Legislative Efforts in Pharmacogenomics

Kristine Ashcraft

“I knew right away that something was wrong and asked for help. To find out later that it could have been avoided? I wish I would have known to have testing earlier.”

Abby Yoder
Pittsburgh, PA

CYP2C19

One study showed that patients with a PGx variation like Abby’s were 34.3% more often suicide victims, a 9.1% increase (p=0.0065).

Rahikainen AL, et al. Completed suicides of citalopram users-the role of CYP genotypes and adverse drug interactions. Int J Legal Med. 2019;133(2):353-363.

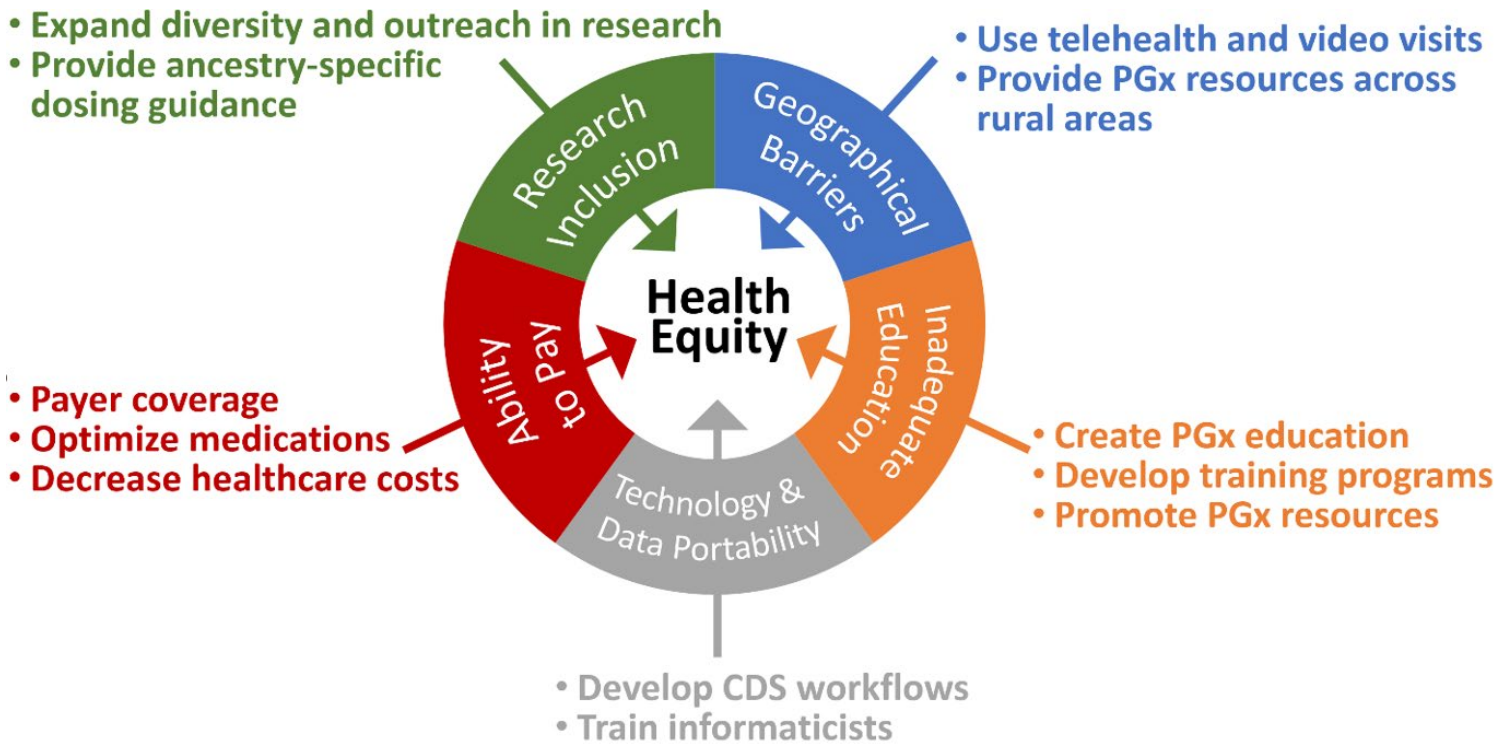
Barriers to Pharmacogenomics (PGx) Becoming Standard of Care

Key Strategies for Genomic Implementation Success

- **Prioritizing EHR integration**
- **Improving clinicians' knowledge**
- **Engaging patients to participate**

Sperber, N.R., Carpenter, J.S., Cavallari, L.H. *et al.* Challenges and strategies for implementing genomic services in diverse settings: experiences from the Implementing GeNomics In pracTicE (IGNITE) network. *BMC Med Genomics* 10, 35 (2017). https://doi.org/10.1186/s12920-017-0273-2

Closing Disparity Gaps in Pharmacogenomics



Formea CM, Schultz AJ, Empey PE.Pharmacists closing health disparity gaps through pharmacogenomics.J Am Coll Clin Pharm. 2022;5(8):844-852.

Pharmacists are Accessible Medication Experts

Association of American Medical Colleges (AAMC) predicts a shortage of 122,000 physicians by 2032 [1]

90% of Americans live within 5 miles of a pharmacy [2]

Pharmacists complete **5X more hours of coursework** on pharmacology and pharmacotherapy than physicians [3]

1. National Association of Chain Drug Stores. Re: Health Care Workshop, Project No. P131207. http://www.nacds.org/ceo/2014/0508/supplementa l_comments.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4239972/
3. https://www.futuremedicine.com/doi/full/10.2217/pgs-2019-0009

Pharmacists Increase Uptake of PGx Guidance by Providers

PGx Results to Physicians

Recommendations Followed:

46%

J Med Econ. 2015 Oct 19:1-16

PGx Results to Pharmacists

Recommendations Followed:

77%

https://doi.org/10.1371/journal.pone.0170905

Patients Want to be Informed About PGx Testing

When educated about pharmacogenomics most of a diverse group of community participants agreed:

- physicians should **inform patients of all pertinent available tests** for a specific problem, including genetic testing
- the **decision to use a particular test**, including genetic tests, **rests with the patient**
- **insurance companies are obligated to understand the benefits offered** by the tests

American Society for Pharmacovigilance (ASP) and the Hope and Healing Center & Institute (HHCI) Community Dialogue: What are the Ethical and Practical Implications of Pharmacogenomics? Final Report November 19, 2020

PGx Barriers that Legislation Can Address

- **Education** of healthcare providers and the general public about the importance of PGx and availability of evidence-based, actionable guidelines to reduce medication risk
- **Integration** of genetic test results and clinical decision support (CDS) in clinical workflows
  - Need same policy emphasis as drug interactions for quick alerting in EHRs
  - Genetic test ordering easily accessible from clinician workflows within EHRs
  - Genetic test results, especially PGx, are sharable and stored discretely to help patient throughout lifespan

PGx Barriers that Legislation Can Address

- **Alignment of guidelines and reimbursement** with evidence and technology
  - Cover CPIC A or B and FDA for safe administration, as in recent Medicare LCDs
  - Full panel testing is often conducted yet only single gene testing is covered, which prevents using full genetic information to benefit patients and is not cost-effective
  - US Preventive Services Task Force should include a representative from the genetics community and the Task Force should cover PGx testing for those with risk factors
- **Funding** for PGx aimed at improving equity, diversity and access and that aligns with impact across patient care continuum
- **Recognition of Pharmacists as Providers** as they are the specialists most trained to order and interpret PGx testing and reduce spiraling medication harm and costs

State Legislation Addressing Barriers to Access

New Jersey Assembly Bill 1322

Sponsor: Representative Christopher DePhillips (R)

NJ Assembly Bill for DPYD

- Requires physician to offer patients for DPYD genetic testing prior to patient undergoing chemotherapy.
- Mandates that health insurance plans in this State are to cover expenses incurred in conducting one test

Biomarker Legislation

Biomarker Legislation Addresses Coverage Gaps

- Requires state-regulated insurance plans including Medicaid to cover comprehensive biomarker testing when supported by medical and scientific evidence

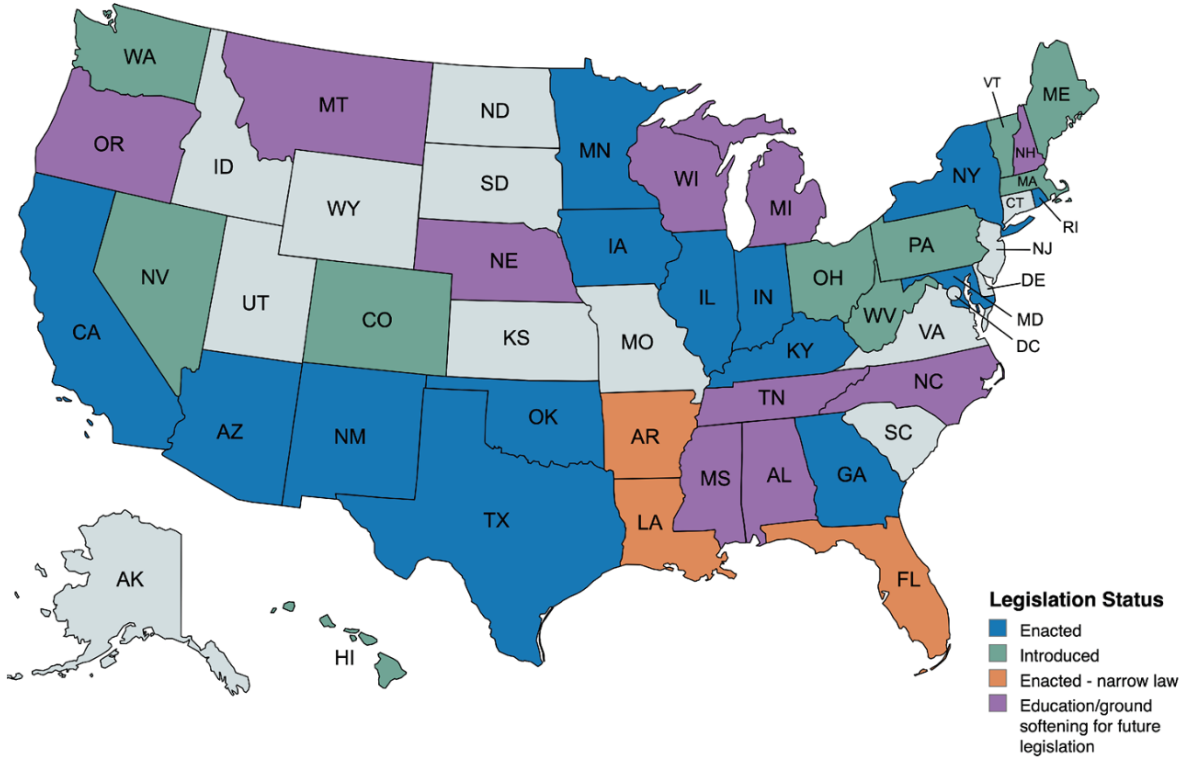
- Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:
  - Labeled indications for an FDA-approved or -cleared test
  - Indicated tests for an FDA-approved drug;
  - Warnings and precautions on FDA-approved drug labels
  - Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
  - Nationally recognized clinical practice guidelines and consensus statements.

- **Disease and stage agnostic**

Note: PGx advocate outreach resulted in language changes to make PGx coverage more clear

Biomarker Legislation

NCOIL endorsement typically drives nationwide adoption



Enacted: AZ, CA (7/1/24), GA, IA, IL (7/1/24), IN, KY, MD (7/1/25), MN (1/1/25), NM, NY, OK, RI, TX

Enacted with limitations such as cancer Dx only: AR*, LA*, FL** (7/1/24)

Introduced/Expected in 2024: CO, HI, MA, ME, NV, OH, PA, VT, WA, WV

Education/Ground Softening for Future Legislation: AL, MI, MS, MT, NC, NE, NH, OR, WI

**Private Plans Only **Public Plans Only*

Updated map: https://www.fightcancer.org/what-we-do/access-biomarker-testing

Why?

Thank you to ACS CAN for sharing slides they used to demonstrate the need for biomarker legislation!

Unequal Access to Biomarker Testing

- In metastatic non-small cell lung cancer (NSCLC), eligible Black patients are less likely to receive biomarker testing compared to white patients
- There are socioeconomic inequalities in biomarker testing and targeted therapy utilization across cancer types
- There are lower rates of testing in community settings versus academic medical centers
- These disparities in access and use of guideline-indicated biomarker testing and targeted therapy can potentially widen existing disparities

Barriers: Insurance

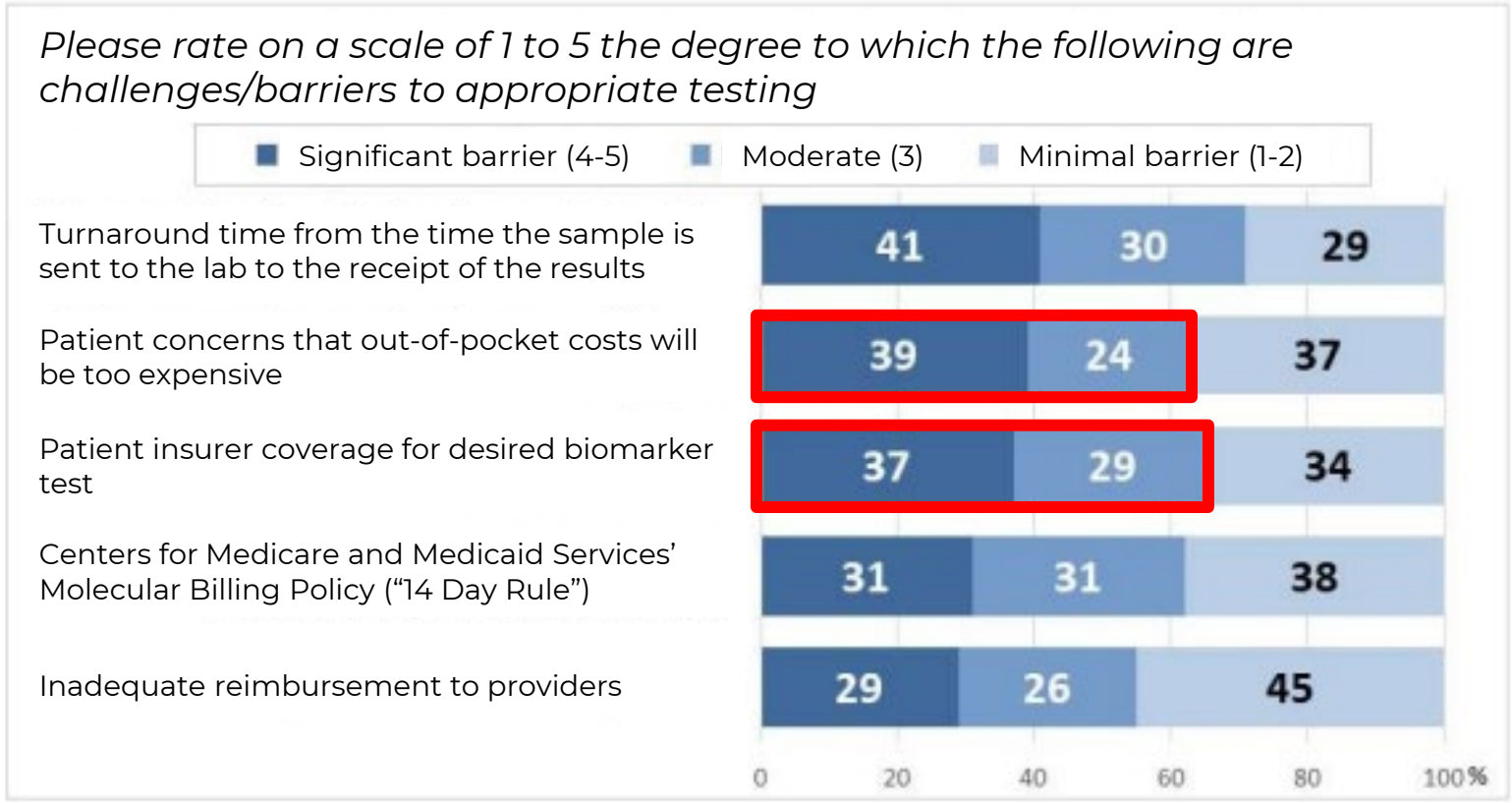
- **Coverage of tests differs greatly across payers**
  - Most plans are covering some biomarker testing for some patients.
  - Coverage policies generally more common for single-gene tests vs. multi-gene panel tests
- **Plans aren’t necessarily following the evidence**
  - A recent paper in Personalized Medicine highlights gaps between insurance coverage and clinical practice guidelines.
  - Although 91% of plans evaluated reference NCCN treatment guidelines in their biomarker testing policies, 71% are “more restrictive” than these guidelines for biomarker testing in breast, non-small cell lung cancer, melanoma and/or prostate cancer patients.

Wong, W., et al. (2022) Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.

Barriers: Insurance

Provider experiences

- National survey of oncology providers found top barriers to appropriate use of biomarker testing:

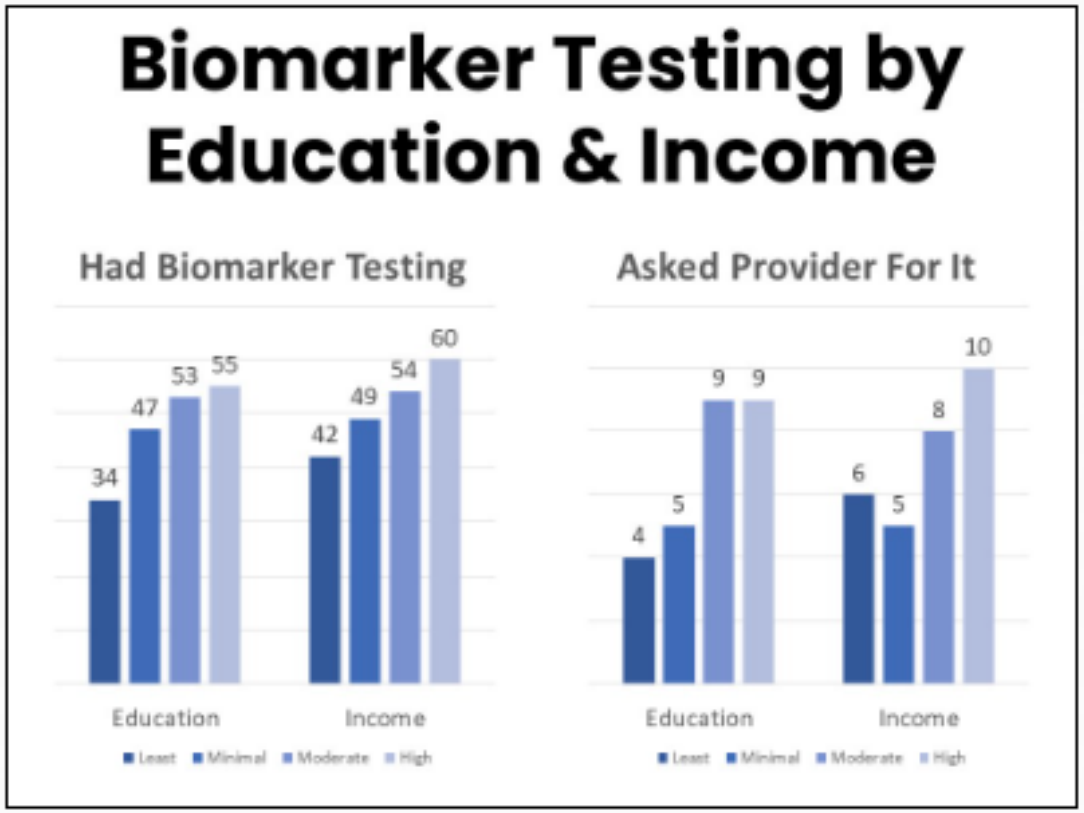


Understanding Provider Utilization of Cancer Biomarker Testing. ACS CAN. Dec. 2021.

Barriers: Insurance

Patient experiences

- *Survivor Views* survey on biomarker testing found more patients (49%) are receiving biomarker testing than in 2020 (39%)
  - **Half of patients tested report it allowed them to avoid unnecessary treatments or procedures**
  - Three percent were able to enroll in a clinical trial because of their results
- Disparities persist by income, education, insurance type
- **Of those who did not receive biomarker testing, 9% report lack of insurance coverage of needed testing as the reason**
- Patients who received testing overwhelmingly agree it helped their providers better treat their cancer



Survivor Views. ACS CAN. October 2023.

Why Disease-agnostic?

- **Biomarker testing applications extend beyond oncology**
- Biomarker testing is increasingly important for the treatment of diseases including:
  - Arthritis and other autoimmune conditions, rare diseases
  - FDA recently approved test for risk of preeclampsia
  - Research is happening in many other areas including Alzheimer's, other neurological conditions, and cardiology.
- **Cancer patients and survivors have high rates of comorbidities**
- Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.
- As patients are living longer, and some cancers become more of a chronic condition, cancer patients are often living with one or more comorbidities.
- Most common comorbidities include diabetes, cardiac conditions (COPD, congestive heart failure, cerebrovascular disease, peripheral vascular disease), renal failure, and rheumatological conditions.
- A recent study found that nearly two-thirds of patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.

Pushback and Questions

- Does not
  - Require coverage of testing for screening purposes
  - Require coverage of unproven or unnecessary testing
  - Require coverage of biomarker testing for every cancer patient
  - Set reimbursement levels
- Limitations
  - Only applies to state-regulated plans
  - OOP costs may still be a barrier
  - Addresses coverage. Additional work ongoing to address other barriers.
- Questions about costs to states, payors
- Milliman study projects premium impact of $0.08-0.51 PMPM
- Growing evidence about cost avoidance, more efficient care delivery.

The landscape of biomarker testing coverage in the United States. Gabriela Dieguez and Jennifer Carioto. Milliman. February 2022

Laying the Groundwork

Efforts to educate on the issue and build momentum towards bill introduction makes for a more successful campaign:

- Build strong, diverse coalition, including non-oncology stakeholders
- Collect patient stories
- Educate lawmakers/volunteers

Continuing these strategies after bill introduction:

- Keep coalition engaged, informed and involved in work
- Utilize patient stories
- Meeting with lawmakers to secure support
- Coalition advocacy events with volunteers
- Engage media

Biomarker Legislation – How to Help

Learn more:

fightcancer.org/biomarkers

ACS CAN has active legislation in CO, MA, NJ, OH, and PA and continuing legislative efforts in HI, ME, NV, VT, and WA. Many states have ongoing education campaigns and will transition to legislative efforts in the coming year.

If you would like to assist in state efforts, contact:
hilary.gee@cancer.org or cori.chandler@cancer.org

Work Is Not Done When Legislation Passes

Lessons Learned from California

- Biomarker legislation and AB425 mandating PGx coverage for Medi-Cal patients both passed with a go-live date of 7/1/24
- In California both AB-425 and biomarker were not in the original draft budget which would delay implementation
- Orchestrated outreach led to both being incorporated into the revised draft budget
- Budgeting and implementation need to be monitored
- **Be prepared to proactively or reactively inform payers of these policies if coverage is denied**.

National Legislation Addressing Barriers to Access

H.R. 7848 The Right Drug Dose Now Act of 2024

Primary Sponsor: Representative Eric Swalwell (D-CA-15)

Original Cosponsor: Representative Dan Crenshaw (R-TX-2)

Right Drug Dose Now Act Reintroduced 3/29/24

Originally introduced by Swalwell and Emmer 2/28/22

1. **National Action Plan for Adverse Drug Event Prevention** – assessment and update to include PGx within 180 days of enactment

2. **Education on Pharmacogenomics for Healthcare Professionals** – as a key component of adverse event reduction

3. **Improving EHR Systems to Utilize Pharmacogenomic Information** – flag for appropriate testing and drug-gene interactions, gather RWE

4. **GAO Study on FDA Drug-Gene Labels**

5. **FDA Adverse Event Reporting System Update** – patient friendly submission option, automate reporting from EHRs

Note: Separate bill to be introduced later by Swalwell only will authorize funding

Energy and Commerce Subcommittee Member Leadership

Currently, the bill is in energy and commerce so targeting these members is especially important - https://energycommerce.house.gov/representatives

Energy and Commerce Subcommittee Member Leadership

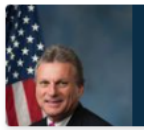
MICHAEL BURGESS
R Texas – District 26

BOB LATTA
R Ohio – District 5

MORGAN GRIFFITH
R Virginia – District 9

GUS BILIRAKIS
R Florida – District 12

RICHARD HUDSON
R North Carolina – District 9



BUDDY CARTER
R Georgia – District 1

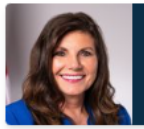
NEAL DUNN, M.D.
R Florida – District 2

GREG PENCE
R Indiana – District 6

DAN CRENSHAW
R Texas – District 2

JOHN JOYCE
R Pennsylvania – District 13

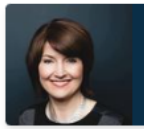
TROY BALDERSON
R Ohio – District 12



DIANA HARSHBARGER
R Tennessee – District 1

MARIANNETTE MILLER-MEEKS
R Iowa – District 1

JAY OBERNOLTE
R California – District 23



CATHY MCMORRIS RODGERS
R Washington – District 5

Energy and Commerce Subcommittee Member Leadership

JOHN SARBANES
D Maryland – District 3

TONY CARDENAS
D California – District 29

RAUL RUIZ
D California – District 25

DEBBIE DINGELL
D Michigan – District 6

ANN KUSTER
D New Hampshire – District 2

ROBIN KELLY
D Illinois – District 2

NANETTE DIAZ BARRAGÁN
D California – District 44

LISA BLUNT ROCHESTER
D Delaware

ANGIE CRAIG
D Minnesota – District 2

KIM SCHRIER
D Washington – District 8

LORI TRAHAN
D Massachusetts – District 3

FRANK PALLONE
D New Jersey – District 6

Right Drug Dose Now Act – How to Help

Learn more and sign on to support at fourthcause.org/rightact

- Email Kristine.Ashcraft@youscript.com if you want to volunteer to lead and/or support state efforts to:
  - Request meetings with House representatives to sign on in support of the legislation
  - Request meetings with Senators to introduce the Senate companion bill
  - Talking points and sample slides provided on request

Pharmacy and Medically Underserved Areas Enhancement Act (S. 1491)

Original Co-Sponsors:
Senators Chuck Grassley (R-IA), Cindy Hyde-Smith(R-MS), Robert Casey (D-PA), Ben Lujan (D-NM) and Sherrod Brown (D-OH).

Pharmacy and Medically Underserved Areas Enhancement Act

- Introduced 5/9/23 and referred to Committee on Finance
- This bill would allow pharmacists to be reimbursed for certain healthcare services under Medicare Part B in:
  - Medically Underserved Areas (MUAs)
  - Medically Underserved Populations (MUPs)
  - Health Professional Shortage Areas (HPSAs)
- Consistent with Medicare reimbursement for other non-physician practitioners, pharmacist services would be reimbursed at 85% of the physician fee schedule.

How to Help

Reach out to your members of Congress via email to ask them to support legislation that addresses pharmacists lack of provider status.

A next step would be to set up a meeting with your representative at his or her district office.

Visit ASHP to learn more.


start
somewhere

Questions?

Kristine Ashcraft
President and Founder

206-930-9062

kristine.ashcraft@youscript.com