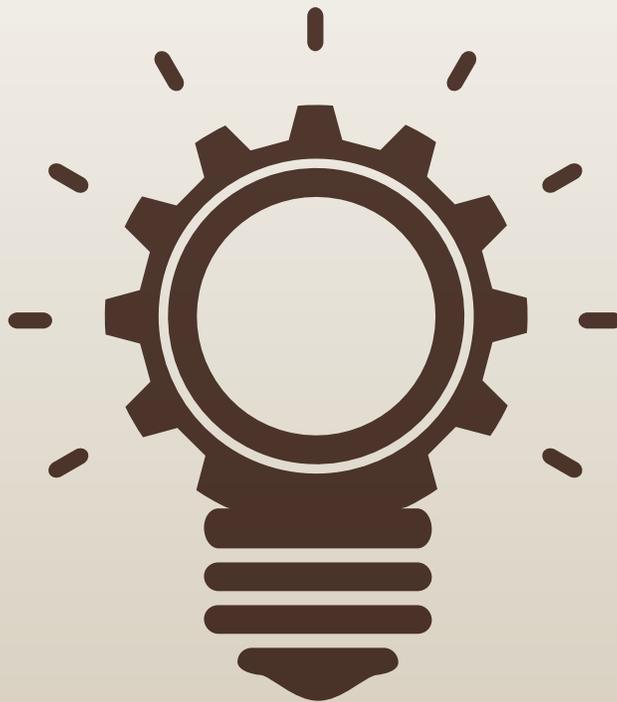


Working with Regulators: A Focus on CMS

An Educational Program of the Cancer Policy Institute at the Cancer Support Community in Partnership with Uniting a Community (UaC):
Policy, Advocacy, Education and Action Network



Tool Kit: A Guide for Patient Advocates

The Cancer Policy Institute *at the* 
CANCER SUPPORT COMMUNITY

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ABOUT THE CANCER SUPPORT COMMUNITY

The Cancer Support Community (CSC) is an international nonprofit dedicated to providing support, education and hope to people affected by cancer. CSC offers a menu of personalized services and education for all people affected by cancer. Its global network brings the highest quality cancer support to the millions of people touched by cancer. These support services are available through a network of professionally-led community-based centers, hospitals and community oncology practices as well as online at www.cancersupportcommunity.org and over the phone at 1.888.793.9355, so that no one faces cancer alone.

A Message from Kim Thiboldeaux

President and CEO
Cancer Support Community

“We want to know what matters most to patients and family members. We are very interested in exploring how best to engage patients in the regulatory process.”

–Shari Ling, MD, Deputy Chief Medical Officer, CMS

The Affordable Care Act (ACA) is the tip of a very large, multi-faceted iceberg, one that is moving inexorably forward and will result in broad, deep changes in the way that health care in this country is understood and delivered. These changes are already exerting a significant impact on cancer research and care, and will continue to do so for the foreseeable future. This is also an era in which the patient voice and genuine, active patient participation have become integral to the process of developing and implementing biomedical research and health care policy.

That process is complex and multidimensional—but also well-defined and transparent. The ability to influence the outcomes requires that an organization have a working knowledge of how the process works, which agencies are responsible and who makes the decisions. It is also critical to understand the ways in which electoral politics at both the national and state level impact health care policy. While that sounds straightforward, the regulatory process often can appear impenetrable to the organizations who seek to make their voices heard and influence the outcomes.



Kim Thiboldeaux

This Tool Kit is intended as a practical guide for patient advocacy organizations in their efforts to educate themselves about the regulatory process, develop appropriate staff expertise and responsibility for this area, and ultimately make a difference. We hope that it contributes to opening the doors to patient engagement and productive interaction between your organization and the individuals charged with formulating, reviewing and enacting the rules that shape cancer care delivery in this country.

Our special thanks to GlaxoSmithKline and Uniting a Community for sponsoring the meeting we held on Working with Regulators in June, and for their ongoing support of our efforts.

Warm regards,

A handwritten signature in black ink, appearing to read "K. Thiboldeaux". The signature is fluid and cursive.

Kim Thiboldeaux
President and CEO

Understanding the Landscape: How are Rules Proposed and Enacted

THE CENTER FOR MEDICARE AND MEDICAID SERVICES

The Center for Medicare and Medicaid Services (CMS) is the federal body, authorized by Congress, responsible for administering Medicare, Medicaid and the Children's Health Insurance Program (CHIP) within the Department of Health and Human Services. CMS administers the Medicare program and works with state governments to administer Medicaid and CHIP.

MOVING TO A PATIENT-CENTERED PROCESS

CMS is currently engaged in an agency-wide program to transform their decision-making process from one that is primarily product and volume driven to one that is “people-centered and outcomes driven.” This effort represents a fundamental change in the function of CMS and opens new doors to patients and their advocates to access and influence both the process and its outcomes.

In terms of oncology specific issues, this means:

- Patient-centered measures of cancer care are critical to incentivize improvements
- CMS welcomes input from the cancer community on the quality issues that most affect patients and caregivers
- CMS is working with a range of external stakeholders to align the best measures across settings (meaning that the same measures will apply to oncologist offices, community hospitals, academic medical centers and cancer centers)
- Increased emphasis on improved outcomes and quality of care
- Increased emphasis on coordination of care
- The development of new payment systems that emphasize value-based purchasing, episodic care, care management, cost-effectiveness and data transparency

Patient-reported outcomes are a critical component of this transformation. CMS now includes patients in all of its work developing measures as a means of understanding the outcomes that are most important to patients and families. CMS is also working with a number of other agencies and organizations to develop and incorporate patient reported outcomes for a wide range of clinical reporting and outcomes measurement programs. While some of this is driven by the requirements of the ACA, it also reflects a broader, deeper change in health care policy and delivery.

The time is right to make the voices of cancer patients, their caregivers and advocates heard in a meaningful way. Achieving that goal requires that advocates understand how rules are proposed and implemented and the ways in which they can best influence this process.

CMS FACTS AND FIGURES

CMS is the largest purchaser of health care in the world

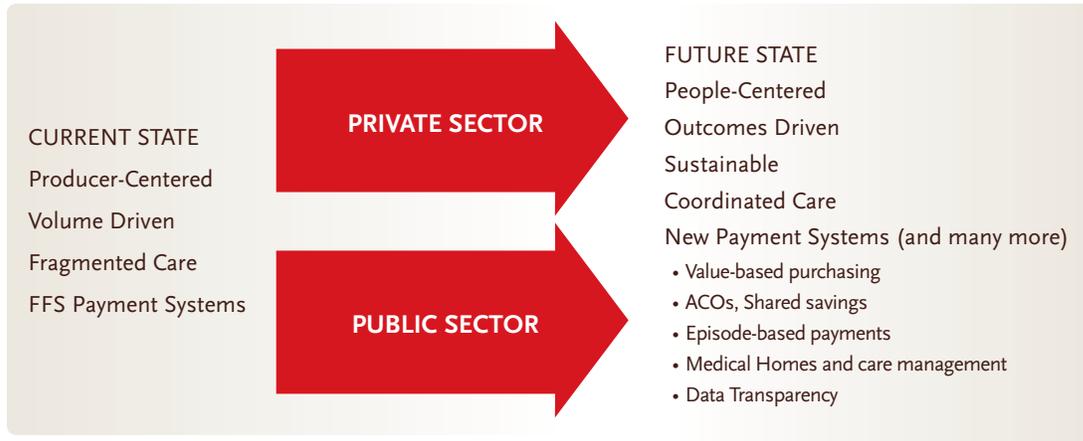
Medicare and Medicaid combined pay approximately one-third of national health expenditures—approximately \$800 billion a year

CMS provides health care coverage to roughly 105 million beneficiaries or 1 in every 3 Americans

Millions of consumers will receive health care coverage through new health insurance authorized by the Affordable Care Act

(Source: Shari Ling, MD, CMS Deputy Chief Medical Officer, Center for Clinical Standards and Quality)

DELIVERY SYSTEM AND PAYMENT TRANSFORMATION

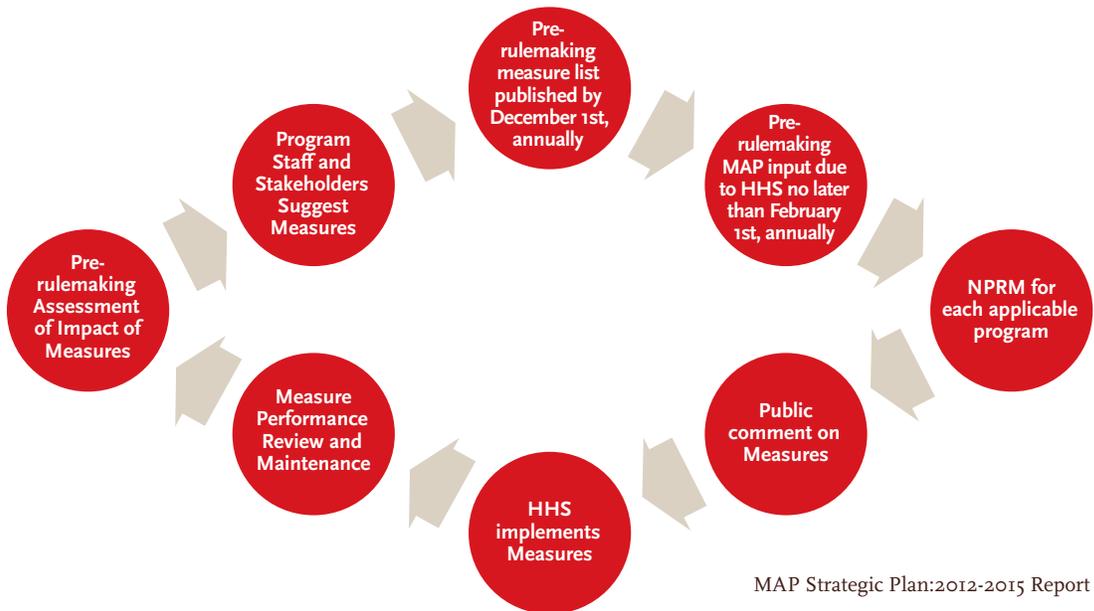


THE REGULATORY PROCESS 101

CMS—as with all federal agencies—makes decisions about what it will and will not cover through a regulatory process. While this process is transparent and the points at which advocates can access it are well-defined, it is also complex and can be difficult to track and respond to in a timely, effective way.

The outline below summarizes the basic process by which rules are proposed, reviewed and implemented.

MEASURE SELECTION PROCESS MEASURE IMPLEMENTATION CYCLE



NOTE: While this outline describes the overall process that federal agencies follow to propose and implement rules, there are many other considerations that influence the decision-making process and the opportunities to intervene and comment. These are discussed in more detail below.

AN AGENCY DECIDES TO BEGIN RULEMAKING:

1. If Congress passes a law that directs the agency to take action on a specific subject
2. If the agency surveys its area of responsibility and establishes a goal or issue as a priority for action

AN AGENCY INVOLVES THE PUBLIC IN A PROPOSED RULE BY:

1. Publishing its annual “**Regulatory Plan**” in the fall, and its “Agenda of Regulatory and Deregulatory Actions” in the spring and fall. Together, these are referred to as the **United Agenda.**” Most of this material is available in the *Federal Register*, and all of it is posted on [reginfo.gov](https://www.reginfo.gov) and [regulations.gov](https://www.regulations.gov).
2. Informal information gathering with people and organizations interested in the issue. This occurs prior to issuing a proposed rule.
3. Publishing an “**Advance Notice of Proposed Rulemaking**” in the *Federal Register*. The Advance Notice is a formal invitation to participate in shaping the proposed rule.

Note: Having someone in your organization charged with monitoring the Federal Register is critical to participating in the regulatory process.

4. Once the Advance Notice is published, any individual or group can respond by submitting comments to develop or improve the draft proposal, or recommend against it.

Note: Some agencies develop rules by negotiating. In this process, they invite interested persons or groups to meetings in which they attempt to reach a consensus on the proposed rule.

5. The agency then issues a **Notice of Proposed Rulemaking (NPRM)**. All proposed rules must be published in the *Federal Register* to notify the public and give them the opportunity to submit comments. In general, agencies allow 30 to 60 days for comment, although that can vary.
6. Agencies can extend or re-open the comment period when they feel they need more information or when comments have raised new issues not discussed in the initial proposed rule.
7. Agencies can also hold public hearings, either because they are required to do so, or because they want to collect more information or increase public understanding of the proposed rule.

Note: Many agencies are now using webinars and interactive sessions to broaden the audience for their public hearings.

8. The agency has the option of establishing a second period for reply comments. This is not required by law.

Note: Most agencies now strongly prefer that comments be submitted electronically. This makes the comments more available to the public and helps the agency organize the comments. Instructions for submitting electronic comments are found in the Federal Register. For information on using the federal rulemaking portal, go to [regulations.gov](https://www.regulations.gov) and click on the “Help” pages.

PUBLIC COMMENTS AFFECT THE PROPOSED RULE BY:

1. Allowing access to any interested party to submit a comment on any part of the proposed rule
2. Contributing the body of scientific evidence and expert opinion
3. Providing persuasive new data or policy arguments
4. Posing difficult questions or criticisms

Note: This is not a “vote,” and the agency cannot base its final decision on the number of comments received. Generating large numbers of form letters is not an effective intervention. It is much more important to provide information and comments that are evidence based and supported by facts and data.

ONCE THE COMMENTS ARE RECEIVED, THE AGENCY CAN:

1. Move forward with the **Final Rule**—if it is convinced the rule will help accomplish the goal or solve the problem
2. Continue the rulemaking process, but change aspects of the rule
3. Issue a new supplemental proposed rule that reflects major changes
4. Terminate the rulemaking

THE FINAL RULE

1. Has a preamble, summary, effective date and supplementary information
2. Is published in the *Federal Register*
3. Generally goes into effect no less than 30 days after the date of publication
4. Is integrated into the Code of Final Regulations on the date of publication

Note: There are exceptions in which an agency can issue a Final Rule without first publishing a Proposed Rule. These include emergencies, instances in which a public comment period is deemed “impractical and unnecessary,” and when the rule affects only internal agency procedures or federal employees.

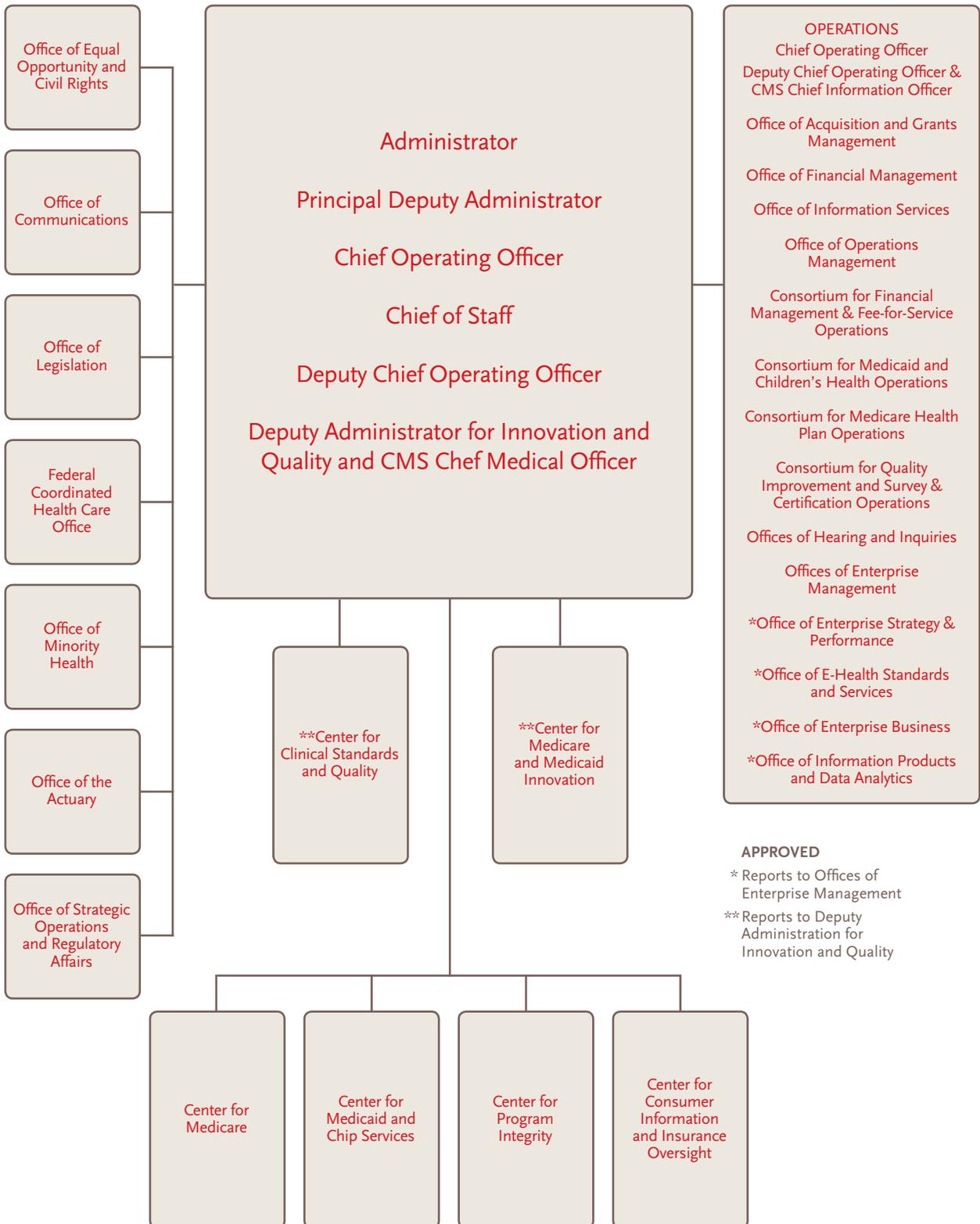
- Final rules that are issued without first publishing a proposed rule are often characterized as “interim final rules” or “interim rules.” These rules are effective immediately upon publication but can be altered if public comment warrants.
- **Direct Final Rules** are those in which the agency decides that the proposed rule is unnecessary because it is routine or non-controversial. For these, the agency sets an effective date contingent on not receiving negative comments during the comment period.

AFTER THE FINAL RULE IS ISSUED:

- The regulatory process enters the compliance, interpretation and review phase. This is designed to provide those responsible with enforcing the rule with needed materials and training.
- The comment period is re-opened only if the courts set aside all or any part of the Final Rule.
- The agency may issue interpretive rules and policy statements. These are guidance documents and are not subject to the notice and comment period.

HOW CMS IS ORGANIZED

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

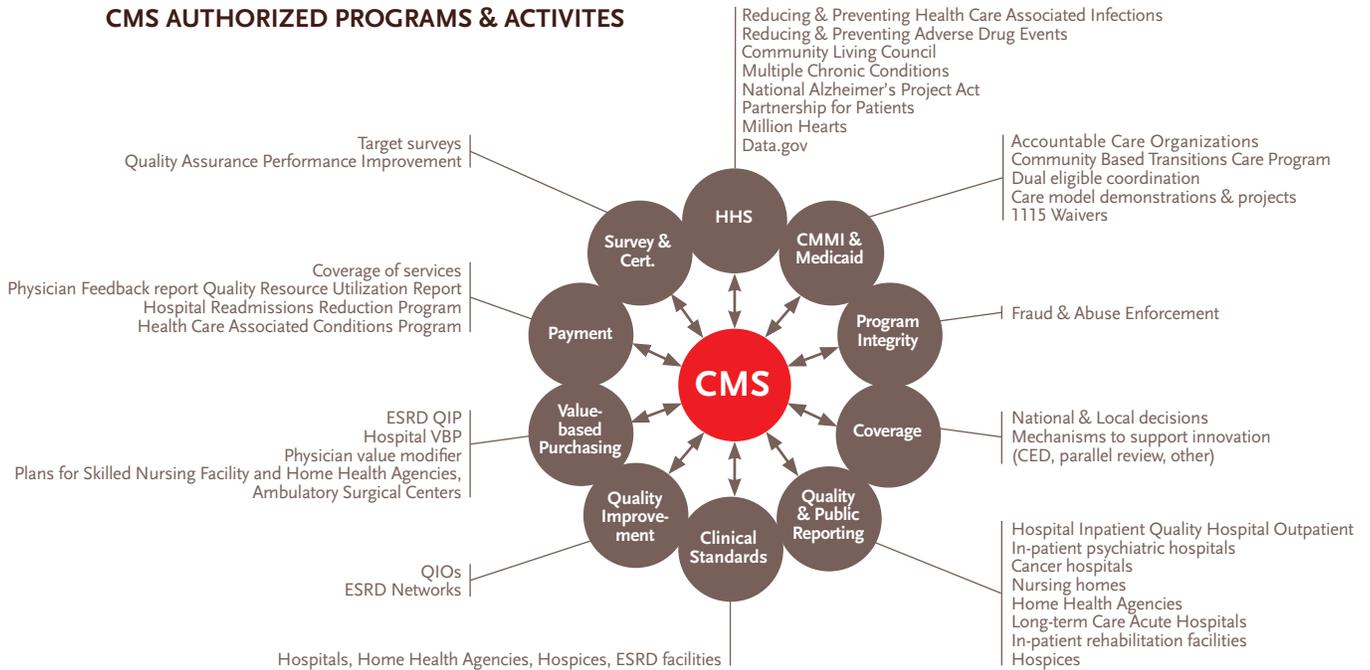


APPROVED

* Reports to Offices of Enterprise Management

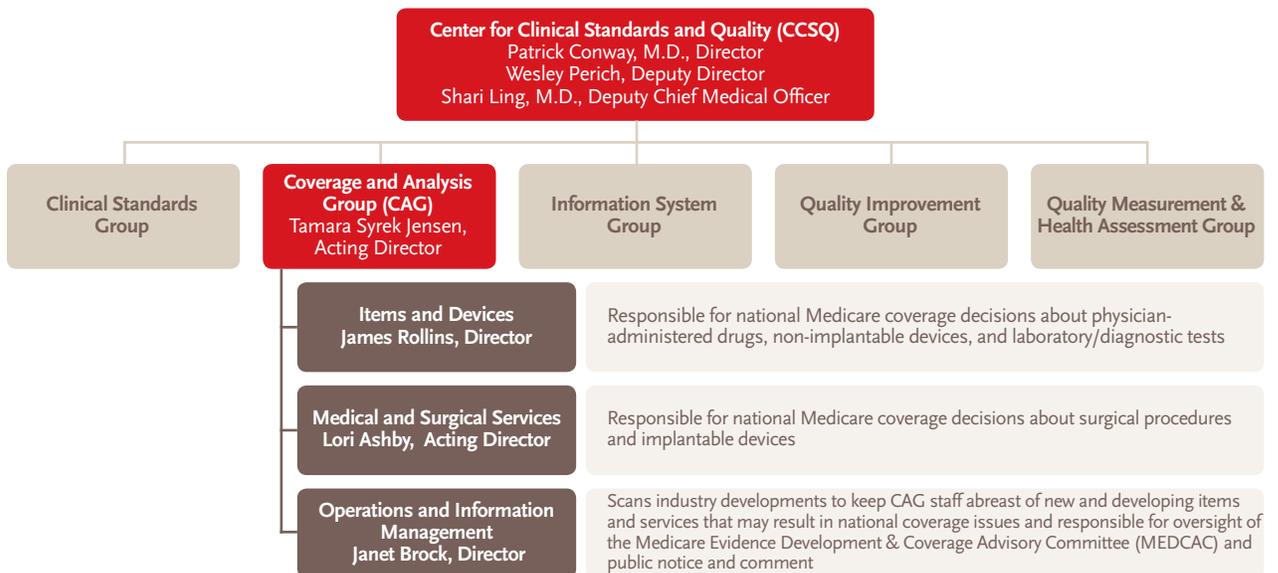
**Reports to Deputy Administration for Innovation and Quality

CMS AUTHORIZED PROGRAMS & ACTIVITIES



- The two charts included here show the organizational structure of CMS and the scope of the agency's programmatic responsibilities. The Coverage and Analysis Group, responsible for proposing and implementing many of the national coverage decisions that impact cancer patients, is housed in the Center for Clinical Standards and Quality (CCSQ). CCSQ oversees National Quality Initiatives. This group is very open to patient input. Understanding the structure of CCSQ and maintaining communications with key staff is critical to optimizing access and influence in the rule making process.

CCSQ OVERSEES NATIONAL QUALITY INITIATIVES AND INCLUDES THE COVERAGE AND ANALYSIS GROUP



Sources: https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CCSQ.html (Page last updated 6/2/2014) and http://cms.hhs.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf (Document last update Spring 2010).
CCSQ: Centers for Clinical Standards and Quality

NATIONAL VS. LOCAL DECISION COVERAGE DETERMINATIONS

CMS coverage decisions are made at both the national and the local level.

- National Coverage Determinations (NCDs) are issued by the Coverage and Analysis Group and bind all local Medicare contractors. Less than 5 percent of all coverage determinations are NCDs. These are usually high-volume, controversial and/or expensive procedures. Proposal and implementation follow set timelines and involve a lengthy public process.
- Local Coverage Determinations (LCDs) are issued by local Medicare contractors and govern a specific part of the country. If there is no NCD, groups known as Medicare Administrative Contractors (MACS) can develop an LCD. This process also follows set timelines, but the review process is generally faster than that of an NCD. By definition, this means that there can be variations in coverage from one area of the country to another. LCDs make up about 25 percent of coverage decisions.
- Articles are policy updates, coding and claims guidance issued by local Medicare contractors. These account for almost 80 percent of changes in Medicare policy in a given year.

WHAT TRIGGERS AN NCD?

CMS can initiate an NCD as the result of either an internal or external request or need.

- External requests come from a range of stakeholder groups—such as MACS, providers, beneficiaries or professional societies. They result from either a situation in which there is a national non-coverage policy in place, or in which there is substantial variation on LCDs.
- CMS can also generate NCDs internally. These usually arise as a result of major technological advances with potential clinical or economic impact, extensive literature or an important new study on a specific issue, or major concerns about inappropriate use of a technology or treatment.

Whether external or internal, the triggers that lead to NCDs are based on several major categories. These include:

- Effectiveness of the therapy
- Safety of post-market concerns
- Off label or expanded use
- Utilization spikes/High patient volumes
- Challenges to the standard of care
- Cost concerns

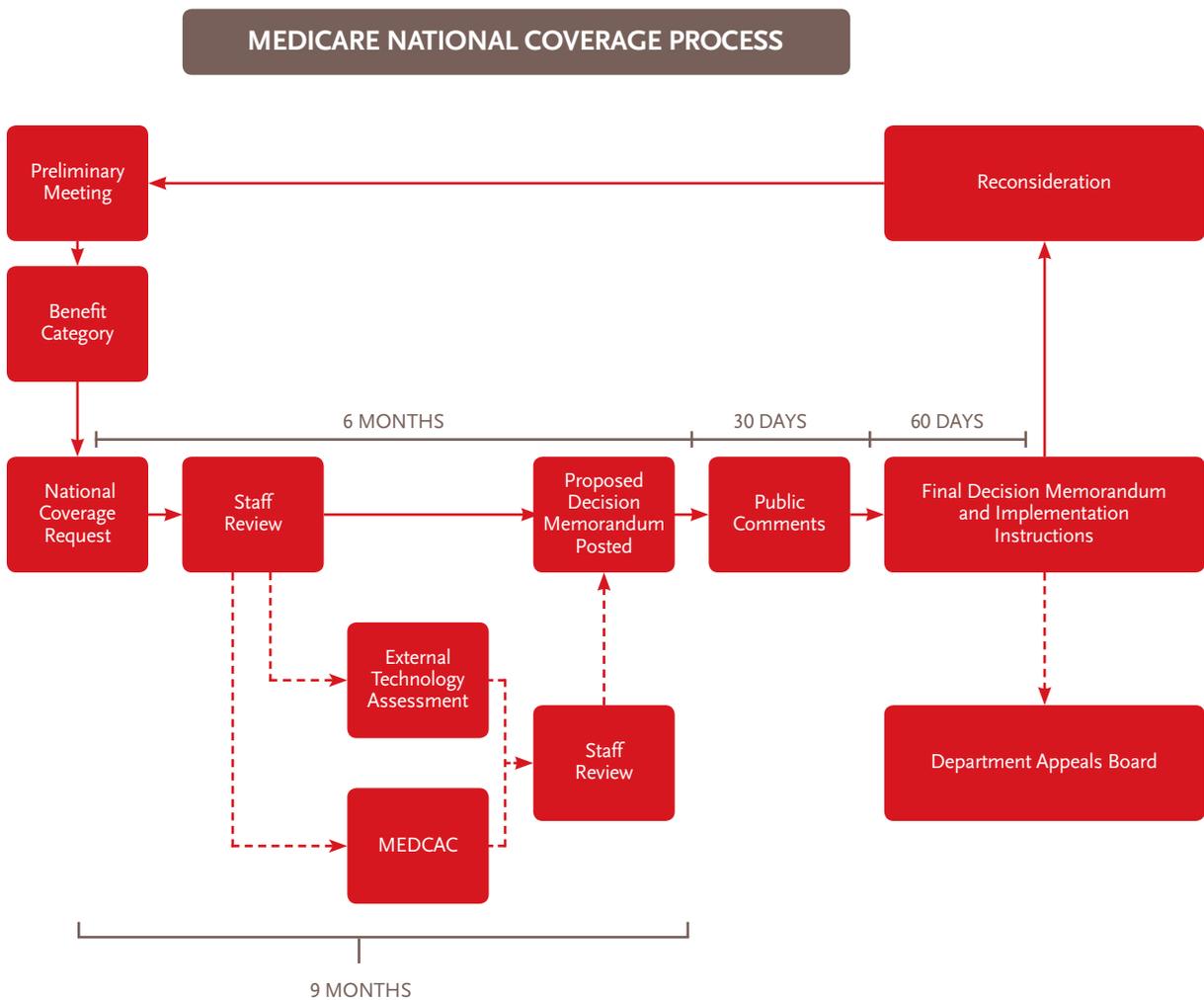
Within CMS, the standard that drives the NCD process is “reasonable and necessary,” meaning that the evidence is sufficient to conclude that the item of service in question:

- Improves health outcomes
- Is generalizable to the Medicare population
- Is generalizable to the general provider community

In other words, the new therapy or approach must be demonstrated to provide improved clinical outcomes to the Medicare beneficiaries. Those outcomes include:

- Longer life with improved function
- Longer life with arrested decline in function
- Significant improvement in symptoms allowing for better function
- Reduced need for tests and treatment

NCD PROCESS



The key checkpoints in the NCD process are:

- Formal request for a NCD Decision (with a 30-day comment period)
- Determination of the benefit category
- CMS internal review of evidence
- Technology assessment by an expert medical panel (MEDCAC)
- Proposed determination (with a 30-day comment period)
- Final determination posted on the CMS website 60 days later

Understanding the landscape of CMS and its decision-making process is critical to knowing when and how best to access, intervene and influence that process. The next section of this Tool Kit addresses those issues.

Working with CMS: A Guide to Access and Influence

Developing a working knowledge of the mechanics of the regulatory process and the role that CMS plays is only the first step in assuring that the patient voice is heard, and matters. It is critical to:

- Monitor CMS activity to be aware of proposed new rules
- Understand the engagement opportunities available to patient advocates in the national coverage process
- Understand the types of evidence and data that influence the decision-making process
- Understand the benefits—and potential risks—of proactively requesting a coverage decision
- Develop strategies to optimize engagement with CMS and its key staff

MONITORING CMS NCD ACTIVITY

There is no reliable list of planned or future NCDs, (The Potential NCD Topics has not been updated since November 2012), but there are a number of resources available to help track CMS activities and proposed rules.

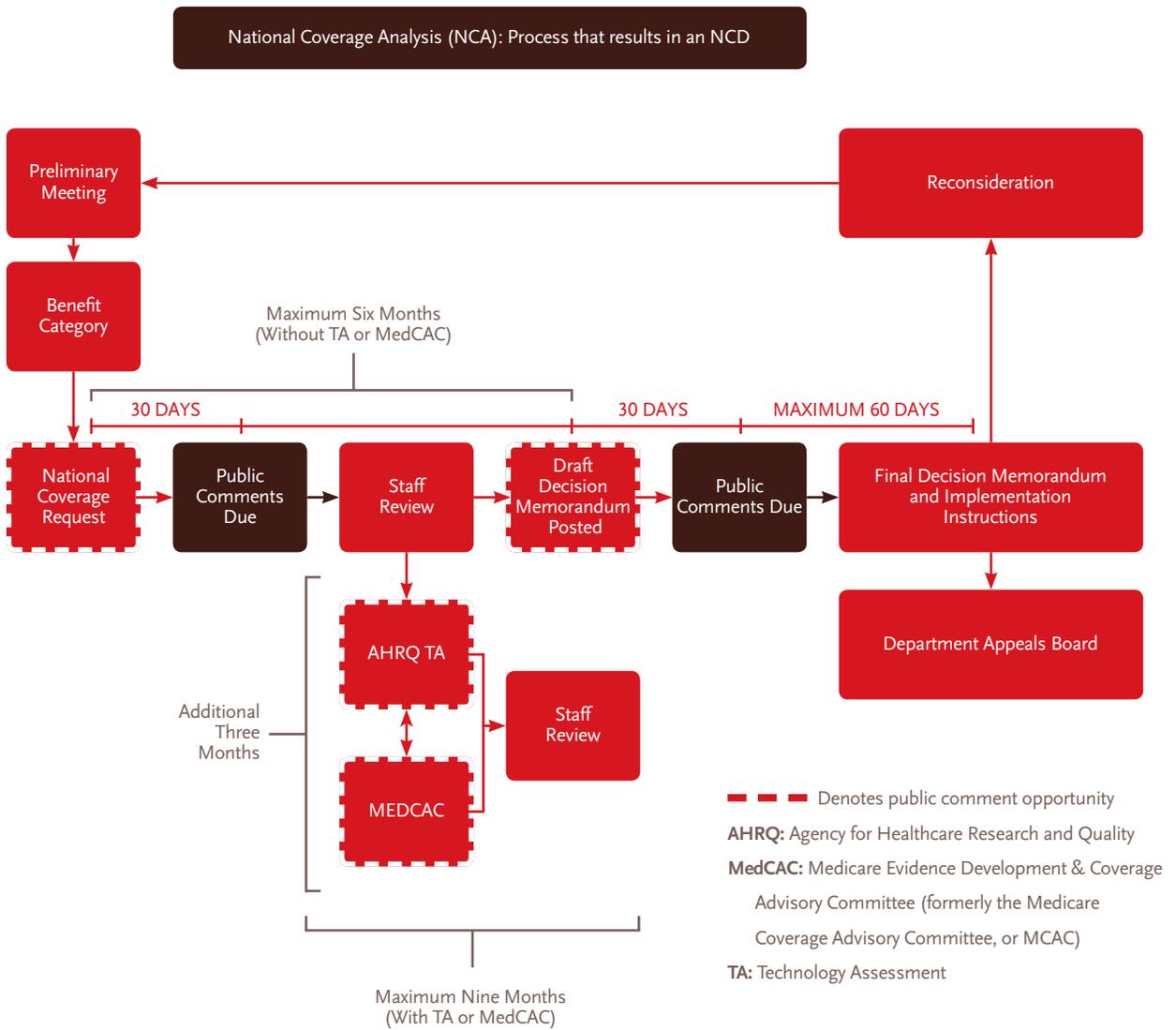
- Sign up for the CMS coverage listserv to receive notification regarding updates on CMS coverage pages. Find this by going to CMS.gov and looking on the bottom right of any page.
- Check <http://go.cms.gov/1mADpFS> for a list of all open NCDs. Click on each NCD to find a tracking sheet that lists the dates for public comment
- Monitor the Federal Register.
- Monitor the Agency for Healthcare Research and Quality (AHRQ) technology assessments in progress. These are often signals that CMS is interested in opening an NCD on the topic. <http://1.usa.gov/1kMexdy>.
- Join the National Quality Forum. This organization provides multiple information tools, forums and resources for patient groups interested in understanding and influencing quality measure in health care delivery.

ENGAGEMENT OPPORTUNITIES WITH CMS

The CMS regulatory process provides many opportunities for stakeholders to interact with staff, to provide comments and to influence the outcomes. These include:

- Requesting that an NCD be opened or reconsidered
- Providing early input on a trial design of a therapy likely to be reviewed by Medicare prior to launch
- Responding to an open NCD to inform coverage parameters

MEDICARE'S NCD PROCESS INVOLVES MULTIPLE STEPS AND OPPORTUNITIES FOR COMMENT



Medicare requests MEDCAC meetings and/or AHRQ TAs for a subset of NCDs when they feel an additional review of the evidence by other experts would be helpful

REQUESTING THAT AN NCD BE OPENED

When an issue of importance presents itself to the patient community, the temptation is always to take a proactive stance and to ask CMS to make a decision on coverage at the national level. According to Jenny Gaffney, a Director at Avalere Health, “Given the high stakes associated with pursuing an NCD, which is time and cost intensive, with its multifaceted strategy, the life sciences industry has historically supported local coverage processes.”

The decision to request an NCD is a strategic move that should be undertaken only under select circumstances and with considerable due diligence. If there is no NCD, coverage may already be available. In others, there may not be a compelling need for a NCD.

Generally, it MIGHT be advantageous to request an NCD when:

- Existing national coverage denies or restricts coverage for beneficiaries
- Existing national coverage is outdated or does not represent current data
- Coverage policies at the local level are negative
- There is significant variation in local coverage
- Medicare is a big payer for the technology
- There is a robust evidence base

PREEMPTIVE DUE DILIGENCE IS NECESSARY AS ENGAGEMENT WITH CMS IS NOT ALWAYS ADVISABLE OR REQUIRED

Factors to Help Determine Whether to Engage CMS	Example Areas of Due Diligence
Assess existing local and national Medicare coverage	Are there existing policies that dictate coverage for your item and service? Is it more restrictive than desired? Who is the decision-maker you would need to engage with (e.g., CAG vs. local MAC)?
Determine coding and payment	Does your item or service have an adequate code and payment rate in place?
Evaluate the competitive landscape	How will other players affect the coverage situation (physician societies, manufacturers, hospitals)?
Understand the evidence base	Does your evidence base and that in the public domain align with Medicare's evidence requirements? Are there any potential gaps?
Understand the evidence base	How do professional societies align or do not align with your position given their influence with the Agency?
Assess risk/benefit of engaging at national or local level	What are the pros and cons of engaging at the national level and the local level? Are you prepared for either outcome, positive or negative? If so, what are the next steps?
Assess risk/benefit of engaging at national or local level	Why are you asking for CMS' time? What do you aim to accomplish?

Stakeholders benefit most from the coverage process when a targeted approach is applied. It is not advantageous to engage CMS for a broad therapeutic area or list of therapies.

Before engaging CMS proactively to request an NCD, it is highly advisable to seek advice and counsel from a professional group with expertise and experience in this area. CMS also strongly encourages communication with the Coverage and Analysis staff via conference call or meeting prior to submitting a formal NCD request.

ENGAGING CMS PRIOR TO LAUNCH

When a promising new therapy or technology appears on the clinical horizon, it can present opportunities for advocates to engage with CMS prior to its actual launch.

MEETING WITH CMS PRIOR TO LAUNCH IS A STRATEGIC DECISION FOR PRODUCT SPONSORS AND OTHER STAKEHOLDERS

Key opportunities to meet with CMS prior to launch may include:

Evidence Base	<ul style="list-style-type: none">• Identify the strength of the current evidence base to gain an understanding for what gaps exist and may influence coverage• Gain insight into how CMS perceives the specific “therapeutic need” for beneficiaries based on the existing epidemiology and demographics
Trial Design	<ul style="list-style-type: none">• Obtain guidance on trial design to elucidate any concerns that may currently exist in a specific protocol• Gain informal agreement that the existing or proposed design meets the evidentiary needs
Policy Clarification	<ul style="list-style-type: none">• Enhance understanding of the current policy on a specific class of products and why coverage has been difficult or denied• Seek to understand what quality of life parameters may also influence coverage for this therapeutic area

A SUCCESSFUL MEETING WITH CMS PRIOR TO LAUNCH MAY YIELD VALUABLE INSIGHT

Create Awareness	<ul style="list-style-type: none">• Provides a lens into how receptive Medicare is to evaluating or re-evaluating coverage for a specific product or class of products• Gauges Medicare’s initial reactions to the strength of the evidence supporting the use of the product or class of products
Gain Insight	<ul style="list-style-type: none">• Reveals what level of impact quality of life measures have on the evidence base though these measures may be more subjective• Identifies expectations of collaborative support (if appropriate) by other industry members or stakeholders
Inform Actions	<ul style="list-style-type: none">• Elucidates potential areas of concern for CMS including additional types of evidence that may be needed to influence coverage• Guides preparation of a potential coverage request that will resonate best with CMS

Building a relationship of mutual collaboration will only enhance communication and trust for when an explicit request is made

As with requesting an NCD, opting to engage CMS prior to launch is a strategic decision in which the benefits and the potential risks need to be weighed carefully.

ENGAGING CMS ON AN OPEN NCD

The CMS process for proposing and implementing rules presents a number of opportunities to engage the agency and to provide both formal and informal input. These include:

- Submitting evidence-based public comment letters
 - When the NCD is initially opened
 - When the proposed NCD is posted
- Many NCDs involve “technology assessments” (TAs) conducted by the Agency for Healthcare Research and Quality (AHRQ) or convene a Medical Evaluation Development and Coverage Advisory Committee (MEDCAC).

For AHRQ TAs, patients can provide written comments. For MEDCACs, patients can provide both written comments and public testimony. Every MEDCAC also includes at least one patient advocate that sits on the panel.

Gaining access to these processes requires careful monitoring as well as ongoing engagement with CMS staff.

AHRQ TAs commissioned by Medicare are available at <http://1.usa.gov/Rz6158>

Upcoming MEDCAC meetings are listed at <http://go.cms.gov/1lPKb6M>. Presentations to these panels include both scheduled and ad hoc public comments.

The MEDCAC pool of potential panel members is available at <http://go.cms.gov/1ri5hTD>.

Note: Many agencies are now using webinars and interactive sessions to broaden the audience for their public hearings.

Note: Most agencies now strongly prefer that comments be submitted electronically. This makes the comments more available to the public and helps the agency organize the comments. Instructions for submitting electronic comments are found in the Federal Register. For information on using the federal rulemaking portal, go to regulations.gov and click on the “Help” pages.

WHAT TYPE OF EVIDENCE IS MOST EFFECTIVE?

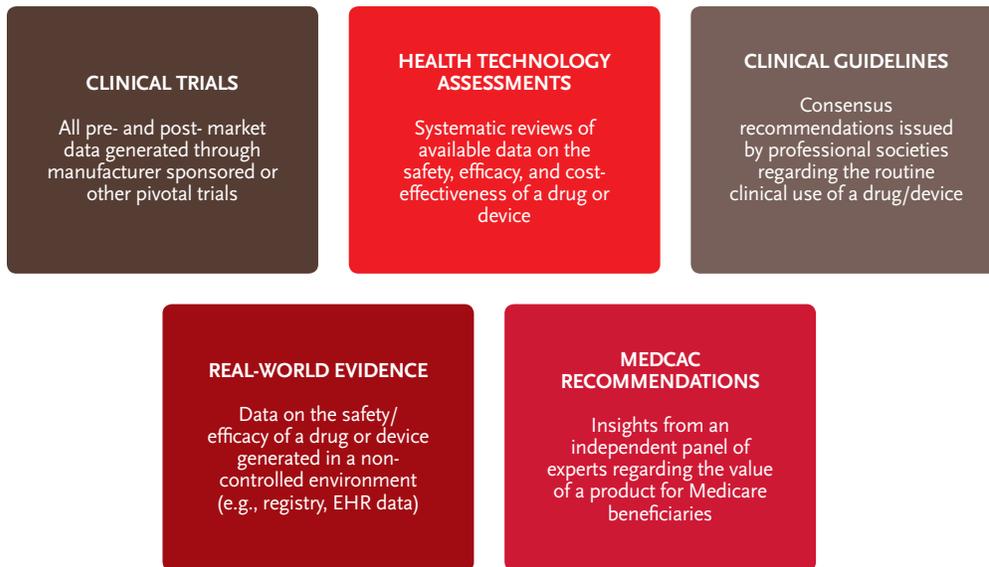
“Public comments providing information on unpublished evidence, such as the results obtained by individual practitioners or patients, are less rigorous and therefore less useful for making a coverage determination.”

—CMS, Revised Process for Issuing NCDs, August, 2013

The CMS determination process is evidence-based, which means that public comment letters and testimony need to address key issues of evidence in order to be effective. There are many circumstances in which the patient story or testimonial is compelling and appropriate, but anecdotes and individual narratives carry little weight with CMS.

Nor do generating large quantities of form letters or emails on a specific issue influence the outcome of a determination decision. The most effective public comment letters are those that cite published evidence regarding the clinical need for the intervention.

CMS LEVERAGES SEVERAL TYPES OF EVIDENCE TO INFORM ITS COVERAGE ANALYSES



All of the evidence bases listed above are directed to answer the following questions:

- For what distinct populations is this therapy effective?
- How does the therapy compare to the standard of care in improving health outcomes?
- How does the new therapy impact the over 65 population?
- Can the evidence be generalized to “real world” settings? This means that Medicare wants assurances that a new therapy will work effectively outside of a controlled clinical study.

The most effective sources of evidence to answer these questions are generally:

- FDA Approval. Medicare coverage decisions are often tied specifically to FDA approved indications.
- Published clinical trial evidence—with a preference for U.S.-based studies
- U.S. and international technology assessments
- Professional society consensus statements and guidelines (e.g. NCCN Guidelines)
- Additional evidence collected as a result of Coverage with Evidence Development (CED) decision.

An effective, persuasive letter addresses all of these points. It is important to note that patient satisfaction and patient reported data are increasingly becoming not just accepted but required components of the evidence base.

It is also critical that the patient advocacy organization works together to provide CMS and elected officials with a unified voice on important issues. Too often, the cancer community presents itself as fragmented and divided into multiple, usually site-specific factions.

The ability to define common ground and speak with one voice is essential to assuring that comments and communications have the maximum impact on the outcomes of the regulatory process.

See appendix for examples of well-constructed public comment letters.

OUTCOMES OF THE NCD PROCESS

There are a number of possible outcomes from the National Coverage Analysis process. The chart below lists examples. Note that most NCAs result in a Coverage with Evidence Development (CED) decision—meaning that more evidence is required or that there are restrictions to the coverage.

AN NCA CAN RESULT IN A VARIETY OF OUTCOMES, RANGING FROM BENIGN TO DETRIMENTAL FOR PATIENT ACCESS

The majority of NCA's end in coverage with restrictions or CED



Notes on Staffing and Consultants

Many large patient advocates groups have full-time government relations specialists and maintain a presence on Capitol Hill and in their state capitols. These organizations have the resources and expertise to monitor regulatory activity, communicate with CMS and elected officials, track issues of importance to the cancer community and generate comments and evidence-based letters as needed.

For smaller organizations, all of these functions can present challenges. Staff often wear multiple hats and have little time to dedicate to effective engagement in health care policy and regulatory matters.

Here are some suggestions for getting involved and being heard.

1. Appoint a staff member to monitor key health care issues that impact the community and develop a working knowledge of the regulatory and legislative processes. That individual can be a mid- to senior-level staff person in administration or in communications.
2. Align your organization with larger groups that do have government relations and health care policy groups. Take advantage of the information they provide, support their efforts with evidence-based comments when appropriate. Participate in “Hill” days and other forums that provide information to government and agency officials on key issues.
3. Consider engaging a consultant. This can be done at many levels, either on an ongoing basis or for a specific issue. The key is to match the consultants to your organizational needs in terms of expertise, expense and scope of work. Large organizations, even those with government relations staff, should consider consulting help when contemplating requesting a National Coverage Determination (NCD).
4. Join the National Quality Forum, which is an organization that provides multiple tools and resources for patient groups interested in understanding quality measures in health care delivery.

Summary

- This is an excellent time to be aware of what is happening and active in the world of health care policy and regulation. There are deep and real changes in how decisions are being made—and many of these involve hearing the patient voice and incorporating patient-reported data into the decision-making process.
- The Centers for Medicare and Medicaid (CMS) is the federal agency responsible for making coverage decisions that directly affect 1 in every 3 Americans. CMS indirectly influences a wide range of health care policies and decisions. Within CMS, the Center for Clinical Standards and Quality makes most of the decisions impacting cancer patients.
- The regulatory process, both at the national and local level, offers numerous opportunities for patient advocacy groups to comment, intervene and influence the outcomes.
- In order to influence the decision-making process, it is essential to monitor CMS activity, understand the regulatory process, maintain communications with CMS staff and key legislators and tailor comments to meet standards of evidence-based medicine.
- The most effective comments, whether they are letters or actual testimony, are those based on published clinical evidence. Anecdotes, testimonials and sheer quantity of letters carry little weight in meeting the CMS standard of “reasonable and effective.”
- The decision to request an NCD should not be made lightly. The process is both expensive and time consuming, requiring significant due diligence. There is also the potential to do more harm than good. NCDs should generally be undertaken only with the assistance of experienced consultants.
- Regardless of the size of the organization and resources available to it, there are steps that can be taken to enhance awareness of what is happening on the health care policy front and assure that the voice of your patient community is heard.
- Regardless of the cause, or the issue, that voice will be heard most forcefully and effectively when organizations collaborate and cooperate and provide the decision makers with a unified statement.

RESOURCES

The Cancer Policy Institute of the Cancer Support Community:

<http://www.cancersupportcommunity.org/MainMenu/Get-Involved/Public-Policy-and-Advocacy>

The Centers for Medicare and Medicaid Services: www.CMS.gov

The Federal Register: www.federalregister.gov

The National Quality Forum: www.qualityforum.org

Avalere Health: www.avalere.com

The Institute of Medicine: www.iom.edu

Acknowledgments

The Cancer Support Community gratefully acknowledges the support and expertise that made this meeting and Tool Kit possible. We thank:

GlaxoSmithKline and Uniting a Community

Our Steering Committee

- Carolyn Aldige, Prevent Cancer Foundation
- Meghan Buzby, International Myeloma Foundation
- Diane Dorman, National Organization for Rare Disorders
- Fran Kochman, Uniting a Community
- Laura Koontz, Ovarian Cancer National Alliance
- Brian Rosen, The Leukemia & Lymphoma Society
- Pam Traxel, American Cancer Society Cancer Action Network

Our Speakers

- Shari Ling, MD, CMS
- Lisa Parker, CMS
- James Rollins, MD, CMS
- Jenny Gaffney, Avalere Health
- Rodney Whitlock, Health Policy Director, Sen. Charles Grassley
- Amy Hall, House Energy and Commerce Committee
- Former Sen. John Breaux
- Joe Wall, Goldman Sachs

Sample Letters: Provided by the Association of American Cancer Institutes (AACI)

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

February X, 2014

Dear Administrator Tavenner,

We are writing to express our concern with the Centers for Medicare and Medicaid Services' (CMS) standards for network adequacy in the State Exchange Qualified Health Plans (QHPs). It is crucial for patients with life-threatening illnesses to be able to access appropriate care, yet many QHPs include a limited number, if any, NCI designated cancer or transplant centers in their networks. We urge CMS to formally engage interested patient and provider groups to determine a quantifiable standard on network adequacy.

The Affordable Care Act (ACA) requires the Secretary of Health and Human Services (HHS) to establish regulations for the certification of Qualified Health Plans (QHPs) that are sold in the ACA's health insurance exchanges. To receive certification, a QHP must at a minimum meet the federal requirements for network adequacy. However, the regulations only require insurers to maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay. This standard is ambiguous and does not provide the specificity that is necessary to ascertain whether a QHP has a network that allows meaningful and timely access to appropriate care or medically necessary treatment.

We support the following principles for structuring guidance on QHP network adequacy standards:

1. Guarantee adequate numbers and types of providers and facilities by setting quantifiable standards.
2. Ensure contracted providers and facilities are within a reasonable geographic radius of the plan's members.
3. Improve notification requirements for beneficiaries when there are significant changes to a QHP's network.
4. Where no in-network provider or facility is available for medically necessary services, ensure patients are not penalized with higher out-of-pocket costs when being treated by an out-of-network provider.

We urge CMS to within the next 3 months convene a public stakeholder roundtable of interested patient and provider groups to solicit feedback, and amend and strengthen the federal network adequacy regulations for qualified health plans at 45 C.F.R. § 156.230 in accordance with the general principles outlined above.

Sincerely,

The Honorable NAME
Member of Congress

The Honorable NAME
Member of Congress

Sample Letters: Provided by the Association of American Cancer Institutes (AACI)

Marilyn Tavenner, RN, BSN, MHA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

March 7, 2014

Submitted Electronically to AdvanceNotice2015@cms.hhs.gov

Re: Advance Notice/Call Letter for Medicare Advantage Plans for Calendar Year (CY) 2015

Dear Administrator Tavenner:

The Alzheimer's Foundation of America (AFA), American Academy of Neurology® (AAN), American Association for Cancer Research (AACR), American Brain Coalition (ABC), the American Cancer Society Cancer Action Network (ACS CAN), American College of Cardiology (ACC), the American Heart Association/American Stroke Association (AHA/ASA), American Society of Clinical Oncology (ASCO), the Association of American Cancer Institutes (AACI), the Association of Community Cancer Centers (ACCC), the Brain Injury Association of America (BIAA), the National Coalition for Cancer Research (NCCR), the National Coalition for Cancer Survivorship (NCCS), National Comprehensive Cancer Network (NCCN), the National Multiple Sclerosis Society (NMSS), the National Stroke Association (NSA), the Oncology Nursing Society (ONS), the Ovarian Cancer National Alliance (OCNA), the Parkinson's Action Network (PAN), and Susan G. Komen® (Komen) are pleased to provide comments on the 2015 Advance Notice and Call Letter that the Centers for Medicare & Medicaid Services (CMS) has recently released. AFA, AAN, AACR, ABC, ACS CAN, ACC, AHA/ASA, ASCO, AACI, ACCC, BIAA, Komen, NCCR, NCCS, NCCN, NMSS, NSA, OCNA, PAN, and ONS are among the world's leading organizations representing people impacted by serious or life-threatening diseases and specialty providers and research professionals. Information on our organizations is listed on the final page of our letter.

We urge CMS to correct a long-standing inequity in Medicare coverage by requiring in the final 2015 call letter that Medicare Advantage (MA) plans provide coverage for clinical trials. As the policy currently stands, individuals in MA plans are required to relinquish their MA coverage and revert to standard fee-for-service (FFS) Medicare if they wish to participate in a clinical trial. Providing coverage as part of MA plans—which typically have lower copayments and out-of-pocket costs—rather than Medicare “paying on a fee-for-service basis” is important to the participants who enroll in these plans. MA enrollees typically chose these plans because they involve lower costs than FFS coverage and provide more comprehensive coverage. Treatments for serious or life-threatening diseases can be very costly for the patients involved, regardless of whether the patient participates in a clinical trial. Preserving MA plan coverage is very important.

Our organizations are concerned with the requirement that MA enrollees revert to FFS coverage to participate in a clinical trial. The policy is confusing, may deter MA enrollees from participating in clinical trials, and will likely result in a cost-differential for MA enrollees—when comparing FFS and MA out-of-pocket costs. Most MA plans have lower cost-sharing for Medicare-covered services, and MA enrollees often do not have supplemental coverage. Therefore, the out-of-pocket costs of participating in a clinical trial through FFS will likely be more than if the MA enrollee

were participating on the trial through their MA coverage. MA enrollees, while participating in a clinical trial under the FFS reimbursement, are required to cover all deductibles, copays, and the 20% coinsurance for all charges associated with clinical trial care. CMS seemed to acknowledge this in its 2011 call letter when it stated that “MA organizations are responsible for reducing cost sharing for clinical trials to the amount that their MA plan members would have for similar services provided by in-network providers.”

If over a decade of experience with the clinical trial National Coverage Decision is insufficient to “make statistically valid adjustments to MA capitation rates” (as CMS noted in the final 2012 call letter), our organizations are eager to remedy this. Studies have demonstrated that the routine costs incurred from participation in clinical trials are not significantly greater than receiving standard care. We would be happy to work with CMS to gather the necessary data to change its policy. Perhaps we could do this through facilitating an analysis with the National Institutes of Health (NIH), which enrolls thousands of people on clinical trials each year at sites throughout the country, including the cancer cooperative groups, and now the National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN).

Without the cost-saving potential of MA coverage, the current policy could not only discourage MA enrollees from choosing clinical trials but also exacerbate health care disparities. This issue is of particular concern to us because of our eagerness to ensure access and participation of under-served populations in clinical trials, an issue that is also important to the NIH, NCI and the Food and Drug Administration (FDA). The elderly and those with lower incomes are notoriously under-represented on clinical trials. When having discussions with these patients about participating on a clinical trial, they are very concerned about the impact that participation will have on their insurance coverage and costs. Congress recently indicated its views on the importance of ensuring appropriate representation of under-served populations in clinical trials as part of the FDA Safety and Improvement Act of 2012 (FDASIA). FDASIA explicitly requires the FDA to develop a plan to improve its efforts at communicating available clinical trial data on subpopulations in order to improve the quality of care provided to individuals from such groups. If such individuals are discouraged from participating in clinical trials for cost reasons, there will be little to no data available upon therapy approval, making it more difficult for physicians to appropriately assess the therapeutic value of new drugs and devices once they are available.

For many serious or life-threatening diseases, existing therapies approved by the Food and Drug Administration (FDA) are not sufficient, meaning that clinical trials may offer the best hope for treatment for many patients. In addition, improved participation on clinical trials—particularly among the Medicare-eligible population—leads to a stronger evidence base on the comparative effectiveness of various therapies, an initiative of the ACA. It also provides Medicare with the information it requires to determine the effectiveness of therapies in the Medicare-eligible population.

We sincerely hope that CMS will change its policy in the final 2015 call letter to require that MA plans cover the cost of clinical trials. This would be the most efficient and effective way to accomplish the important goal of increasing the participation of Medicare beneficiaries in clinical trials.

If CMS decides to continue its policy in 2015 of requiring MA beneficiaries to relinquish their MA coverage and revert to a FFS Medicare plan, we urge the Agency to adopt the recommendations described above as soon as possible.

In the interim, the Agency should include the following requirements within the final 2015 call letter:

- 1. Promote Transparency by Requiring MA Plans to Notify Enrollees and Providers of Cost-Sharing Assistance**—The Medicare Managed Care Manual notes that “MA plans pay the enrollee the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan’s in-network cost-sharing for the same category of items and services. This cost-sharing reduction requirement applies to all qualifying clinical trials. MAOs cannot choose the clinical trials or clinical trial items and services to which this policy applies. The MAO owes this difference even if the member has not yet paid the clinical trial provider. Additionally, the member’s in-network cost-sharing portion must also be included in the plan’s out-of-pocket maximum calculation.”

We appreciate that this provides clarity to the MA plan about its obligations. There is currently no requirement, however, that the MA plan provide notice to enrollees and providers about this requirement. Under the current scenario, a patient or provider could submit a claim to the MA plan, be notified that the claim must be submitted to the Medicare contractor, and not be told that the MA plan is required to provide cost-sharing assistance. Greater transparency in the form of meaningful notification—including what information the enrollee or provider should provide to document the patient’s cost sharing responsibility—will help ensure that enrollees can make informed decisions about whether to participate in clinical trials and receive the full Medicare benefits that should be provided through their MA plan.

- 2. Promote Transparency by Requiring Medicare Contractor Notification of Cost-Sharing Assistance**—Medicare contractors should also provide notice to all MA enrollees, or providers who submit claims on their behalf, that the MA plan is required to cover the difference in cost sharing for clinical trials. This will again ensure full notification to enrollees and providers and clarify the documentation that should be provided.

Without the requirement that MA plans and Medicare contractors notify Medicare participants and providers of this assistance, enrollees may not be aware that they are eligible to receive payment from the MA plan for the difference in cost-sharing and therefore may be left with excess costs.

- 3. Promote Transparency by Clarifying the Medicare Clinical Trials Brochure**—We urge CMS to update its own “Medicare and Clinical Research Studies” brochure (www.medicare.gov/Pubs/pdf/02226.pdf) to clarify that MA enrollees are eligible to receive “the difference between Original Medicare cost-sharing and the MA plan’s in-network cost-sharing for the same category of items and services” (as is stated in the Medicare Managed Care Manual). While the brochure mentions that MA plans cannot “keep you from joining a clinical research study,” it should also inform Medicare beneficiaries that the MA plan is required to provide cost-sharing assistance.

4. Minimize Administrative Burdens by Requiring MA Plans and Medicare Contractors to Streamline Process and Timeline for Obtaining Cost-Sharing Assistance—We urge CMS to require both MA Plans and Medicare Contractors to streamline the administrative steps and timeline for MA enrollees to obtain cost-sharing assistance for clinical trials. The system of moving MA enrollees to traditional Medicare and requiring MA plans to reimburse part of the patient’s out-of-pocket costs is confusing and difficult to describe. The Agency should take every precaution to ensure that administrative burdens on Medicare patients are eliminated or at least minimized. In many instances, clinical trials provide individual patients with the best clinical alternative, and needless administrative burdens should not interfere with patient access to such therapies. Ultimately, the best and simplest way to streamline the process is to require that the MA plan provide direct coverage for the clinical trial—without the enrollees reverting to traditional Medicare.

We would be happy to work with CMS to help ensure smooth implementation and address any concerns that plans may have. We strongly believe that MA enrollees should be given clear coverage for clinical trial services—the same as other Medicare-covered services—through their MA plan.

Thank you for your attention to this important issue. If you have any questions, please contact Suanna Bruinooge, Director of Research Policy for ASCO at suanna.bruinooge@asco.org.

Sincerely,

Alzheimer’s Foundation of America
American Academy of Neurology®
American Association for Cancer Research
American Brain Coalition
American Cancer Society Cancer Action Network
American College of Cardiology
American Heart Association/American Stroke Association
American Society of Clinical Oncology
Association of American Cancer Institutes
Association of Community Cancer Centers
Brain Injury Association of America
National Coalition for Cancer Research
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Multiple Sclerosis Society
National Stroke Association
Oncology Nursing Society
Ovarian Cancer National Alliance
Parkinson’s Action Network
Susan G. Komen®

AFA, AAN, AACR, ABC, ACS CAN, ACC, AHA/ASA, ASCO, AACI, ACCC, BIAA, Komen, NCCR, NCCS, NCCN, NMSS, NSA, OCNA, ONS, PAN Comments 2015 Draft Advance Notice/Call Letter

Alzheimer’s Foundation of America

The Alzheimer’s Foundation of America is a national nonprofit organization that unites more than 1,600 member organizations nationwide with the goal of providing optimal care and services to individuals confronting dementia, and to their caregivers and families. Its services include a toll-free hot line staffed by licensed social workers, educational materials, a free quarterly magazine for caregivers, and professional training.

American Academy of Neurology®

The American Academy of Neurology (AAN) is the premier national medical specialty society for neurology representing more than 26,000 neurologists and clinical neuroscience professionals, and is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as multiple sclerosis, Alzheimer’s disease, stroke, Parkinson’s disease, epilepsy, migraine and brain injury.

American Association for Cancer Research (AACR)

The AACR, representing 34,000 laboratory, translational, and clinical researchers; other health care professionals; and cancer survivors and patient advocates, is the world’s oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research.

American Brain Coalition (ABC)

The American Brain Coalition is a non-profit organization comprised of over 85 of the United States’ leading professional neurological, psychological, and psychiatric associations and patient organizations. Together, ABC seeks to advance the understanding of the functions of the brain, and to reduce the burden of brain disorders through public advocacy.

American Cancer Society Cancer Action Network (ACS CAN)

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation’s leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

American College of Cardiology (ACC)

The College is a 47,000 member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.

American Heart Association/American Stroke Association (AHA/ASA)

The AHA is the nation’s oldest and largest voluntary health organization dedicated to fighting heart disease and stroke. Our mission is to build healthier lives by preventing, treating and defeating these diseases—two of America’s leading killers. We fund cutting-edge research, conduct lifesaving public and professional educational programs and advocate to protect public health. To learn more or join us in helping all Americans, call 1-800-AHA-USA1 or visit www.heart.org.

American Society of Clinical Oncology (ASCO)

ASCO is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. In addition, ASCO promotes and provides for lifelong learning for oncology professionals; cancer research; an improved environment for oncology practice; access to quality cancer care; a global network of oncology expertise; and educated and informed cancer patients.

Association of American Cancer Institutes (AACI)

The Association of American Cancer Institutes (AACI) comprises 95 leading cancer research centers in the United States. AACI's membership roster includes National Cancer Institute-designated centers and academic-based cancer research programs that receive NCI support. The Association is dedicated to reducing the burden of cancer by enhancing the impact of the nation's leading academic cancer centers.

Association of Community Cancer Centers (ACCC)

The Association of Community Cancer Centers (ACCC) promotes the entire continuum of quality cancer care for our patients and our communities. Since 1974, ACCC has been helping oncology professionals adapt to the complex changes of delivering quality cancer care while responding to regulatory and legislative changes. ACCC's core purpose is to be the leading education and advocacy organization for the cancer team. Nearly 19,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices are affiliated with ACCC.

Brain Injury Association of America (BIAA)

The Brain Injury Association of America (BIAA) is the country's oldest and largest nationwide brain injury advocacy organization, founded in 1980 by individuals and family who wanted to improve the quality of life for their family members and patients who had sustained brain injuries. The mission is to advance brain injury prevention, research, treatment and education and to improve the quality of life for all people affected by brain injury. The Association is dedicated to increasing access to quality health care and raising awareness and understanding of brain injury. With a network of state affiliates, local chapters and support groups, BIAA is the voice of brain injury.

National Coalition for Cancer Research (NCCR)

The National Coalition for Cancer Research (NCCR) is comprised of 23 nonprofit national cancer organizations. Its membership includes cancer researchers; nurses and physicians; cancer centers and specialized research institutions representing cancer patients, survivors and their families. The mission of NCCR is to transform public policy to enable every individual to participate in, and benefit from, cancer research.

National Coalition for Cancer Survivorship (NCCS)

The National Coalition for Cancer Survivorship (NCCS) is a cancer patient advocacy organization dedicated to assuring quality cancer care for all from the time of diagnosis through treatment and post-treatment survivorship. NCCS relies on the available scientific evidence, informed by patient experience, to improve the quality of cancer care, reform the cancer care delivery and payment systems, and enhance patient involvement in treatment decision-making.

AFA, AAN, AACR, ABC, ACS CAN, ACC, AHA/ASA, ASCO, AACI, ACCC, BIAA, Komen, NCCR, NCCS, NCCN, NMSS, NSA, OCNA, ONS, PAN Comments 2015 Draft Advance Notice/Call Letter

National Comprehensive Cancer Network (NCCN)

NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives.

National Multiple Sclerosis Society

The National MS Society is a collective of passionate individuals who want to do something about MS now—to move together toward a world free of multiple sclerosis. The Society helps each person address the challenges of living with MS through its 50-state network of chapters. The Society funds cutting-edge research, drives change through advocacy, facilitates professional education, and provides programs and services that help people with MS and their families move their lives forward.

National Stroke Association (NSA)

National Stroke Association's mission is to reduce the incidence and impact of stroke by developing compelling education and programs focused on prevention, treatment, rehabilitation and support for all impacted by stroke.

Oncology Nursing Society (ONS)

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing.

Ovarian Cancer National Alliance

The Ovarian Cancer National Alliance is the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the organization advocates at a national level for increases in research funding for the development of an early detection test, improved health care practices, and life-saving treatment protocols. The Ovarian Cancer National Alliance educates health care professionals and raises public awareness of the risks and symptoms of ovarian cancer. The Ovarian Cancer National Alliance is a 501(c)(3) organization established in 1997.

Parkinson's Action Network (PAN)

The Parkinson's Action Network (PAN) is the unified voice of the Parkinson's community advocating for better treatments and a cure. In partnership with other Parkinson's organizations and its powerful grassroots network, PAN educates the public and government leaders on better policies for research and an improved quality of life for people living with Parkinson's.

Susan G. Komen®

Susan G. Komen is the world's largest breast cancer organization, funding more breast cancer research than any other nonprofit while providing real-time help to those facing the disease. Since its founding in 1982, Komen has funded more than \$800 million in research and provided \$1.7 billion in funding to screening, education, treatment and psychosocial support programs serving millions of people in more than 30 countries worldwide. Komen was founded by Nancy G. Brinker, who promised her sister, Susan G. Komen, that she would end the disease that claimed Suzy's life. Visit komen.org or call 1-877 GO KOMEN. Connect with us on Facebook and Twitter.

The Cancer Policy Institute *at the* 
CANCER SUPPORT COMMUNITY

HEADQUARTERS OFFICE

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www.CancerSupportCommunity.org

*The Cancer Support Community
Cancer Policy Institute would like
to thank the members of Uniting a
Community for their partnership.*



American Cancer Society
Community Oncology Alliance
International Myeloma Foundation
Leukemia and Lymphoma Society
Ovarian Cancer National Alliance
Prevent Cancer Foundation

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on CMS was made possible
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