cancer should have health insurance that ensures access to high-quality cancer care delivered by a cancer specialist and provides the full range of services needed by patients in a timely manner.



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13

President's Budget: Skinny



NIH Funding: Bipartisan Support



Senator Roy Blunt
@RoyBlunt

Following

Continued investments in NIH medical research will give doctors the tools they need to pursue new treatments and cures.



Blunt Highlights NIH Research During Opening Remarks



News Releases

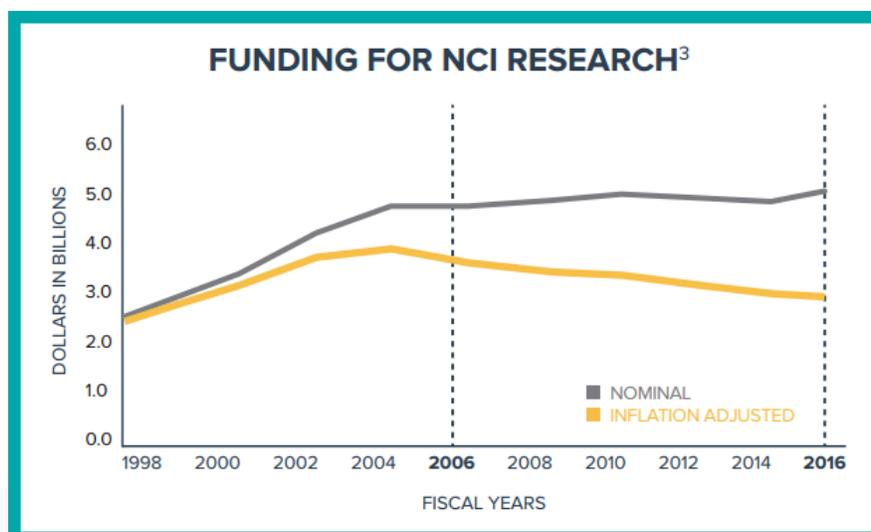
Sen. Murray Secures Major Funding Boost for the National Institutes of Health

Jun 07 2016

Murray and colleagues advance bipartisan bill through key subcommittee, providing the NIH an **increase of \$2 billion to support medical research for patients and families in Washington state and nationwide**



But the Problem Remains



2018?



Congress

Flat?



Administration

Proposed 20% cut to
NIH and NCI

340B Program

- Established by Congress 1992
- Intent: allow hospitals caring for low-income patients to obtain drugs at substantially reduced prices
- Program has experienced dramatic growth
- Bipartisan concerns about size, scope and impact on consolidation



340B Activity

- Pending Legislation/Hearings on Capitol Hill
- White House willingness to engage
- Administrative Action

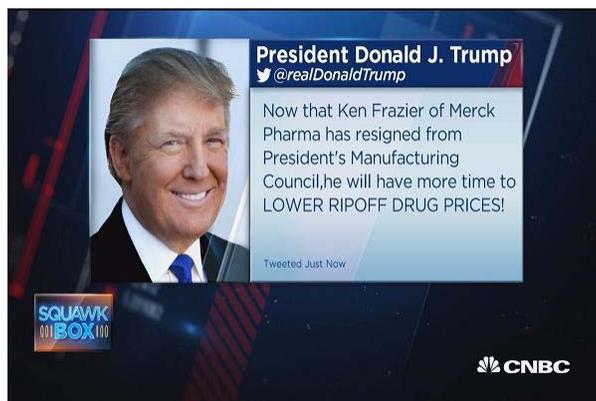


ASCO Position

- 340B **eligibility for all oncology providers** providing care to underserved and low-income populations.
- Increase program **oversight**
- **Transparency** by covered entities on use of 340(b) funds
- **Do not use inpatient data** (e.g. DSH) to determine eligibility of providers to participate in 340B.



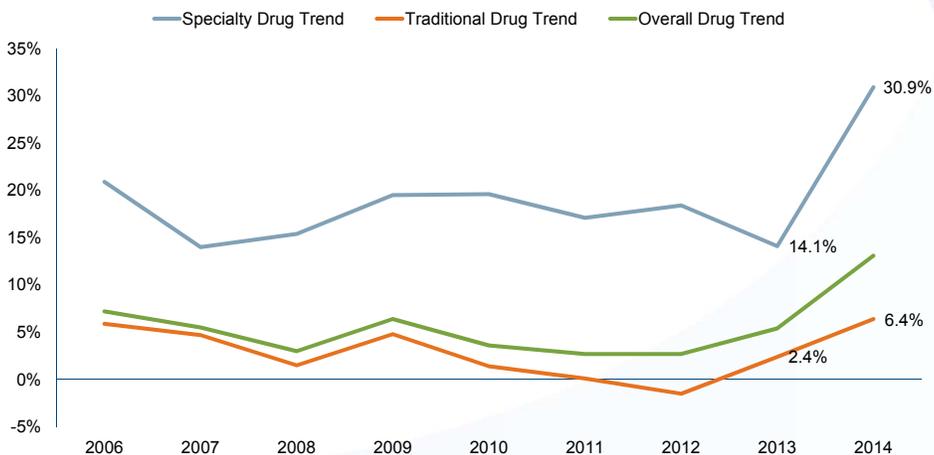
Drug Price Definitely on the List



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A Growing Issue...

Express Scripts drug spending growth trend by therapy class, 2006 -2014



Source: Express Scripts 2014 Drug Trend Report and Year in Review. Available at <http://lab.express-scripts.com/drug-trend-report/> and <http://lab.express-scripts.com/drug-trend-report/introduction/year-in-review>

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...but what action?



Donald J. Trump
@realDonaldTrump

Follow

"I am working on a new system where there will be competition in the Drug Industry. Pricing for the American people will come way down!"

Proposed Part B Demonstration Withdrawn

A Community Effort



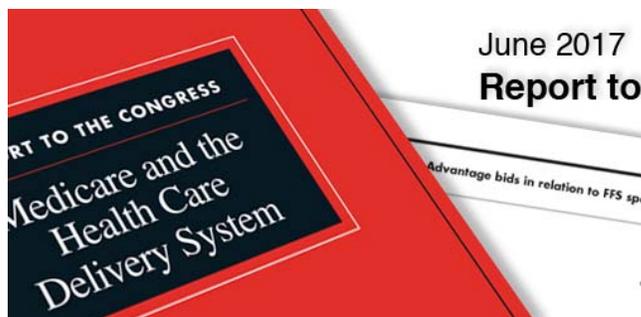
Debra Patt, MD
House Energy and Commerce
Committee Hearing
May 17, 2016

"too big"
"a lot of mistakes"



Andy Slavitt
Former CMS Administrator
Politico Interview January, 2017

MedPAC To Congress on Part B Drugs



- Improved ASP system (reporting, inflation control)
- Transition to Drug Value Program (DVP)

Possible Steps



- President, Congress promising action:
 - Medicare negotiation for drug price?
 - Re-importation of drugs?
 - Performance based pricing?
 - Resurfacing Part B demo?
- ASCO position: hold physicians accountable for utilization...not market entry pricing

Growing Administrative Burden

- Physicians spend 27% of time with patients
- For every hour with patients, two additional hours on EHR and desk work
- 1-2 hours personal time each night on EHR



Ann Intern Med.
2016;165:753-760. doi:
10.7326/M16-0961

Easing Administrative Burden

- High quality pathways
- Interoperable EHRs
- Prior Authorization/Payer requirements
- Streamline quality reporting: one activity to satisfy many requirements



Addressing Administrative Burden

- HHS Initiative
- Congressional Inquiry
- RFI in Proposed Physician Fee Schedule Rule

Utilization Management

- Streamline preauthorization
- **Instead of** step therapy, specialty tiers, restrictive formularies, **use** of high quality value based pathways
- Provide oral parity
- Evidence driven policies

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American Society of Clinical Oncology Policy Statement
On the Impact of Utilization Management Policies for Cancer Drug Therapy

Introduction

High healthcare costs, including escalating drug prices, have led to a renewed focus among policymakers, providers, and payers on strategies to guide the effective use of healthcare resources. One such strategy is the development and implementation of utilization management policies, which are payer-imposed administrative rules that may restrict or deny coverage for selected treatments. The American Society of Clinical Oncology (ASCO) is committed to supporting policies that reduce cost while preserving or increasing quality of cancer care. However, it is critical that such policies be developed and implemented in a way that does not undermine patient access to medically necessary care. The purpose of this statement is to review current utilization management policies in use by payers to control the use of cancer drug therapies and to recommend ways to ensure these policies promote rather than hinder patient access to high-quality, high-value cancer care.

Payor Strategies to Control the Use of Prescription Drug Therapies

There are several mechanisms that health plans use to control the use of prescription drug therapies. Such utilization management policies include prior authorization, clinical pathways, step-therapy protocols, restrictive formularies, and specialty tiers. In the case of cancer care, another way coverage is restricted is through opportunity of patient cost sharing between oral and infused anticancer drugs. In January 2017, ASCO joined the American Medical Association and 55 other healthcare organizations in establishing their Authorization and Utilization Management Reform Principles, urging health plans, benefit managers and others to reform utilization management programs.¹ These principles emphasized the importance of clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternatives and exceptions in order to ensure patient access to appropriate care while reducing the administrative burden associated with policy compliance.

Contributions to Decisions

Utilization management policies often flow from assumptions regarding the availability of clinically equivalent oncology drugs within the general class of drugs² or more cases, oncology drugs do not have substitutes that are both equally effective and less expensive for a given patient. Consequently, policies that attempt to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist can threaten both the outcomes for patients and the well-being of their families or caretakers.

ASCO maintains that the most effective means of stewarding limited health care resources is through a value-based health care delivery system. The Society has advanced this concept through several initiatives, including participation in the ASCO Choosing Wisely program, development of a value framework, an evidence performance measurement and quality improvement portfolio, development of a rapid learning system (ASCO-LEAD), value-based payment volume models, and rigorous clinical practice guidelines. We understand that a value-based payment system is still evolving—

are you ready for  **MACRA?**

- ASCO Top 10 Things to Prepare
- Help with “Pick Your Pace”
- The QOPI platform can be used to report the minimum data in 2017 to avoid a 2019 penalty

www.asco.org/MACRA

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31

MIPS Reporting Requirements

Category	2017 Pick-Your-Pace	%	2018 Proposed	%
Quality	<i>Minimal: 1 measure, 1 patient/chart Partial: 90 days, 50% of all patients Full: 6 measures; at least 90 days, 50% of all patients</i>	60	<ul style="list-style-type: none"> • 6 Measures • Full calendar year • 50% of all patients 	60
ACI	<i>Minimal: base score only- 5 measures; for 90 days No performance thresholds used in scoring</i>	25	<ul style="list-style-type: none"> • At least 90 days • Hardship exemption for small practices • 2014 Edition CEHRT 	25
IA	<i>Minimal: 1 activity for 90 days Full: 1-4 activities for at least 90 days</i>	15	<ul style="list-style-type: none"> • At least 90 days • 1-4 activities • Reduced reporting for small/rural practices 	15
Cost	<ul style="list-style-type: none"> • Full year; Calculated automatically by CMS 	0	<ul style="list-style-type: none"> • Full year; Calculated automatically by CMS 	0
Low-Volume Threshold	Criteria • ≤ \$30,000 in Part B allowed charges, OR • ≤ 100 Part B beneficiaries		Criteria • ≤ \$90,000 in Part B allowed charges, OR • ≤ 200 Part B beneficiaries	
Misc.			<ul style="list-style-type: none"> • Virtual Groups added • Facility-based reporting added • Bonus points for small practices 	

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Making Sure MACRA Works for You

- Monitor implementation
 - Comments
 - Meetings

- GOALS
 - Ensure the intent of the law is followed
 - Test multiple innovative alternative payment models
 - Ensure fair treatment in all MIPS scoring categories (e.g., high cost drugs in resource use category)

2018 QPP Proposed Rule: ASCO Comments

- **CMS should not subject Part B to a MIPS adjustment based on a MIPS eligible clinician's performance during the applicable performance period**

- **The use of raw, unadjusted cost data for oncology drugs creates perverse incentives and impose counterproductive penalties on providers serving vulnerable groups of Medicare beneficiaries with cancer**
 - CMS should measure adherence to high quality oncology clinical pathways
 - If CMS proceeds with using cost data from Medicare claims as a measure of cost performance in MIPS, the costs of Part B and Part D drugs must be excluded or adequately risk-adjusted
 - We support efforts to develop oncology-specific episodes for evaluating resource use under MIPS

- **ASCO supports the concept of providing additional points to MIPS scoring based on the complexity of services provided**
 - the HCC system is fundamentally flawed, CMS should use a different methodology

2018 QPP Proposed Rule: ASCO Comments

- **CMS should promote the use of measures that are clinically relevant to cancer**
- **ASCO strongly supports the Agency's plans to include the ASCO Quality Training Program and QOPI Practice Certification for credit in the MIPS improvement activities performance category**
- **ASCO commends CMS for proposing to recognize leadership in clinical trials within the inventory of MIPS improvement activities**
 - **CMS should clarify that helping patients identify and participate in clinical trials would qualify for recognition as a clinical practice activity**

2018 QPP Proposed Rule: ASCO Comments

- **ASCO supports the Agency's efforts to alleviate the regulatory burdens of electronic health record reporting and to promote opportunities for small and rural practices to achieve success in the Advancing Care Information performance category**
- **We applaud CMS for proposing to implement virtual groups in 2018 allowing small and independent oncology practices to benefit from the collaborative and technical aspects of group reporting in MIPS**
 - **CMS should expand this concept to permit groups of oncologists (and other specialists) within large multispecialty practices to form their own virtual groups**
- **We support the proposal to increase the low-volume threshold to help mitigate the adverse impacts of MIPS on small practices, especially in rural and underserved areas**
- **ASCO strongly urges the Innovation Center to implement additional oncology-focused APMs, to provide flexibility to oncologists to choose the best option for their patients and their practices**
 - **CMS should embrace oncology-focused Advanced APMs that differ from the Oncology Care Model (OCM)**

You Need to Know These People



Steve Grubbs, MD
Vice President, Clinical Affairs



Walter Birch
Division Director



Elaine Towle
Division Director

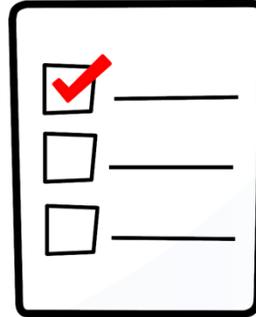
- MACRA readiness, reporting
- Financial analysis
- Practice transformation
- Medical home
- QOPI, QOPI Certification
- Performance improvement
- Alternative payment models

Action Increasing in the States

State Affiliate Council Chair's Report to ASCO Board (August, 2017)

Reviewed Key Issues/Topics:

- Engaging Fellows in Community Practice
- MACRA Education Initiatives
- Medicaid Changes
- Maintenance of Certification
- Medicare's 14-Day Rule
- Opioid Epidemic



are you
ready for
MACRA?

ASCO's 2017 State Advocacy Priorities

High Priority:

- Opioid Therapy**
- Safe Handling of Hazardous Drugs**
- Oral Chemotherapy Parity**
- Clinical Pathways**

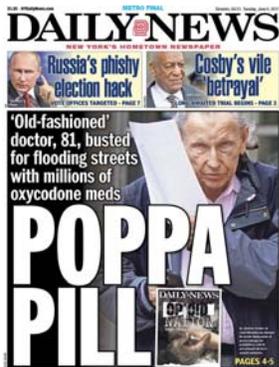
New in 2017:

- ASCO Utilization Management Policy**
- ASCO Statement on Access to Investigational Drugs**

Also Tracking

- Tobacco ("Tobacco 21," Smoke free workplace)
- Medicaid (Clinical trials coverage)
- Right to Try
- HPV Vaccination
- Prescription Drug Costs
- Biosimilars
- Brown Bagging/White Bagging
- Prior Authorization
- Specialty Tiers
- Step Therapy/Fail First

Opioid Crisis



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"We lose a
VIETNAM [WAR]
every single year to drug overdoses."
- HHS Secretary Tom Price

States are Reacting

>400 Bills in 46 States



- Limitations on dose or number of days
- Central database
- Provider education

ASCO Weighs In

- Policy statement & brief
- Comments to CMS and FDA
- Outreach to Congress during federal legislation development
- Assistance to dozens of ASCO state societies/affiliates with new legislation/regulation pending
- Work with AMA on new resolutions regarding data collection and PDMP use



Federal Activity



New Jersey Governor Christie
with
President Trump

- Commission on Combating Drug Addiction and the Opioid Crisis: Executive Order March 29

- Multiple stand-alone bills in Congress

Commission's Preliminary Report

- Declare national emergency
- Invest in treatment
- Mandate provider education
- Increase access to medication-assisted treatment
- Federal funding to enhance PDMPs
- NIH partner with industry to develop non-opioid pain relievers



Clinical Pathways

- State Affiliate concerns with development and use of pathways
- Focus of advocacy:
 - Improving pathways development
 - Addressing practice burden



Pathways Can Work

- Policy statement defining high quality pathways published January 2016
- ASCO criteria published February 2017
- Model legislation



2017 Clinical Pathways State Bills

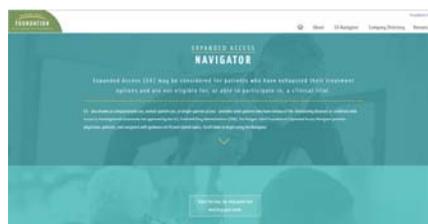
- **Connecticut: House Bill 5960**
 - Establishes requirements for pathways used by health carriers
 - Led by CT Oncology Association and CT State Medical Society
 - No hearing date set
- **California: Assembly Bill 1107**
 - To improve development of oncology pathways by plans
 - Supported by Association of Northern California Oncologists (ANCO) and Medical Oncology Association of Southern California (MOASC)
 - Opposed by health plans
 - Passed out of committee

Right to Try 37 States enacted laws ~

Concerns About Bills

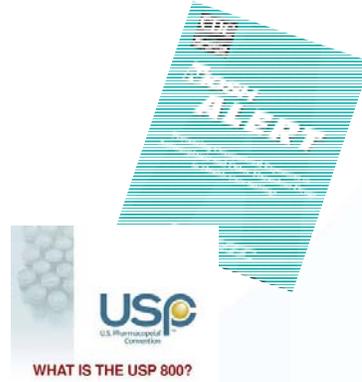
- Removing FDA review of safety and efficacy
- No provision for IRB, associated patient protections
- No systematic data collection on safety and efficacy, which could help all patients

Two Developments



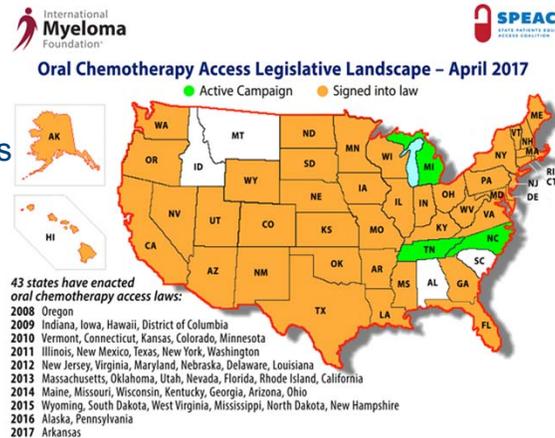
Safe Handling of Hazardous Drugs

- ASCO Task Force working on updated safety standards
- Supporting State Affiliates on state regulatory activity
- Submitted comments on USP <800>
- Supported AMA Resolution
- Reaching out to CDC/NIOSH



Advancing Oral Parity Laws

- Laws in 43 states and DC
- ASCO participate in cancer treatment fairness coalitions
- ASCO supports 2017 bills:
 - AR HB1592: Passed!
 - NC H206/S152
 - TN HB1059/SB922
 - MI SB 492



Fall 2017, State Affiliate Council Meeting Topics

Meeting Topics:

- Maintenance of Certification
- Financial Stressors in Oncology Practice
 - USP 797/800
 - White Bagging
 - Pharmacy Benefit Managers
- Medicaid Changes
- Prescription Drug Monitoring Programs
- MACRA
- ASCO's QOPI QCDR Initiative
- Emerging Issues: Preparing for 2018

ASCO STATE/REGIONAL
**AFFILIATE
PROGRAM**

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Be Involved. Make Your Voice Heard. Join ASCO's ACT Network today!

- Contains draft messages on federal bills that you can personalize and send directly to Congress
- Sends advocacy alerts and policy updates on important issues
- Provides ASCO's position on federal legislation

For more information: Visit

www.asco.org/ACTNetwork

ASCO | ACT Network

New State Advocacy Resources

- **ASCO.org State Advocacy page**
 - State legislative calendar
 - State cancer fact sheets
- **State ACT Network**
 - Congressional Quarterly clickable map tracking state bills
 - State action alerts
- **Toolkits**
 - On opioids, pathways, oral parity, the safe handling of hazardous drugs, step therapy, prior authorization, and specialty tiers
 - May include policy statements and briefs, model legislation and FAQ's

