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FasterCures

Vital Voices Workshop:
Opportunities for Patient Organizations to Engage CMS

April 28, 2025

FasterCures Programs

Mission: To build a biomedical innovation system that is effective, efficient, and driven by a clear vision: patient needs above all else

R&D Environment

- ENRICH-CT (Enabling Networks of Research Infrastructure for Community Health Through Clinical Trials)
- Representation in Clinical Trials
- Future of Biomedical Innovation

Policy

- CMS/FDA Alignment: Accelerating Treatments to Patients
- Building Patient Engagement Capabilities at CMS
- Prevention-First Health

Patient Engagement

- TRAIN (The Research Acceleration and Innovation Network)
- LeadersLink
- Patient Engagement in Medtech Development
- Vital Voices: Patient Engagement with CMS

Innovation

- Future of Cancer Care in the US
- Cell, Gene, and RNA Therapies
- Emerging Technologies
- Data and AI

International

- Project Prevent
- Global Cancer Care
- Anti-Microbial Resistance
- Early Warning System

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Background

- The Centers for Medicare and Medicaid Services (CMS) is the bellwether to which other payers and value assessors look for guidance and leadership.
- Patient organizations bring unique, real-world insights that can shape CMS's decisions on treatment access, yet many groups are unaware of how or when to effectively engage.
- Providing patient organizations with practical tools and peer-driven examples strengthens their ability to advocate for equitable, patient-centered care policies.

Workshop Objectives

- Provide an overview of relevant CMS offices and programs, highlighting the entities responsible for stakeholder engagement.
- Discuss CMS decision-making processes, including how and when they involve stakeholders, what information the agency uses for decision-making, and the role of patients/patient organizations.
- Highlight case studies, promising practices, and lessons learned from patient organizations engaged with CMS.

Agenda

9:00–10:00	Check-In and Breakfast
10:00-10:30	Welcoming Remarks and Table Introductions
10:30-11:00	Overview of CMS Centers, Functions, and Resources for Patients
11:00-11:30	Patient Organization Opportunities to Engage with CMS for Medical Product Access Determinations
11:30-12:00	Expert Panel Discussion: Strategies for Engaging CMS
12:00-12:50	Lunch
1:00-2:15	Patient Organization Case Examples
2:15-3:00	Brainstorming your CMS Engagement Approach
3:00-3:15	Workshop Reflections and Closing Remarks
3:15-4:00	Participant Networking
4:00-4:30	American Dream Discovery Center Tour (Optional)

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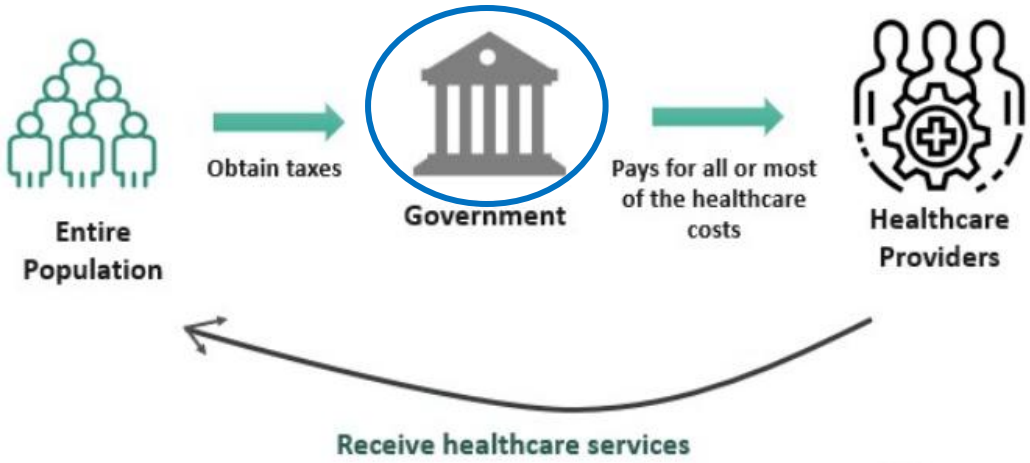
Overview of CMS Centers, Functions, and Resources for Patients

Lee Fleisher, MD, M.L

Senior Advisor to FasterCures
Founding Principal and CEO at Rubrum Advising, LLC
Former Chief Medical Officer and Director of the Center for Clinical Standards and Quality (CCSQ) at CMS

Complex US Payer Landscape



Public Payers
- Medicare (14.2%)
- Medicaid (19.8%)
- Military (1.4%)

Private Insurers
- Employer-Sponsored (49.6%)
  Fully Insured or Self Insured

Individual Market
- Non-Group (5.9%)
- Uninsured (9.2%)

Public-Private Programs
- Medicare Advantage
- Medicaid Managed Care

State and Federal Exchanges
- Affordable Care Act Health Insurance Marketplace

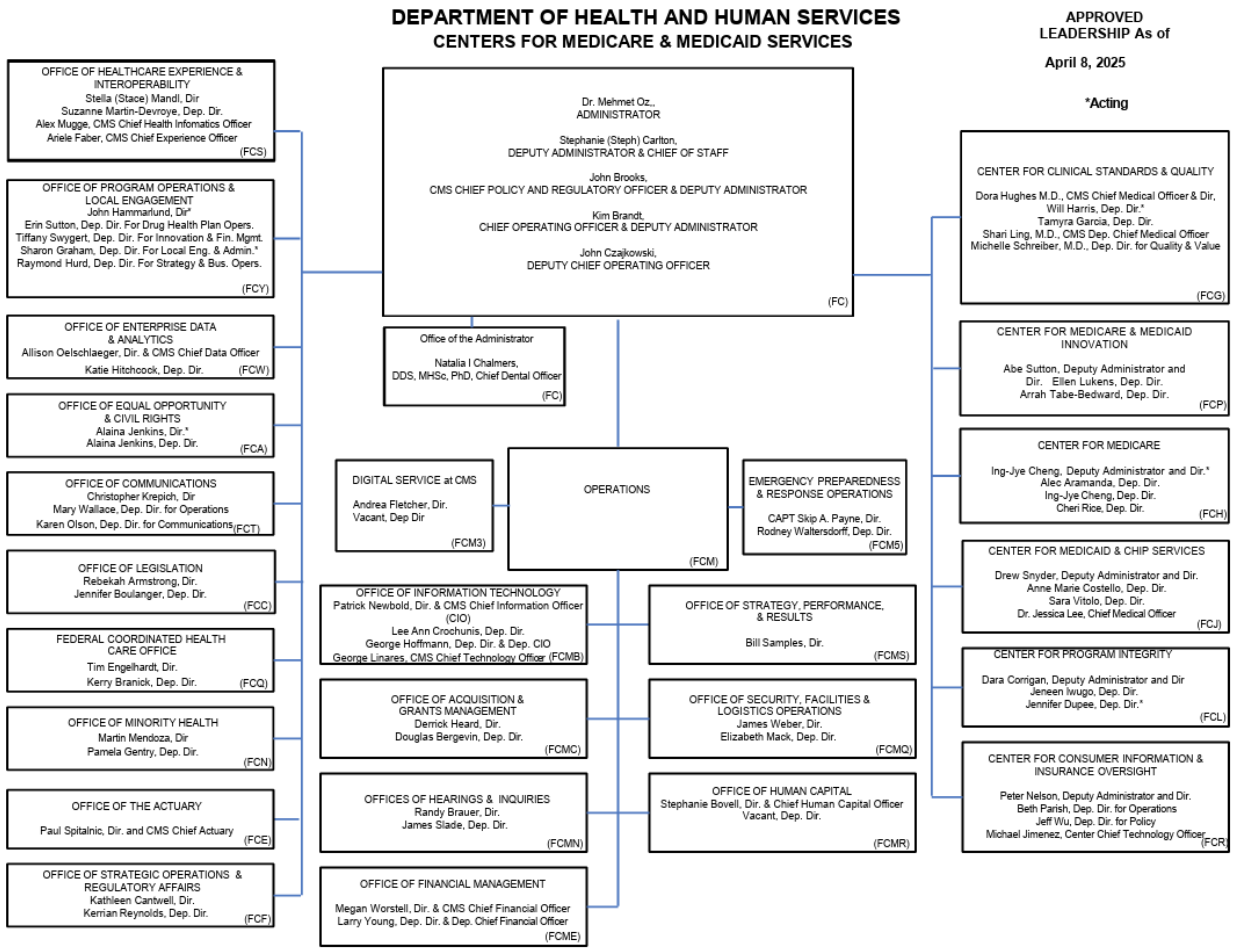
FDA and CMS Authorities Definition by Statutes

"Responsible for protecting the public health by ensuring the **safety, efficacy, and security** of … drugs, biological products, and medical devices."[1]

Authority to determine whether a particular medical item or service is "**reasonable and necessary**"[2] **for the treatment of an illness or injury.**

Center for Medicare and Medicaid Services

New CM Director: Chris Klomp

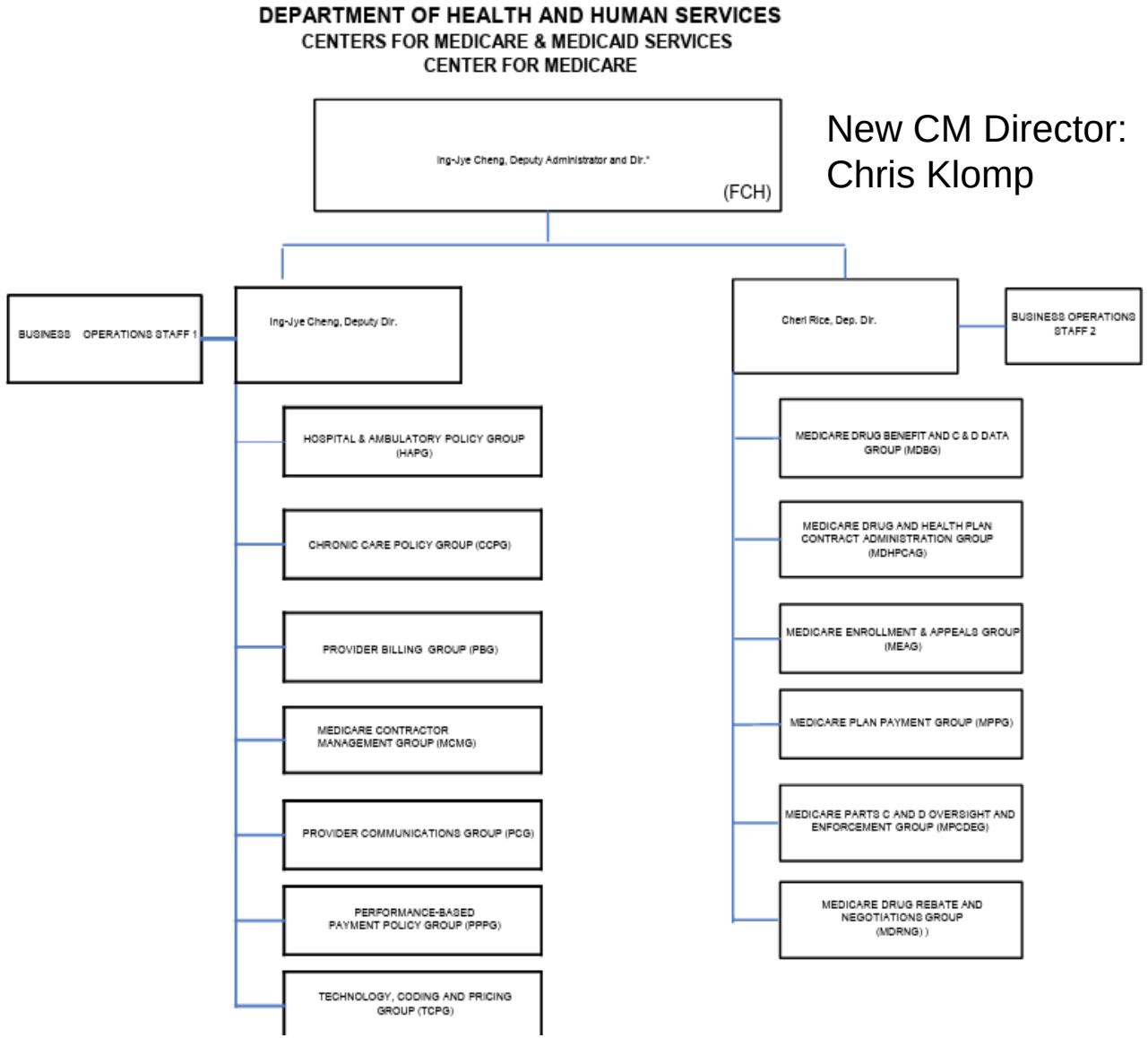


- History/Origin
  - Established in 1965 alongside the creation of Medicare and Medicaid under the Social Security Amendments signed by President Lyndon B. Johnson.
  - The original Medicare program included Part A (Hospital Insurance) and Part B (Medical Insurance).
- Purpose
  - Ensure access to high-quality, affordable healthcare for beneficiaries of Medicare, Medicaid, and CHIP.
  - Sets standards for healthcare quality, drives innovation in care delivery
  - Oversees regulations that promote equity and value across the U.S. healthcare system.

https://www.cms.gov/about-cms/who-we-are/organizational-chart
https://www.cms.gov/about-cms

Center for Medicare (CM)

- Focal point for the formulation, coordination, integration, implementation, and evaluation of the Medicare program.
- Develops and implements a strategic plan, objectives and measures for the Medicare and prepare CM to meet future challenges with the Medicare program and its beneficiaries.
- Identify program vulnerabilities and implementation of strategies to eliminate fraud, waste, and abuse.
- Manage Part C (Medicare Advantage) and Part D (prescription drug plans), Medicare fee-for-service providers, and contractors.



New CM Director: Chris Klomp

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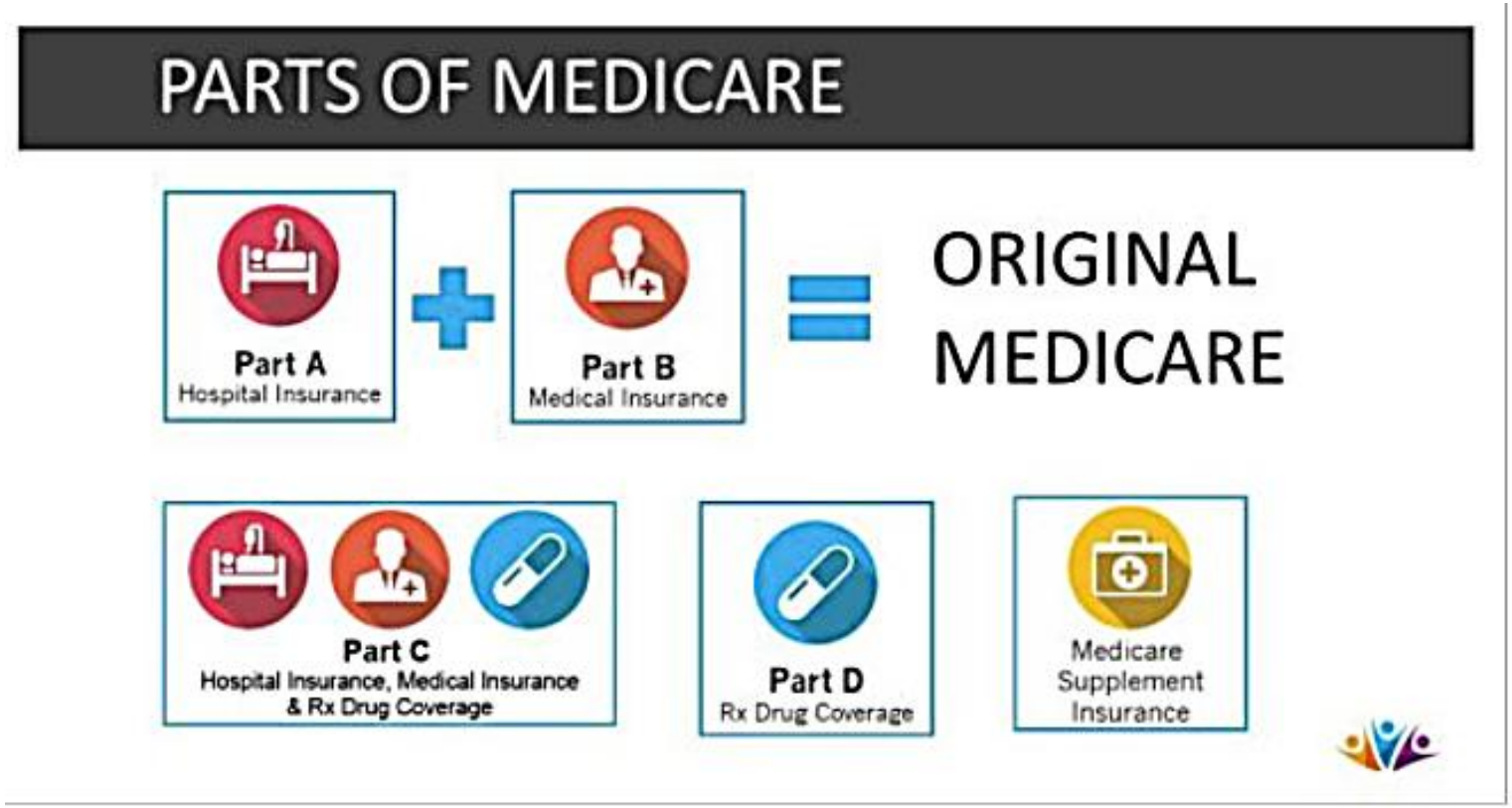
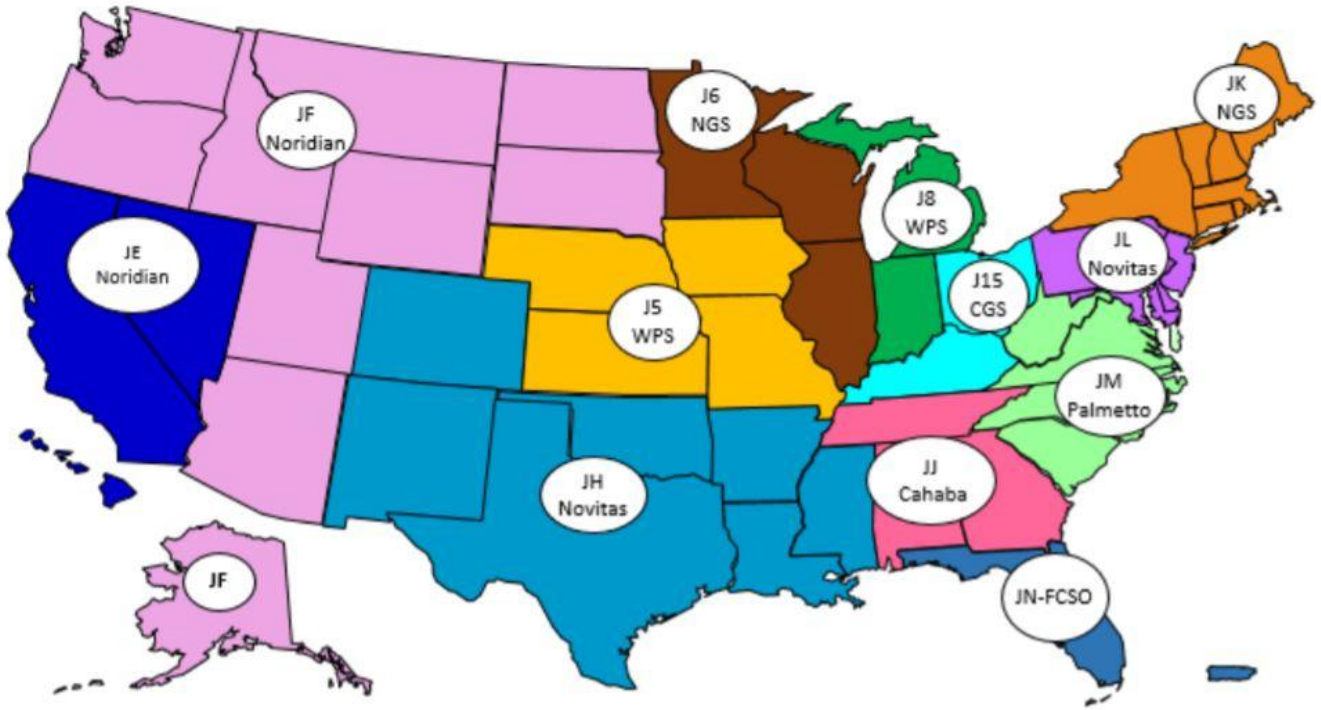
Medicare Parts A-D



https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare

https://sfgmedicare.com/medicare-101/parts-of-medicare/

Medicare Administrative Contractors (MACs)



- Medicare Administrative Contractors (MACs) are private insurers contracted to manage Medicare claims within designated geographic areas.
- They process Medicare Part A and Part B medical claims, as well as Durable Medical Equipment (DME) claims for Fee-For-Service (FFS) beneficiaries.
- More about MACs
- MACs Coverage Areas/Maps

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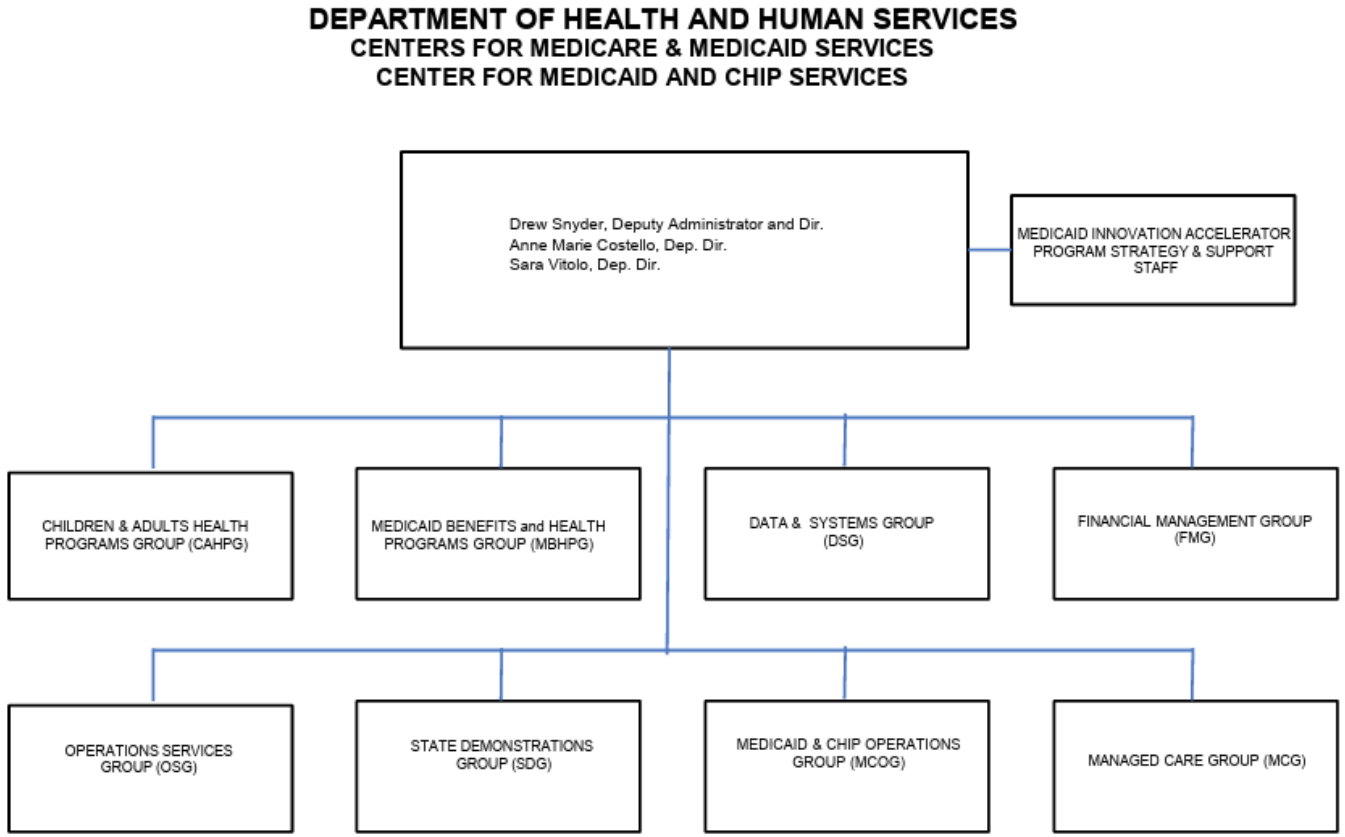
NCD, LCD, & Claim-by-Claim Coverage

NCD	LCD	Claim-by-Claim
• Coverage decision made by **CMS** on if a service or item meets the reasonable & necessary (R&N) threshold. • All MACs & MA plans must follow the coverage criteria & specifications laid out in NCDs. • If a product does not have the evidence required to get an NCD, they may choose to apply for an NCD with Coverage with Evidence Development (**NCD with CED**) – allowing Medicare reimbursement while additional clinical evidence is collected to support long-term coverage.	• Coverage decision made by Medicare Administrative Contractors (**MACs**) on if a service or item meets the R&N threshold. • With an LCD, a product may be covered by Medicare within the jurisdiction the MAC oversees. • MACs outside of this jurisdiction may choose to abide by the rules set forth by the LCD but are not required to do so. • Medicare Advantage (MA) plans must follow LCDs within their applicable jurisdictions, but if outside of these geographic boundaries, are not obligated to do so.	• When there is no coverage determination for a service or item, Medicare Administrative Contractors (**MACs**) make individual determinations of coverage on a per-case basis. • Medicare coverage determinations often inform coverage decisions of private/commercial payers. • This does not guarantee coverage or non-coverage but rather leaves the decision to whoever is reviewing the claim. • Requires thorough documentation.

More details for opportunities to engage in these processes will be presented in the next presentation.

Center for Medicaid and CHIP Services

- Setting federal guidelines for enrollment, eligibility, premiums, cost-sharing, and other processes.
- Develops policies and programs to provide health insurance for low-income children and adults.
- Coordinates with states, providers, and patients to support program operations and ensure access to care delivery services.



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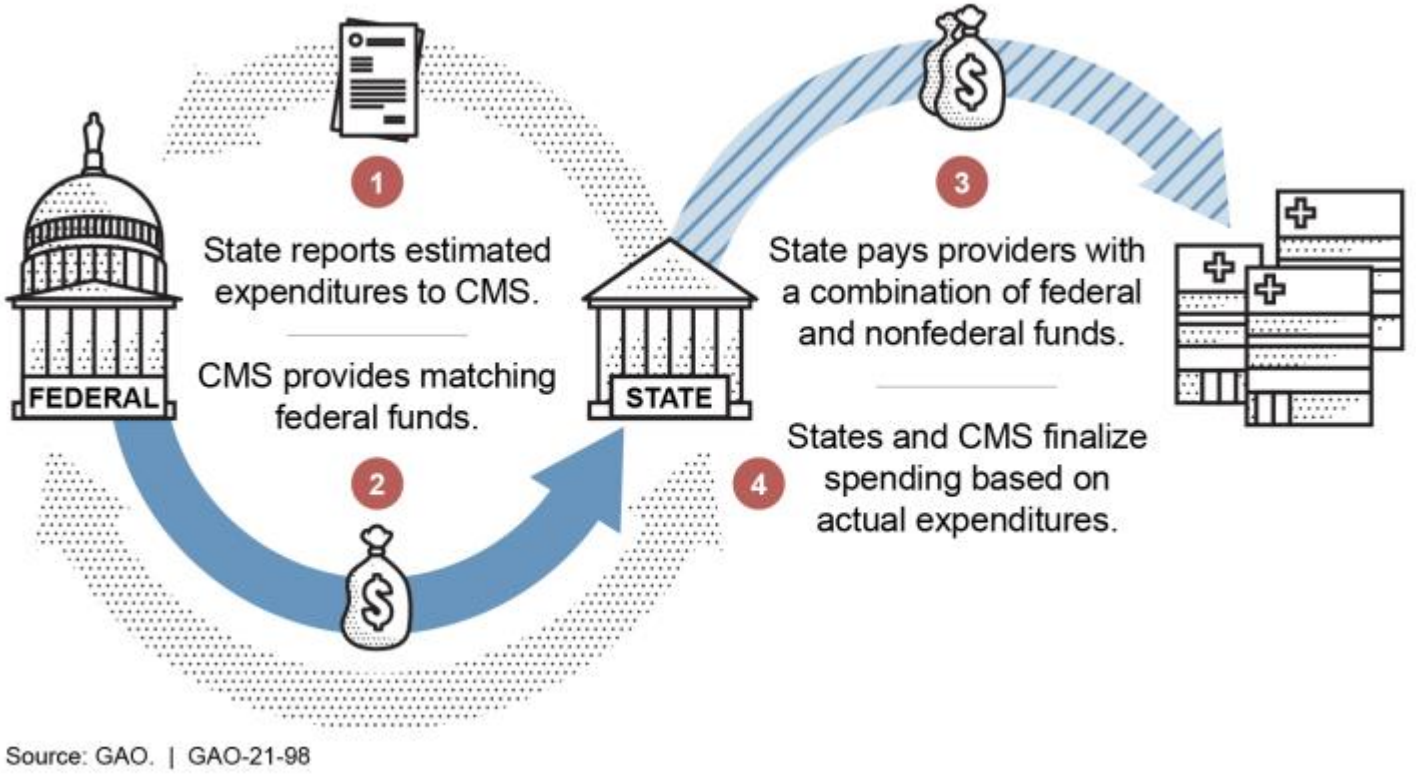
Administration of Medicaid

Centers for Medicare & Medicaid Services oversees Medicaid at the federal level.

CMS through the Center for Medicaid & CHIP Services (CMCS) sets federal rules and guidelines that states must follow to receive federal matching funds.

The Social Security Act (SSA) provides flexibility to states through waivers and demonstration projects (1115 and 1915), allowing them to operate their Medicaid programs outside federal rules.



Source: GAO. | GAO-21-98

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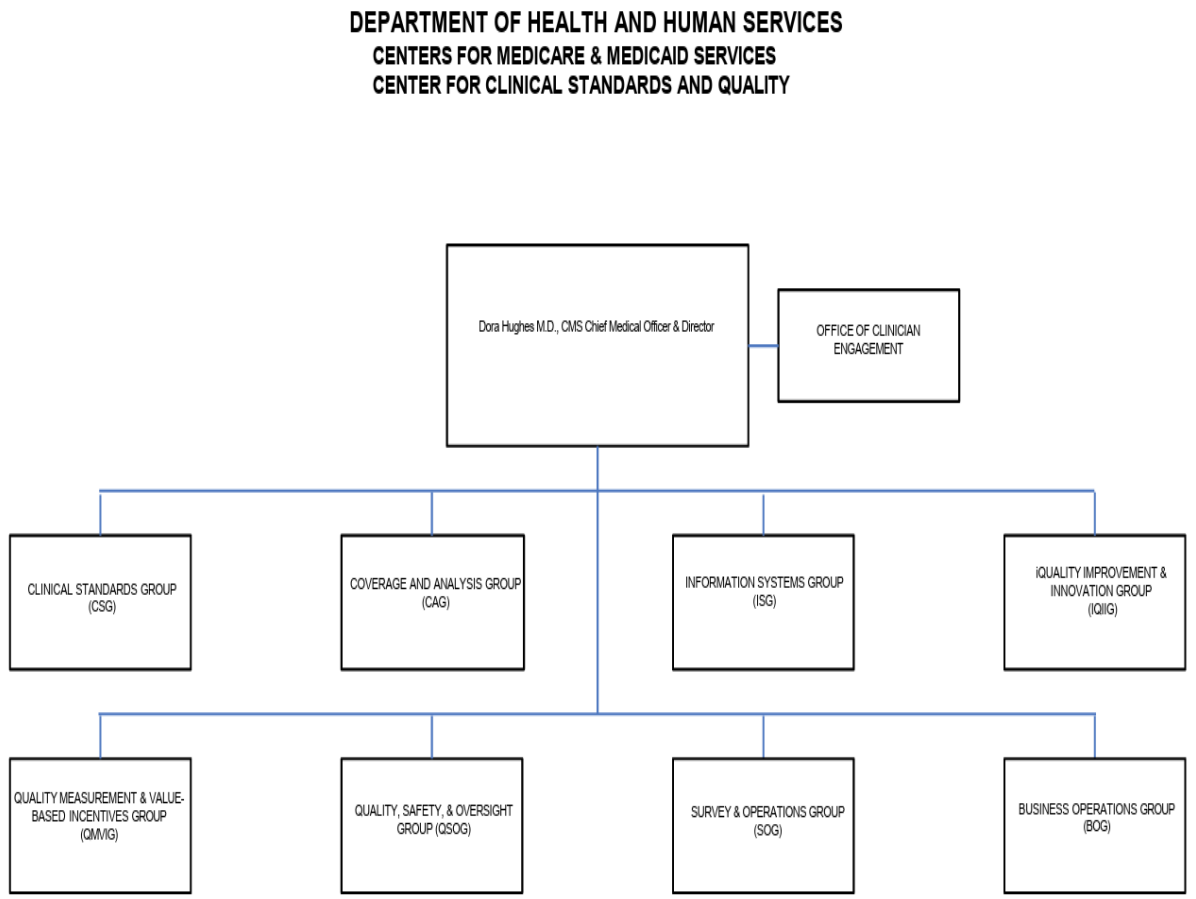
Medicaid Stakeholder Engagement Opportunities

- **Medicaid Advisory Committees (MCAC):**
  - Advise and guide the state on health and medical care services and are required to include Medicaid members and patient advocates
- **Beneficiary Advisory Councils (BAC):**
  - State-level advisory groups must also include current or former Medicaid members, family members of beneficiaries, and caregivers.
- **Managed Care Organizations (MCOs):**
  - Contract with state Medicaid agencies to provide services and administrative benefits to members and coordinate state-level MCACs/BACs.
- **1115 or 1915 waiver programs:**
  - Provide access to tailor-made healthcare options to groups of people with particular needs or health conditions. Patient organizations can provide public comments on proposed waivers.
  - Ex.) Home and Community Based Services Special Interest Groups
- Other resources

https://www.medicaid.gov/medicaid/access-care/medicaid-advisory-committees-and-beneficiary-advisory-councils
https://www.medicaid.gov/medicaid/home-community-based-services

Center for Clinical Standards and Quality (CCSQ)

- Serves as the lead for quality, clinical, medical science, and survey and certification policy across CMS programs.
- Monitors and evaluates the quality standards of Medicare, Medicaid, and the Clinical Laboratory and Improvement Amendments (CLIA)
- Develops scientific and clinical coverage policies for new and existing technologies and advises the CMS administrator



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CCSQ Stakeholder Engagement Opportunities

- Public Listening Sessions
  - Opportunity for stakeholders to share perspectives and lived
- Advisory Panels & Workgroups
- Comment Periods for Proposed Rules
- Reaching out directly to office staff

Patient Organization and Patient Engagement Opportunities for CMS Medicare Decision-Makings

Kristi Martin, MA, MPA

Director, Camber Collective
Former Chief of Staff and Senior Advisor to the Deputy Administrator of CMS

Vital Voices Workshop
April 28, 2025

Overview of Coverage and Payment Policies and Opportunities for Public Engagement

Kristi Martin, Director, Camber Collective

CAMBER
COLLECTIVE

Agenda

- CMS Medicare Coverage Determination Process
- Medicare Drug Pricing Negotiation Program
- Part A New Technology Add-on Payments
- Part D Formulary Reviews
- CMMI Model Development
- Considerations for Engaging CMS

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Medicare Coverage Determination Processes

Items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category)

National Coverage Determination (NCD)

- Describe the circumstances for Medicare coverage nationwide for a specific medical service, procedure, or device
- Evidence-based process, with opportunities for public participation
- Formal request process
- Public comment period, typically 30 calendar days
- Medicare Evidence Development & Coverage Advisory Committee (MedCAC)
- CMS coverage updates listserv, annual report, NCD database

Local Coverage Determination (LCD)

- Absent an NCD, an item or service may be covered at the discretion of the Medicare Administrative Contractors (MACs)
- Evidence-based process, with opportunities for public participation
- Informal meeting for requests and formal request in writing
- Public comment period, minimum 45 calendar days, and open meeting
- Contractor Advisory Committee (CAC)
- LCD What's New report

Opportunities to Engage MACs

- **MACs**
  - Operate and process Medicare FFS program
    - Process claims, review medical records for claims
    - Provider enrollment, reimbursement, education, and redetermination requests
  - Coordinate with CMS and other FFS contractors
  - **Establish local coverage determinations (LCDs):**
    - Public Comment Period – Stakeholders can submit written feedback on draft LCDs during a 45-day public comment window.
    - Carrier Advisory Committee (CAC) Meetings – Clinicians and subject matter experts provide input on clinical evidence and policy recommendations.

Medicare Drug Price Negotiation Program

Public Comment

- Guidance/rulemaking
- Annual via formal process
- Formal written comment on policy and operations

Data Submissions

- Current negotiation cycle
- PRA with public comment
- Health Plan Management System (HPMS)
- Data and information on selected drugs and therapeutic alternatives

Public Engagement Events

- Current negotiation cycle
- Virtual and in person
- Public town hall focused on the clinical considerations
- Private patient-focused roundtables on each selected drug

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New Technology Add-on Payment

- Temporary payment adjustment provided by CMS to hospitals under Medicare Part A for innovative new medical services and technologies
- Newness, cost, substantial clinical improvement
- Annual New Technology Town Hall meeting and public comment
- Inpatient Prospective Payment System (IPPS) rulemaking
- Alternative pathways
  - Certain transformative new devices
  - Certain antimicrobial products

Part D Formulary Review

Statutory Formulary Requirements

- Protected classes
- 2 drugs/class
- May require more than two drugs for class if additional drugs present unique and important therapeutic advantages, and their absence would substantially discourage enrollment by beneficiaries

Part D Rulemaking

- Annual rulemaking for policy and operations
- Publish in the fall, with 60-day comment period
- Finalize the following spring ahead of the plan bid due date

Oversight and Compliance

- Considers the specific drugs, tiering and utilization management strategies employed in each formulary
- Use of prior authorization, step therapy, and quantity limits consistent with clinical guidelines
- Outlier analysis and clinical justifications

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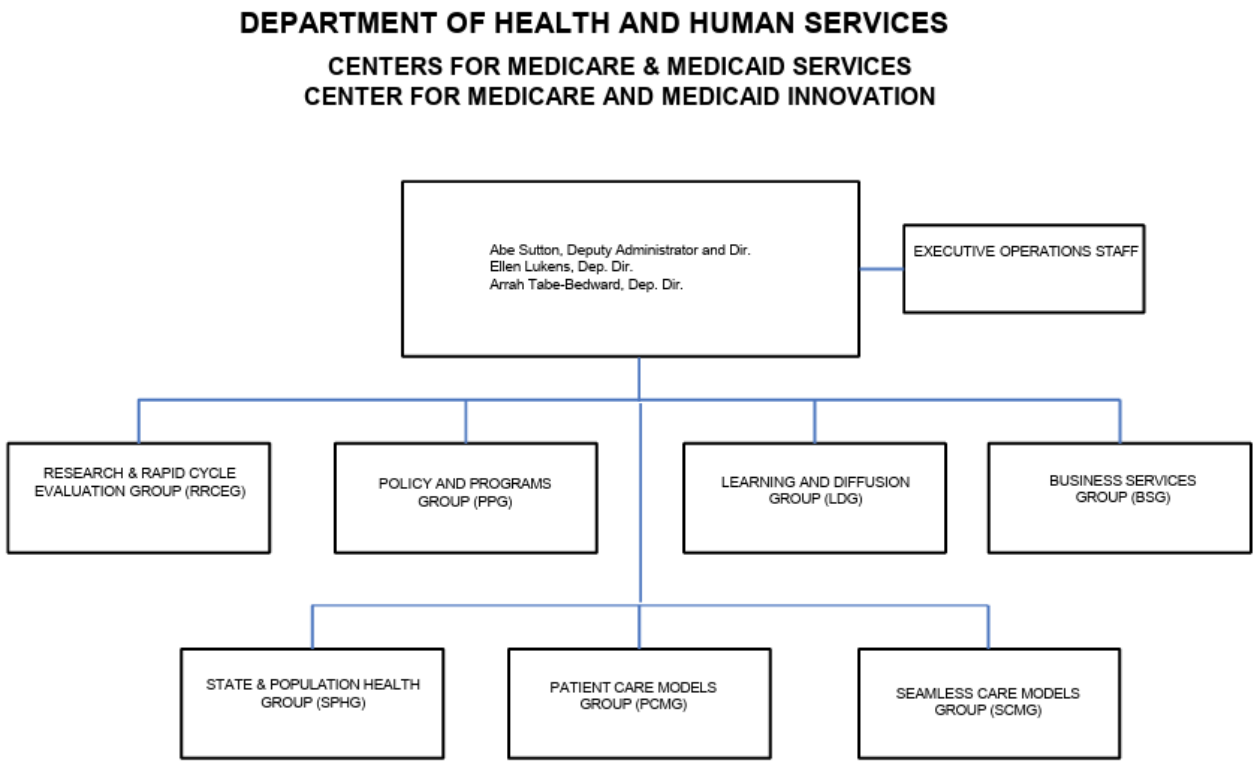
Center for Medicare and Medicaid Innovation (CMMI)



- Tests innovative payment and service delivery models to improve care quality and reduce costs.
- Value-Based Care:
  - Designing care so that it focuses on quality, provider performance, and the patient experience
- Alternative Payment Models
  - A payment approach that gives added incentive payments to provide high-quality and cost-efficient care

https://www.cms.gov/priorities/innovation/about

CMMI Patient Engagement

IDEATION & DEVELOPMENT

- How does the theory of action align with patients' priorities?
- How can quality measures capture patient experience?
- How does the model impact affordability for all patients?
- Will the model increase equitable access to health care across demographic and socio-economic profiles?

RECRUITMENT & RULEMAKING

- What kind of information about a model do patients want to understand?
- How can the Innovation Center communicate the intended benefits of receiving care under the model to patients?

APPLICATION

- Does model applicant distribution provide equitable access for patients to receive care?
- Are the model applicants equitably reaching patients?
- What communication tools are best for patients?

IMPLEMENTATION & EVALUATION

- How are patients experiencing the changes in care delivery?
- How are patients experiencing changes in their health outcomes/quality of life?
- What is the impact of the model on the patient?
- How are we mitigating adverse impact on patients?

SCALABILITY

- How will scaling or expanding a model or its features affect patients?
- How do we ensure that the benefits that patients have gained are built into new programs after a model ends?

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https://www.cms.gov/priorities/innovation/media/document/cmmi-strategy-pcc-webinar-slides
https://www.cms.gov/priorities/innovation/models/recent-milestones-updates

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CMMI Model Development

- Released announcement in March 2025 to align portfolio
- Develop alternative payment models (APMs) which reward health care providers for delivering high-quality and cost-efficient care
- CMS consults with experts across the health care field, including providers, clinicians and hospital systems; patients and patient advocates; policy analysts; other Federal agencies and state governments; members of the Physician-Focused Payment Model Technical Advisory Committee (PTAC); and others
- Town halls, listening sessions, Requests for Information, and proposed payment rules

Consideration for Engaging with CMS

Collect Your Thoughts and Information

- Define the problem
- Collect your evidence
- Articulate your ask (concern, clarification, recommendation)
- Develop strategy
- Deploy tactics

Tactics

- Formal and informal opportunities
  - Meetings
  - Correspondence
  - Public comments
  - Public events
  - RFIs
- Individual organization and coalitions

Key Points

- Connecting the dots between clinical evidence and lived experience
- Express your expertise and experience
- Bridge between various stakeholders (government and nongovernment)

CAMBER COLLECTIVE

Expert Panel Discussion: Strategies for Engaging CMS

Panelists

June Cha PHD, MPH

Policy Director

FasterCures

Milken Institute

Catherine Koola Fischer MPH

Director of Patient Engagement

Institute for Clinical and Economic Review (ICER)

Kristi Martin MA, MPA

Director

Camber Collective

Jean Moody-Williams RN, MPP

Founder and CEO

JDMW Healthcare Advisors

(formerly CMS)

Patient Organization Case Examples

Presenters

Rich Brennan

Vice President of Government Affairs

The ALS Association

Jason Harris

Vice President of Government Relations & Advocacy

National Psoriasis Foundation

Kelly Maynard

President and Founder

Little Hercules Foundation

Tiffany Westrich-Robertson

CEO, Co-Founder, and Board President

AI Arthritis

MODERATOR

Kristin Schneeman

Senior Director

FasterCures,

Milken Institute

Patient Organization Case Examples

Tiffany Westrich-Robertson

CEO, Co-Founder, and Board President, AI Arthritis

“We don’t represent the patient voice, we *are* the patient voice.”

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

www.AiArthritis.org

Patient Identified Issues
Patient "Infused" Solutions

Programs & Projects, Guidance, Resources, Opportunities

Peer-to-Peer

- Conversations, social media, focus groups, DM's, texting, programs
- Connecting the dots and "ah-ha" moments.

Global Network

- Avoid duplication of efforts, resource repository, champion others, collaborate

Innovative 1sts

- Every project is based on problem-solving. What needs to happen to improve outcomes?
- Every project has some novel spin, all LED BY PATIENTS.

Focus on the 95/5

- Knowledge = Empowerment Patient-Led Public Policy Education & Action Program
  - The 95%, ALL VOICES
  - Patient-LED

New Era of Patient Engagement

Government Prescription Drug Affordability Reviews

September 2023

COLORADO

Prescription Drug Affordability Board

We want “real” patients

- The 5% traditional advocate may be biased (i.e., if patient orgs are scripted)
- Better representation of all patient/caregiver groups (other 95%)
- CMS - patient organizations welcome/equal engagement opportunities
- Meeting request CMS - Group input appreciated

November 2023

CMS

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IRA Drug Negotiations

Patient voices needed (CMS)

- AiArthritis recruited 40% of all participants in the Enbrel and Stelara Listening Sessions.
- Peer-to-peer recruitment: Few social media posts/newsletters, high DM’s, personal social media pages with vague/interesting conversation starters
- Peer-to-peer guidance: “Check your email!” Assistance with PDFs/Word

Patient Engagement

Feedback, Opportunities, Adjustments for 2025

We want “real” patients

- The 5% traditional advocate may be biased (i.e., if patient orgs are scripted)
- Better representation of all patient/caregiver groups (other 95%)
- CMS - patient organizations welcome/equal engagement opportunities

Patient voices needed, engagement limitations (CMS)

- Listening Sessions 2024 - Appreciate but challenging!
- Data collection/patient information usage (still unsure)
  - Similar to HTA (limited, needs improvement)
  - Similar to insurance model (therapeutic alternatives/NMS)
- Encouragement to submit comments for improvement

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2023/2024

Patient Engagement

Feedback, Opportunities, Adjustments for 2025

2023/2024

We want “real” patients

- **Of the 40% recruited, 40% of those had never spoken publicly**
  - “We got you.” “Trust us” (peers). “We will help you **PREPARE” - will will NOT script or train you.**
- Several hours day and night working on peer-to-peer recruitment, created associated **education** (“the why you should participate/what is this anyway”).

Patient voices needed, engagement limitations (CMS)

- “Check your spam!” & 4 day turnaround to people who don’t use email regularly. 24 hour follow up, repeat.
- Still left with a lot of questions (from us and the participants):
  - “What did they do with my testimony?” “Did my input do anything?”
- We **struggled finding diverse** pools of respondents who represented various disease subgroups and other demographics, particularly the 95%.

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

PATIENT INCLUSION COUNCIL

EACH PIC COALITION

A two-part, disease agnostic coalition that unites patient organizations and allied groups (EACH), ***as well as patients and caregivers (PIC)*****, to advocate for drug affordability policies that benefit patients.** *Focuses on CMS IRA Drug Negotiations & PDABs.*

Who better to lead a coalition tackling processes in development, without a blueprint, and designed to increase patient voices & highlight patient-reported needs? *(And for PDABs… patient organization seat at the table.)*

www.EACHPIC.org

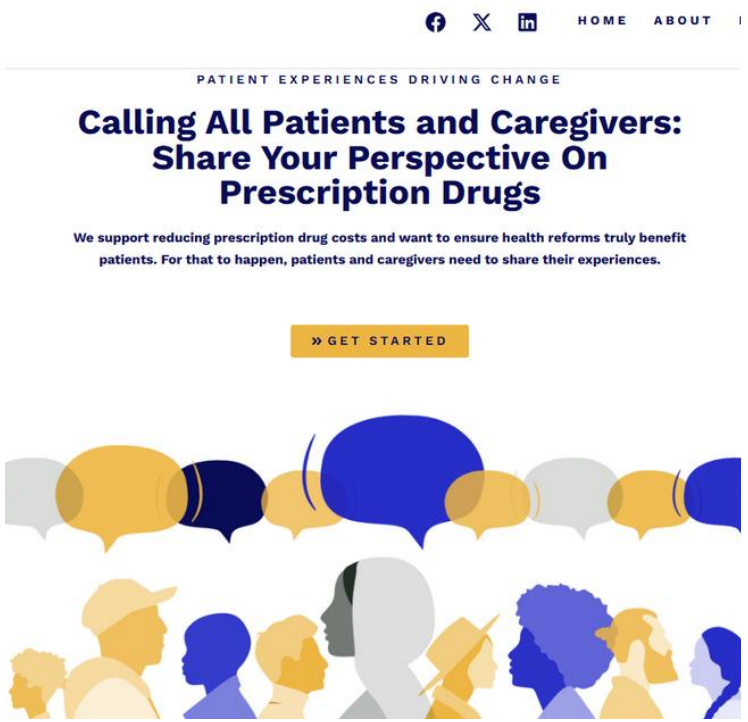
EACH/PIC

Guidance (NOT training/scripting), Resources, Opportunities, Projects

Peer-to-Peer/National Network

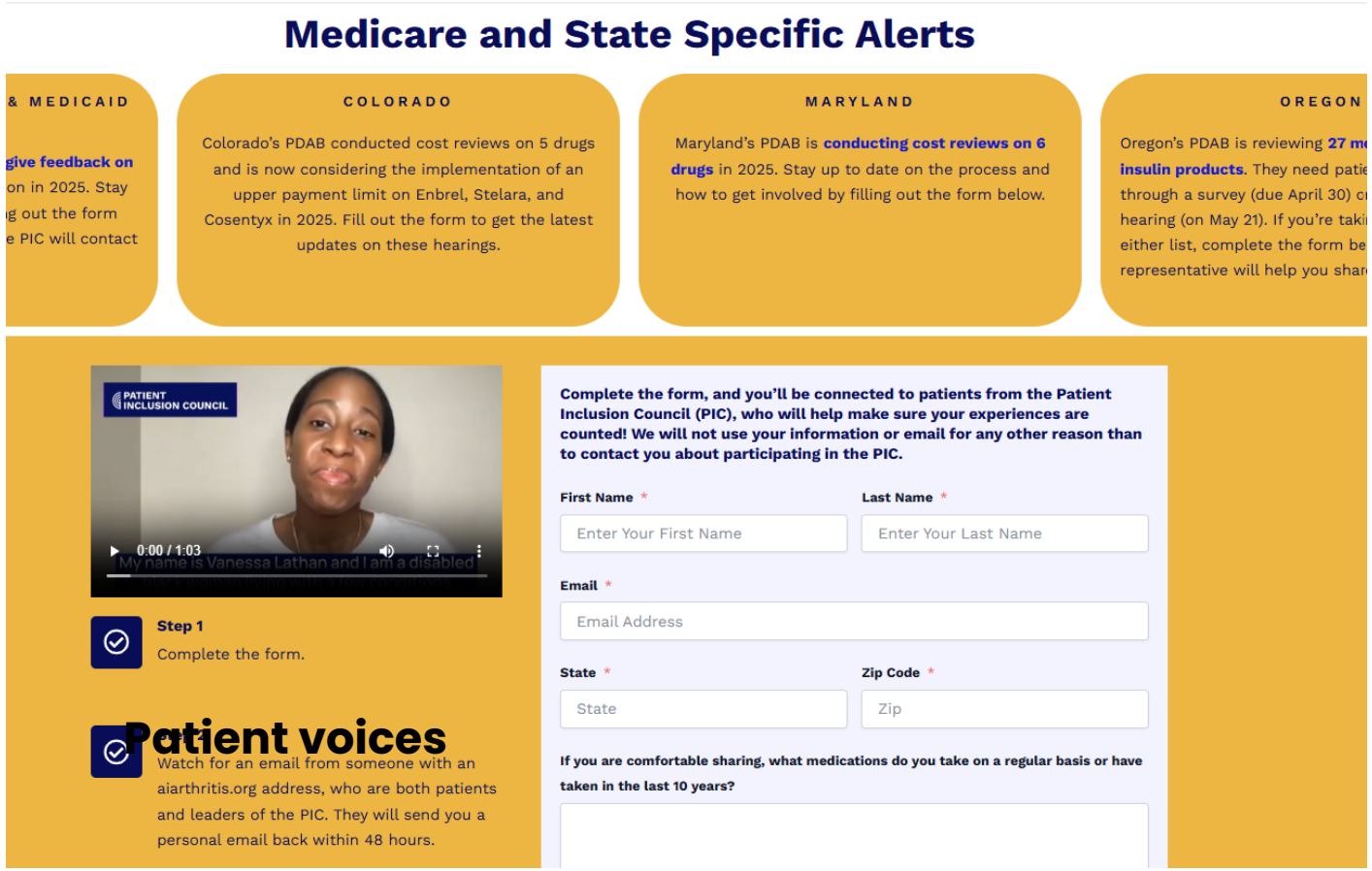
- Avoid duplication of efforts, resource repository, champion others, collaborate
- Patient Org fair and equal seat at the table
- Peer-to-peer recruitment, education, preparation (NO TRAINING)
- PIC: Leave your opinions at the door, share your truth

PIC - Adopted 95/5



Problem Solving: SURVEY

- Patient opportunity - affordability & unaffordability WHY. PDABs, CMS, Legislators. Data matters. PRP led/Patient Orgs/Data Scientist



Patient voices

- PIC (led by AiArthritis) recruited 60% of Otezla participants
- PIC also recruited an additional 6 for other roundtables
  - Challenge explaining the process to EACH participants
  - We do all the heavy lifting, will notify (and invite) EACH participants of engagement
- We plan to start following up with CMS meetings, including EACH/PIC and EACH and PIC.
  - Including OUR SURVEY DATA

PATIENT INCLUSION COUNCIL

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Patient Engagement

Feedback, Opportunities, Adjustments for 2025

We want as many patients/caregivers as possible

- While we still think conversations SHOULD involve affordability challenges as well - specific to Medicare/drugs under negotiation (“affordability review”) we respect non-Medicare patients/caregivers are welcome to help understand the disease and medications overall (data).
  - *But... it seems the affordability/unaffordability why would be vital if the patient experience data is being used to influence the negotiations?*

Improvements! And continued challenges...

- We can (and will) submit more testimony from patients who did not participate/end of April).
- Private, discussion format.
- 4 day turnaround, email, forms, “Check Spam”, FOLLOW UP!
  - PIC SERVICES!!!
- Not sure how our participation influences negotiations.

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2025

Take Aways

- **OPPORTUNITY**
- **ALL VOICES**
- **CHALLENGES**
- **PEER-LED WORKS**
- **OPPORTUNITY (AGAIN)**
- **5% + 95% (25% goal)**
- **COLLABORATE, CONNECT, IMPACT**

Thank you!

Patient Organization Case Examples

Jason Harris

Vice President of Government Relations & Advocacy,
National Psoriasis Foundation

Patient Organization Case Examples

Rich Brennan, MA

Vice President of Government Affairs, The ALS Association

Patient Organization Case Examples

Kelly Maynard

President and Founder, Little Hercules Foundation

Patient Community Wish List DUR/P&T
Everylife Foundation for Rare Diseases
Access & Value Working Group

 Transparency/Timeliness	 Patient/Advocate/Expert Participation	 Policy/Access
• Public Notice of meeting at least 30-days or consistent with State Open Meetings law, whichever is greater. • Agenda including name of drugs being reviewed and speaking sign-up posted at least 14 days prior to scheduled meeting. • Allow applications for speakers once agenda is posted. • If coverage policy/criteria changes are proposed, those proposed changes are also posted. • All methodologies for value assessments or other pricing determinations including those of the "underlying health economics considerations" should rely on multiple sources and become public within at least 30-days prior to the meeting or consistent with the State Open Meetings law. • States require their Managed care organizations to publish their DUR/P&T meeting information and public coverage policies.	• Acceptance of written and oral testimony from patients and caregivers. • Virtual meeting attendance options continue to be available post COVID19. • Uniform processes across Medicaid agencies (i.e., meeting announcements, speaker policies). • In states where there is an RDAC or a specialized utilization board, make use of that expertise in clinical reviews of rare disease or condition products. Alternatively, rare patient and specialist empaneled in committee. • State programs perform outreach to advocacy organizations to identify rare disease expertise in each state. • Testimony is given prior to vote. • Accessible meeting format for everyone. • Committee consultation with specialist experienced in the treatment of applicable rare disease.	• Prior authorization policy criteria/proposed criteria available publicly and easily accessible. • Require all newly approved drugs for rare disease to be reviewed at the next medical coverage review meeting **unless FDA approval becomes public less than 30 days prior to the meeting;** require medical coverage review meetings to be conducted at least quarterly. • Prohibit the sole use of QALYs to inform Medicaid coverage decisions or the use of such data points as part of coverage review discussions. • Products approved under the Accelerated Approval Pathway are no longer considered experimental. • Address coverage gaps upon FDA approval and any significant delays.

Brainstorming your CMS Engagement Approach

Brainstorming your CMS Engagement Approach

- (30 minutes) At your tables discuss the following questions:
  1. What are some ideas, concepts, or approaches that stood out to you today that might help you rethink your organization's approach to engaging with CMS?
  2. How might those approaches need to be adapted for your patient organization or patient community?
  3. What are some thoughts about how to ensure that the data and information collected are able to be used by CMS?
  4. What are some ideas or possible next steps that your organization might pursue to prepare for CMS engagement?

- (10 minutes) Each table will briefly report out on some of the highlights that emerged for each question

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Discussion Reflections and Closing Remarks

FasterCures' Capacity Building Portfolio

Emerging

Support emerging nonprofit research organization leaders through mentorship, a collaborative peer support network and access to experts, programming, and events.

Programs:

- **Rare as One Mentorship Program**
- **LeadersLink**

Established

Increase capacity to advance innovative therapies through addressing patient foundations' greatest needs and fostering an environment that leverages knowledge sharing, highlights best practices, and creates new connections.

Programs:

- **TRAIN**

Advanced

Provide philanthropic innovators with thought leadership opportunities to help drive change in biomedical research and development.

Programs:

- **Changemakers**

Events Thought Leadership Marketing

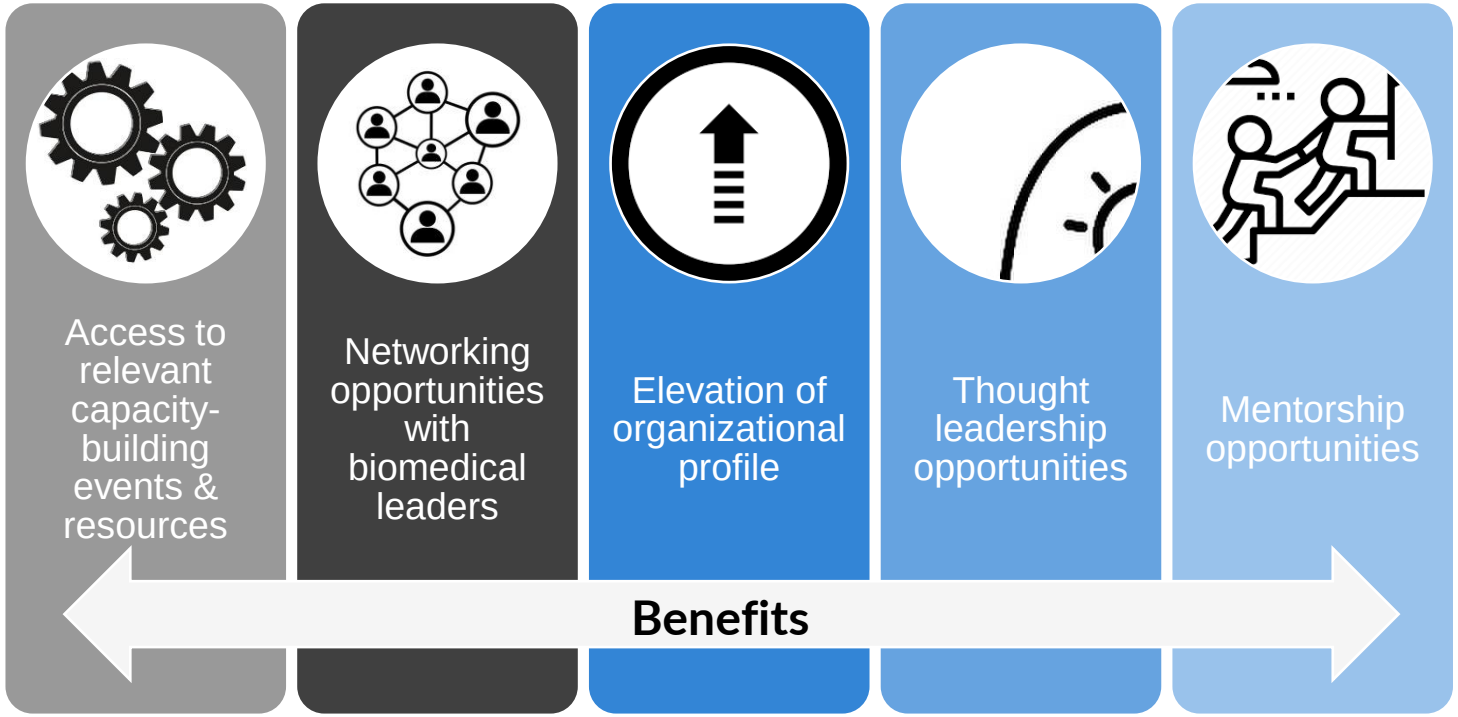
TRAIN: The Research Acceleration & Innovation Network

TRAIN's objectives are:

- **Encourage innovative and best-practice approaches to entrepreneurial philanthropy in medical research**
- **Build more and better networks between disease foundations and other R&D stakeholders**
- **Encourage more collaboration and idea and resource sharing among TRAIN stakeholders**
- **Provide capacity-building assistance to TRAIN stakeholders to address their top priority areas**

Join TRAIN and/or serve as a mentor for a rare disease org!

Join TRAIN and enjoy the following **benefits:**



There is no cost to apply and membership is free!

Apply to TRAIN today!

Questions? TRAIN@milkeninstitute.org

MILKEN INSTITUTE

FasterCures LeadersLink

- LeadersLink is a unique mentorship program designed for emerging executive leaders of nonprofit organizations who conduct or fund biomedical research.
- Benefits of the program include:
  - ▪Being paired with an experienced mentor who can help provide valuable insights and feedback along your leadership development journey.
  - ▪Acquiring knowledge and relationships to complete an individualized capstone project that addresses their critical needs as an executive leader.
  - ▪A community of peers at other nonprofit research organizations, mentors and experts, and a broad network of professionals across the biomedical ecosystem.

If you are interested in participating as a mentee, mentor, or expert, we encourage you to learn more here.

Applications for new program mentees and mentors open in January 2026!

MILKEN INSTITUTE

Upcoming Milken Institute and FasterCures Events

Global Conference

- May 4-7, 2025
- Los Angeles, CA

Future of Health Summit

- November 2025 (Dates TBD)
- Washington, DC

Join Communities of Practice

- Open to members of TRAIN and Rare as One Mentorship Program
- Platform to discuss areas of shared challenge and need
- Collaborative opportunities to share promising practices, strategies, and ideas

Links to Relevant Resources

- CMS Resources:
  - Public Comments | CMS
  - OHEI Stakeholder Engagement | CMS
  - Medicare Coverage - General Information | CMS
  - CMS Organizational Chart | CMS
  - Legislative-Mandates-Supplemental-Material
  - Medicare Drug Price Negotiation | CMS
- Additional Resources:
  - 21st Century Cures Act | FDA
  - How patient advocates can engage with CMS - Bio.News
  - Engaging Consumers in Medicaid Program Design: Strategies from the States - PMC
  - Engaging Patients in Value-Based Payment - Partnership to Improve Patient Care
  - National Health Council: Medicaid Resources
  - ICER: Patient Engagement Resources
  - Little Hercules Foundation: Rare Access & Coverage Education
  - Coalitions: MapRX, ITEM Coalition, and EACH/PIC.

Next Steps and Future Work

- The FasterCures team will continue advancing our work on patient engagement with CMS
- A series of webinars on this topic will be hosted throughout the summer—invites and additional details coming soon!
- We will be compiling our work on this effort into a toolkit that will be released in Q1 2026.
- Please reach out if you're interested in connecting with us on this initiative.

Thank You!

For additional questions or to learn more about TRAIN,
please contact TRAIN@milkeninstitute.org