The PATIENTS Program
at the University of Maryland
School of Pharmacy

PATIENTS Professors Town Hall: Recommendations for the CMS Drug Price Negotiation Program

FINAL REPORT

apx
applied patient experience

UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

PATIENTS Professors (Alphabetically, by last name):

Tanisha Armstrong
Kenneth Baxter
Cynthia Chauhan
Karen Cushnyr
Jennie Flanagan
Brian Gutierrez
Elaine LaLone
Barbara Palmer
Sandra Powell
Belinda Rogers
Nancy Thomas
Jeff Wells
Donald Young

Report Prepared by:

The PATIENTS Program
Hillary Edwards
Joe Howarth

Applied Patient Experience, LLC
Joe Vandigo
Christina Miller

For questions or requests:

University of Maryland
School of Pharmacy
220 Arch Street, 12th Floor
Baltimore, MD 21201
Phone: 410-318-9331

Applied Patient Experience, LLC
2201 Wisconsin Ave NW,
Suite 200
Washington, DC 20007
Email: **jvandigo@appliedpx.com**

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Executive summary:

The Inflation Reduction Act (IRA) gives the Centers for Medicare and Medicaid Services (CMS) new authority to negotiate drug prices based on multiple factors, including a drug's clinical benefit based on comparative effectiveness research. While CMS has suggested they are interested in considering the outcomes and experiences of patients during their decision-making process, they do not yet seem to have a formal plan in place to engage patients in a systematic way.

Patient perspectives can only be valued and considered if engagement occurs early and meaningfully throughout the process to identify and assess data and determine how the data are weighted and used in CMS decision making.

The PATIENTS Professors, who are trained patient(?) experts in continuous patient engagement in research, undertook a series of discussions for the CMS Patient Engagement Town Hall Initiative centered on the question, "Are there touchpoints you would like to see built into CMS' process to engage the patient community?". The goal of this initiative was to provide insights and recommendations to CMS to ensure patient perspectives can be sought and are represented in CMS' decision making.

The CMS Patient Engagement Town Hall initiative involved the following steps:

- Assembly of participants
- Development of facilitation guides
- Convening a background meeting for attendees
- Convening the Town Hall
- A series of small-group consensus sessions
- Co-development of themes and recommendations to guide CMS implementation of the Drug Price Negotiation Program provisions of the IRA

After analyzing the Town Hall conversation using evidence-based qualitative techniques, four inter-related themes emerged:

1. Patient engagement should meaningfully involve patients, caregivers, and other key stakeholders instead of a simple "check the box" exercise.
2. Patients and key stakeholders should be engaged continuously throughout the negotiation process by including touchpoints over the course of the process to ensure patient perspectives are considered in all decision making
3. Information collection should be proactive and inclusive.
4. Trust can only be built through transparency via multiple communication channels.

These four themes were the keystones to constructing the recommendations in this report. The recommendations are also grouped by time frame for effective implementation and provide action items for today as well as for longer-term planning. Table 3 provides the outline of these recommendations.

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List of abbreviations

CMS	Centers for Medicare and Medicaid Services
IRA	Inflation Reduction Act
MFP	Maximum Fair Price
PATIENTS	PATient-centered Involvement in EvaluatiNg effectiveness of TreatmentS
DPNP	Drug Price Negotiation Program

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1. Introduction

1.1 Background

Patient involvement in government and health policy decision making is limited, despite more than ten years and billions of dollars of evidence and methods development. Surprisingly, recent Centers for Medicare and Medicaid Services (CMS) guidance for the implementation of the Medicare Drug Price Negotiation Program (DPNP), which involves using comparative effectiveness research to assess the relative clinical benefit of a drug to establish a price the government will pay for Part B and Part D drugs, does not outline a clear plan to engage the patient community*, or prioritize research studies that were guided by meaningful patient engagement.[1]

When the initial guidance was released in March of 2023, the PATIENTS Program (**Appendix A**) at the University of Maryland, Baltimore and Applied Patient Experience believed there was both a need and an opportunity to include the patient perspective in this program, especially since the program involves establishing therapeutic alternatives, evidence of effectiveness relative to alternatives, identification of subgroups of interest, and determining unmet need.

The PATIENTS Professors Academy is a 5-week program offered by the PATIENTS program that brings together patients, caregivers (both informal and professional), government representatives, researchers, and pharmaceutical representatives to learn from each other on how to conduct patient-centered and community-engaged health research in line with the PATIENTS 10-Step Engagement Framework.[2,3]

In comment letters to CMS we advocated for establishing and applying a patient-centered approach as this new program begins to take shape. We also launched this project to bring a patient perspective to the application of patient-centricity in the implementation of the CMS Drug Price Negotiation Program by developing recommendations alongside the PATIENTS Professors trained in the 10-step framework for continuous patient engagement.[3–6]

1.2 Significance

The lived experiences and perspectives of individuals living with a condition should be essential to the design and conduct of policymaking and research.[7] Continuous patient engagement in developing public healthcare policy can lead to more public buy-in, practical implementation, and trust in government agencies. As a result, policies will reflect the experiences of individuals who directly interact with the healthcare system.

The perspective of patients, who are the experts in how they experience diseases and treatments, are critical to inform evidence on clinical benefit. Failure to continuously engage patients in an unprecedented policy process to evaluate the benefits of medicines could risk omitting valuable firsthand expertise on the drugs selected for negotiation and their alternatives. Ultimately, this could risk undermining patients' trust in CMS decision-making.

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*"patient community" broadly encompasses individual patients, family caregivers, and the organizations that represent them; National Health Council. **The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem**. June 2019.

1.3 Study objectives

To better achieve patient engagement in decision-making in the Medicare DPNP, our discussion aimed to determine:

- Why PATIENTS Professors believe it is crucial for patients and caregivers to be engaged in CMS decision-making; and
- Key issue areas and touch points in the negotiation process are needed for engagement to improve public buy-in, effective implementation, and trust and trustworthiness in government agencies.

The long-term objectives of this project are to aid CMS in implementing continuous engagement in drug pricing negotiation – and by extension, agency decision-making more broadly -- and promote continuous engagement in public policy development and implementation moving forward.

1.4 Study description

We incorporated the expertise of the PATIENTS Professors Academy graduates (also known as PATIENTS Professors) to provide recommendations to improve how CMS engages stakeholders in the DPNP. Graduates of The PATIENTS Professors Academy are trained in utilizing the 10-Step Framework for continuous patient and stakeholder engagement to advise companies, government agencies, community-academic partnerships, and other entities on ways to make clinical and translational research more relevant, appealing, and diverse. We hope the results of this initiative offer insights to CMS on opportunities to work with patient communities to improve the negotiation process for DPNP and future programs.

1.5 Report description

This report aims to provide CMS with proactive, positive support and guidance that will help ensure meaningful engagement throughout the DPNP.

1.6 Timing relative to June 30 guidance

Because this project was conceptualized and launched in April 2023, the Town Hall session was conducted prior to the release of the CMS revised guidance on June 30. AppliedPX and PATIENTS staff shared highlights of this revision with the PATIENTS Professors (**Appendix F**). Time was allocated during the consensus meeting for discussion relative to these improvements. The following themes and recommendations also apply to the changes seen in this guidance.

2. Methods

The University of Maryland Baltimore Institutional Review Board (IRB) determined that this initiative did not constitute human subjects research and did not require continuous review (IRB Protocol Number: HP-00106470).

The PATIENTS Program staff and AppliedPX organized a series of town hall meetings to solicit recommendations focused on CMS' proposed process for patient engagement and plan to solicit and review data and factors identified in IRA Section 1194 and draft guidance released on March 15, 2023. These elements were selected with input from the study sponsor (PhRMA) and included determining if a product represents a therapeutic advance, treatment comparator decisions, scope of outcomes and evidence considered, lived experiences and patient-centered outcomes, and variation in different patient populations concerning access and treatment effect.

This project focused on the existing framework for engagement provided by CMS in the draft guidance (i.e., a 30-day data submission window) and how those opportunities for engagement could be improved in revised guidance this year and/or next year.

2.1 Data collection

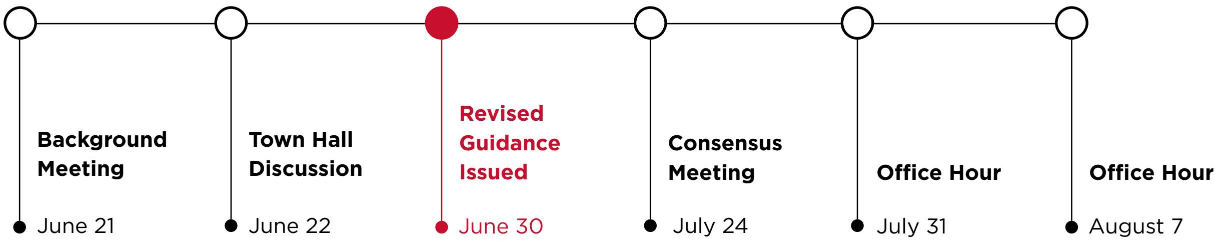
Participants were invited to a series of three virtual town hall-style activities to be held via Zoom web conference software and had the option to participate in two additional office hour sessions:

1. **Activity 1: Town Hall Orientation and Background Meeting (60 minutes).** The first session provided general introductions and descriptions of the roles team members, and participants would have for the following town hall. The session also provided prerequisite knowledge and materials to be discussed in-depth at the town hall. This session provided an overview of key terms, and clarifying information, and answered outstanding questions regarding the conduct of the town hall for all participants. The pre-work aimed to set a level meeting ground for all participants and aimed to improve communication between participants and discussion facilitators (e.g., defining technical jargon).
2. **Activity 2: CMS Drug Price Negotiation Program Patient Engagement Town Hall (150 minutes).** The two-and-a-half-hour town hall provided a deeper dive into the foundational knowledge from the orientation session to focus on the application of continuous patient engagement in CMS's Drug Price Negotiation Program. The draft guidance document was distributed before the meeting, and town hall participants provided feedback on the challenges, benefits, barriers, and opportunities for inclusive patient engagement across the lifecycle of the DPNP program. The project leads served as co-facilitators for the session, prompting discussion with open-ended questions developed before the meeting (Appendix B). Participants responded in the open discussion forum and in the chat functions available through the virtual meeting platform.

3. **Activity 3: Patient Engagement Recommendation Consensus Meeting (60 minutes).** The third session focused on the prioritization and framing of the recommendations that came from the town hall meeting for the final report on recommendations for the implementation of patient engagement methods in the CMS DPNP program. For this facilitated discussion activity, we utilized Mentimeter to elicit community member input to validate the main findings from the thematic analysis of the town hall (**Appendix G**).[8] The participants provided a "member check" on the framing of recommendations and consensus on the prioritization in the final report document.[9] Prior to this activity, participants were provided with the CMS revised guidance and a summary of the patient-centered provisions within this guidance (**Appendix F**).
4. **Activity 4: Two Office Hour Sessions (60 minutes each).** Following the consensus meeting, participants were invited to optional office hour sessions as an additional touchpoint to provide feedback and share additional opinions. PATIENTS Program and AppliedPX staff attended these meetings and discussions were designed to move the draft report and recommendations to completion.

Figure 1 provides a timeline for the scheduling of the initiative activities.

Figure 1. Initiative timeline



2.2 Recruitment and participants

Participants were recruited through the PATIENTS Program's PATIENTS Professors Academy distribution list. The PATIENTS Program facilitators reached out to individuals in the membership who pre-identified the topics and therapeutic areas covered in this initiative as areas of interest. These individuals were invited via email and provided two weeks notice to confirm attendance. A copy of the invitation letter is available in **Appendix A**. A total of 13 individuals participated in all three activities. Twelve of 13 participants provided characteristic information.

Table 1. Participant characteristics

Participants' Characteristics	Number of participants (%)
Primary stakeholder affiliation	
Academia and/or academic researcher	2 (17%)
Community leader	1 (8%)
Health advocacy and/or education	2 (17%)
Patient and/or caregiver	5 (42%)
Other	2 (17%)
Age group (years)	
18-54	3 (25%)
55-64	6 (50%)
65 and over	3 (25%)
US region of residence	
Northeast	3 (25%)
Mid-Atlantic	4 (33%)
Southeast	1 (8%)
Midwest	2 (17%)
Mountain West	1 (8%)
Pacific West	1 (8%)
Preferred pronouns	
She/Her/Hers	7 (58%)
He/Him/His	4 (33%)
Prefer not to answer	1 (8%)
Race or ethnicity (multiple may be selected)	
American Indian or Alaska Native & White	1 (8%)
Black or African American	6 (50%)
Hispanic, Latinx, or Spanish	1 (8%)
Hispanic, Latinx, or Spanish & White	1 (8%)
White	3 (25%)

2.3 Data analysis

With the consent of participants, discussions were audio recorded. The co-facilitators took notes during the sessions as well as archived the chat transcript. Audio of the meeting was transcribed, and a coder re-read transcripts to extract quotes related to each of the identified themes. The research team debriefed on major themes and sub-themes immediately following the town hall (Activity 2) and on a weekly basis as data analysis occurred. To establish credibility, this project instituted a consensus process that serves as a member-checking procedure to "circle back" to participants and allow participants to improve aspects of the interpretations of the data they provided. The entire summary report was shared with 100% of participants, who were then asked to assess the degree to which they agreed with the overall themes and draft recommendations during the consensus meeting process. The consensus meeting instrument and polling results are available in **Appendix E**.

3. Results

The town hall conversation focused on four key themes (Table 2):

1. Patient engagement should not be a “check the box” exercise.
2. Patients and stakeholders should be engaged continuously throughout the negotiations process.
3. Information collection should be proactiveand inclusive.
4. Trust can only be built through transparency via multiple communication channels.

These four themes were then used with the content of the discussion to develop a series of aligned recommendations, grouped by timeline to implementation.

Table 2. Themes and illustrative quotes from Town Hall conversation

Theme	Illustrative Quote
Do not make engagement “check the box”	“I agree about being heard, but being part of the process, but **what I worry about is being part of the process. And it’s just checking off a box**. You gotta be part of the process and knowing that you’re listening to me, and I’m being heard, and thing and feedback, **come back to say, Yes, I heard you. This is what happened. And this is, and we’re making it better because of what happened during this process**. But just being heard, is me being part of that. And that’s got to be heard. And knowing what I say has relevance and benefit.”
Continuous engagement is key	“But what I would like to see is **active engagement of patients** through the whole process in a way that **validates that they are equal participants in the process**.”
Information collection should be proactive and inclusive	“I think the public needs to be not I don’t know what the word is canvassed or reached out to, that there **needs to be a more active engagement of the public and an understanding that not everyone can do it in writing**. That is a very elitist approach to me to say that it must be in writing; they really need to reach out and talk with people and transcribe what people say.”
Transparency builds trust	“I think the **value of having patients engaged in every step is that it no longer happens in a back room. But a patient shines a little bit of light**. The analogy I’ve used in another context is that you turn rocks over and it’s muddy and cruddy underneath. But all that dries up when it’s shining the light on it, sunshine on it. So I think there’s some value in not just the patients being heard, but the community hearing from a patient.”

3.1 Themes

Patient engagement is only successful when it is not a "check-the-box" exercise. There is a clear difference between collecting data that is meaningful to patients and clearly describing how that data and patient engagement was used to reach decisions. When patients provide their time and effort, it must be clear how patient input is considered in final decisions.

Continuous engagement is key. Patients should be included as team members and considered experts throughout the process. This includes going back to the prioritization elements of health care that warrant policy changes—specifically (recognizing this is outside of the remit of CMS) and potentially focusing on other elements of healthcare (e.g., direct patient out-of-pocket costs at the pharmacy counter, improving education about the Medicare program and benefits) rather than drug price negotiation. Several real-world examples are available for CMS to adopt to model its approach, such as programs many PATIENTS Professors first-hand experience with, such as those at the University of Maryland, Baltimore, Johns Hopkins University, and the FDA. Many of the criticisms levied by stakeholders in the policy community and discussed during the session would have been foreseen or could have been mitigated through a robust patient-engagement strategy where patients had a voice throughout the decision-making process.

Creating a review or advisory board is one way to put continuous engagement into practice. The need for an oversight board composed of diverse stakeholders was raised during the discussion. Like an institutional review board examining research studies' ethical implication, this board could offer a similar review at critical points during the negotiation process, such as selecting comparators and outcomes and developing the analytical plan. This board would include patients who can participate in CMS negotiations as partners and help guide engagement and data collection activities to ensure analyses capture the patient's voice and other non-CMS employees who have insight into the patient experience. A single listening session would not be practical to address the need to seek patient community feedback and ensure that feedback is pulled through at all points of the process.

> **"I mean if that's all there is, no, it's not enough. But if it's the first step, then yeah, let's go with it."**

CMS has committed to holding patient-focused listening sessions as part of their updated guidance released on June 30. During our consensus discussion, participants were asked about how this impacts their overall perception of the negotiations process and if these sessions constitute continuous patient engagement.

The three themes that emerged were that: (1) listening sessions alone are not continuous patient engagement, although they are part of a continuous engagement process, (2) more information and detail on the sessions is needed but overall, this represents a positive step in the correct direction, and (3) when implementing listening sessions, accessibility should be ensured so that a variety of viewpoints can be heard and groups are not excluded from the conversation due to language, geographic or disability. Illustrative quotes are presented in **Appendix G**.

Opportunities for receiving patient input and information should take many forms. Patients shouldn't have to do all the work; CMS can only sometimes rely upon patients to provide the information proactively. The group agrees that there is no one way to engage patients and various approaches are necessary. CMS' process to define "clinical benefit" should involve recruiting and engaging diverse patients and caregivers using various methods to maximize outreach and ensure that no interested patient community is left behind. It may not be enough for patients to be able to submit information. An active engagement effort should reflect an understanding that not everyone can provide their perspective online or in writing. There is a need for a multi-pronged approach to reach patients, both to receive input and to disseminate information. The way CMS plans to collect data could be improved by providing additional mechanisms for data submission and active data collection. Specifically, this takes the form of allowing adequate time for comments – significantly longer than the short time described by CMS guidance-- and proactively ensuring the process for obtaining information is inclusive. Utilizing community health workers, focus groups, and a "hotline" that patients could call to provide information or use the training of community health workers to engage individuals directly would be productive. Participants emphasized the need to address that everyone impacted, including individuals with disabilities and individuals for whom English is not their first language, has an equal voice in decision-making. Participants also stressed the importance of accessibility, choice, and understanding patients from a holistic perspective when considering both how input is received and what types of information should be collected.

Transparency using multiple communication channels would build trust. As with how data and information are collected, the approach for dissemination should also be multifaceted. Beneficiaries and patient participants must be aware of how decisions are being made and how their input is being used and affects decision making. By continuously engaging patients, allowing for inclusive data collection practices, and creating a mechanism for accountability, CMS can help restore trust when trust in the government and healthcare institutions has waned.

3.2 Recommendations

With the knowledge that CMS has been given an accelerated timeline through legislation, there is no expectation that patient engagement will occur overnight. As such, recommendations are categorized by time frame. As shown in Table 3, there are things CMS can do today to build trust and transparency and there are elements for which there should be planning for future implementation.

Table 3. Recommendations and recommended practices, by time to implementation

Recommendation	Recommended Practice
Short Term (Prior to December 31, 2023)	
In partnership with the patient community, develop a patient engagement plan that spans the entire negotiation process.	CMS should research existing validated and non-controversial models and speak with patients and experts in the field of patient engagement to shape patient engagement for the remainder of this year (e.g., for patient-focused listening sessions) as well as future years of the program.
Have a touchpoint at each key decision point with the patient community where CMS provides updates and information about planned next steps and the patient community has an opportunity to react and provide suggestions.	Set times for engagement: • Before drug selection • Before listening sessions • After listening sessions but before negotiation concludes • After negotiation is over but before the public explanation is published • After the public explanation of the MFP is published These will provide additional opportunities for patients to react and provide feedback in a back and forth. These touchpoints, as with the patient-centered listening session, should be drug or condition specific.

Recommendation	Recommended Practice
Short Term (Prior to December 31, 2023)	
Provide the patient community with information on analyses used and decisions made before, during, and after listening sessions to facilitate productive patient feedback.	As early as possible before listening sessions or other key meetings, provide the patient community with current thinking and any pre-read and background materials on key elements of information to assess clinical benefit including: • Definitions of key parameters (e.g., therapeutic alternatives, unmet needs, outcomes, subgroups) • Types of data and evidence • Relative weighting of factors • Oher stakeholders engaging This information could include a description of the selected drug and initial thinking and/or illustrative examples of potential comparators, potential indications, and potential outcomes of interest. This recommendation is consistent with having scheduled touchpoints and will improve patients' ability to provide relevant, timely feedback under a short deadline.
Develop a process and template to share how stakeholder feedback guided decision-making and analyses.	Having feedback tells participants that they have been listened to. Much like CMS organizes comments in response to draft guidance, patient and stakeholder comments, input, and how these factors were incorporated into decisions should be placed within final reports. CMS should make public a summary of the learnings from the listening session including: how it impacted CMS decision making, CMS' current thinking on key elements of clinical benefit information, remaining questions CMS has for stakeholders, and questions stakeholders raised with CMS.

Recommendation	Recommended Practice
Short Term (Prior to December 31, 2023)	
Adopt principles of plain language and health literacy when releasing public materials so that these materials are easily understood by the patient community.	CMS must ensure materials and communications are appropriate for individuals with disabilities and those for whom English is not their first language. Additionally, CMS communications should preserve the geographic mix of patient input and representation from every area of the country, especially those that are rural, healthcare deserts, and / or isolated areas. Requests should be broadly distributed via all CMS communications capabilities (e.g., email distribution lists, newsletters), and in partnership with patient, consumer, and physician organizations. Any communications plan should include explicit consideration of outreach to vulnerable populations (e.g., individuals in medically underserved areas). CMS communications seeking input should also announce dates for future listening sessions.

Recommendation	Recommended Practice
Medium Term (Between January 1 – July 1, 2024)	
Implement continuous patient engagement approach.	Formalized adoption of short-term recommendations in a systematic, organized way. Regular basis, across different projects
Train CMS staff in engagement throughout the negotiations process.	Work with subject-matter experts in continuous patent engagement to improve the approach using evidence-based and/or peer-reviewed resources and frameworks (e.g., The PATIENTS Program, the Patient Centered Outcomes Research Institute (PCORI), the Center for Implementation Science) with a focus on empathy, compassion, and the impact of health care on the individual. Ensure that internal or external contractor(s) or staff responsible for receiving and evaluating input include individuals trained in patient engagement, patient-centered outcomes and patient experience data. Any external resources (e.g., other agencies or outside organizations) consulted during the MFP-setting process should be transparently announced and included in the MFP justification.
Develop a plan for third-party evaluation to ensure transparency and accountability in patient engagement in partnership with the patient community.	Involve patients and other subject matter experts in developing the evaluation plan to ensure the metrics that are important to patients are prioritized, including in the call for proposals for potential vendors.

Recommendation	Recommended Practice
Long Term (After July 1, 2024)	
Implement third-party evaluation to ensure transparency and accountability in patient engagement.	Develop a clear communication strategy that prioritizes patient preferences for how to receive information about the negotiations process. This recommendation is consistent with ensuring accessibility and adopting principles of plain language.
Prioritize evidence developed using principles of patient-centricity (i.e., 10-Step Framework, PCORI rubric).	Include references in any communication or output that denote that research considered or utilized was developed or derived from work using a patient-centered framework.

4. Additional PATIENTS Professors viewpoints

During the Consensus Meeting and both office hour sessions, participants were asked if there were additional viewpoints, they would like to include that may differ from those presented in this document. All feedback received dealt with refining the recommendations provided here and no differing viewpoints were provided.

5. Next steps

The project team – PATIENTS Professors, PATIENTS Program Staff, and Applied Patient Experience Staff – are all committed to facilitating patient engagement and patient-centered decision-making that CMS needs to ensure that disease-specific patient-community perspectives are accounted for when evaluating the clinical benefits of selected medicines. However, patient perspectives can only be valued and considered if engagement occurs early and meaningfully throughout the process to identify and assess data and determine how the data are weighted and used in CMS decision making. As such, we call on CMS to utilize these recommendations to adopt a proactive, formalized approach to engaging patients.

6. References

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7. Appendices

Appendix A. The PATIENTS Program and the PATIENTS Professors Academy

The PATIENTS Program is an interdisciplinary research team of community partners and researchers based out of the University of Maryland Baltimore's School of Pharmacy. The PATIENTS Program provides a successfully proven approach to continuous engagement in patient-centered research, known as the 10-Step Framework for Continuous Patient Engagement. Since 2013, the PATIENTS Program has served as a bridge between West Baltimore communities and researchers at the University of Maryland Baltimore. The shared vision is that "patients and stakeholders are heard, inspired, and empowered to codevelop research."

The benefits of approach include:

1. an authentic commitment to—and from—the community,
2. faster recruitment and greater retention in studies,
3. enhanced diversity for representative results and,
4. better patient self-management because of the inclusivity in research.

The PATIENTS Program is housed within the Department of Practice, Sciences, and Health Outcomes Research (P-SHOR) at the University of Maryland, Baltimore, which improves health care through innovation, collaboration, and advocacy to achieve excellence in pharmacy education, practice, and research. There are more than 50 faculty members whose training and expertise encompass pharmacy, public health, pharmacoepidemiology, pharmacoeconomics, health services research, law, and health policy. The health services and outcomes research initiatives promote health services and outcomes research and advances information on public policy and health outcomes related to prescription drug use and delivery. It advocates advanced education and research training in behavioral, economic, and pharmacoepidemiologic health services, and policy analysis as applied to the problems of drug use and drug distribution. The Department addresses these goals by:

- Conducting new and innovative research related to the delivery, use, costs, and safety of pharmaceuticals and other health care products.
- Providing expertise, support and leadership to professional, governmental, community and health-related organizations and agencies.
- Training graduate students, post and pre-doctoral fellows for future academic, industry, and public policy positions through a variety of academic, training and mentoring programs.

The PATIENTS Program provides a successfully proven approach to continuous engagement in patient-centered research across multiple medical specialties. In 2022, the PATIENTS Program launched its **PATIENTS Professors Academy**, a free 5-week virtual program that teaches the PATIENTS Program 10-Step Framework for continuous patient and stakeholder engagement with interactive components led by patient advisors and subject matter experts, so research is conceptualized and driven by communities of patients and their care providers.

The benefits of the PATIENTS Program approach, proven over the past ten years, include:

- An authentic commitment to and from the community.
- Faster recruitment and greater retention in studies.
- Enhanced diversity so that the research results are representative of all of us.
- Better patient self-management due to the inclusivity of the community in research.

The PATIENTS Professors Academy utilizes a hybrid virtual model of synchronous and asynchronous activities.

Online synchronous learning: Five (5) required weekly seminars are taught in a real-time online course environment. Seminar Leaders present content; participants dispersed to breakout rooms to discuss the topic, and participants and seminar leaders discussed the topic together to share results and ideas. In addition, office hours and discussion salons were held in real-time online each week. These optional sessions provided participants the opportunity to interact and ask questions of the PATIENTS Professor and faculty member who taught that week, and these events led to significant conversations and insights. **Appendix Table 1A** provides an overview of topics and seminar leaders for the 2022 Academy.

In 2022, the Academy graduated 90 “Professors.” Graduates of The PATIENTS Professors Academy can advise companies, government agencies, community-academic partnerships, and other entities on ways to make clinical and translational research more relevant, appealing, and diverse. In 2023, 150 Professors graduated from the Academy.

Appendix Table A1. 2022 PATIENTS Professors Academy Topics and Seminar Leaders

Kick-Off Week 1 (July 11) - Diversity, Equity, Inclusion, and Justice

DeJuan Patterson, PATIENTS Professor and passionate advocate for community empowerment, and Donna Jacobs, Senior Vice President Government, Regulatory Affairs and Community Health with the University of Maryland Medical System, led our first Seminar. They asked students about their experience with DEIJ issues in community spaces and policy decision-making

Academy Week 1 (July 11-17) - Health Equity

Dwyan Monroe, PATIENTS Professor and Program Coordinator for the Institute of Public Health Innovation, and Dr. Claudia Baquet, Affiliate Professor at the University of Maryland School of Pharmacy, and advocate for equity in health care, examined the history of health equity and how health research has evolved. They led an interactive discussion about health disparities and how to work towards health equity.

Academy Week 2 (July 18-24) - Responsible Conduct of Human Research and Patient-Centered Outcomes Research

Cynthia Chauhan, a PATIENTS Professor with years of experience as a patient advocate in health research, and Michelle Medeiros, the PATIENTS Program Director of Research, focused on how patient and community input into research can create better health outcomes. Students learned valuable tools to evaluate research and act with confidence in collaborating with clinical researchers.

Academy Week 3 (July 25-31) - 10-Step Framework for Patient Engagement

Daniel Frye, a professional advocate for the blind and vision-impaired, and Dr. C. Daniel Mullins, the Executive Director of the PATIENTS Program, discussed the PATIENTS Program's 10-Step Engagement Framework, the cornerstone of our program. They emphasized how continuous engagement with community partners before, during, after, and between research projects creates mutually beneficial and empathetic partnerships. In addition, they highlighted how institutional structures in healthcare can discourage the blind, vision-impaired, and underrepresented communities from taking part in health care.

Appendix Table A1. 2022 PATIENTS Professors Academy Topics and Seminar Leaders

Academy Week 4 (August 1-7) - Community-Engaged Research

Gail Graham, a PATIENTS Professor, and Karen Morales, the Associate Director of Engagement for the PATIENTS program, will bring together a team of our PATIENTS Professors to discuss the challenges and triumphs in partnering with patients and communities. This team brings years of experience in how to create partnerships. They will share how to sustain partnerships through transparency and including community partners in decision-making.

Academy Week 5 (August 8-14) - Stakeholder Training

Jeff Wells, a PATIENTS Professor with years of patient advocacy experience, and Carly Lovelett, Director of Clinical and Rural Health Research at St. Lawrence Health and a PATIENTS Program partner working in New York's rural North Country, will talk about the importance of a stakeholder advisory board. They will lead students in an exercise where they will create a stakeholder advisory board to address a public health issue. This activity will emphasize why it is important for the voice of patients and stakeholders to be heard at every phase of the research process.

Online asynchronous learning: Each week, participants accessed the content management system for resources such as articles, videos, or podcasts related to that week's assignment. One of the graduation requirements is to complete weekly reflection assignments on each topic. Participants can access materials at any time throughout the Academy or can download resources for later study. Participants are encouraged to share their favorite resources related to the topic to expand the conversation.

Enduring materials: Graduates have perpetual access for all resources and information shared by our Seminar Leaders in addition to recordings of the live seminar.

Appendix B. Recruitment letter

The **PATIENTS** Program
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PATIENTS Professors needed: Apply what you learned to advance patient engagement!

We invite PATIENTS Professors to participate in a series of conversations to guide how the Centers for Medicare and Medicaid Services (CMS) can improve patient engagement. Participants will collaborate with PATIENTS staff to solicit, develop, and prioritize suggestions to be shared publicly.

Background: The Centers for Medicare and Medicaid Services (CMS) is a government entity that runs the Medicare program, a health insurance plan for people 65 and older. CMS also runs the Medicare Drug Plan (Part D), which covers costs for prescription drugs.

In 2022, the US Congress passed a law called the Inflation Reduction Act (The IRA). The IRA directs new federal spending for many different sectors of the government, including healthcare. The Office of Health Economics has created a **brief series of videos** if you are interested in learning more about the IRA and its impact on healthcare pricing and delivery.

One of the things the IRA does is instruct CMS to develop a process to study the comparative effectiveness of drugs that meet certain criteria to determine Medicare prices for these drugs.

The process will include a CMS literature review and analysis of healthcare databases. As part of this process, CMS will consider different aspects of a drug, including its cost, whether it meets an unmet patient need, and the clinical benefits that the drug brings to patients.

This comparison process will help CMS determine the Medicare prices for these drugs. CMS released **guidance that describes the process** in June 2023. The guidance does not include meaningful opportunities for patient engagement nor describe how patients could guide CMS or assist in interpreting the findings of this work.

This is where we need your assistance. Help us develop recommendations for how CMS can more fully include the patient's voice in their guidance. You will also be asked to review a draft report and provide suggestions for the final report.

Time Commitment: Participants are expected to attend three virtual meetings in Summer 2023:

- Introduction to the topic: 1 hour
- Town Hall discussion: 2.5 hours
- Recap, discussion, and consensus development of draft recommendation: 1 hour

Compensation: You will be paid up to $1,000 if you participate in the entire project. This includes attending and participating in all three virtual meetings and providing feedback on the summary.

Public Acknowledgement: When we write and publish the report, each PATIENTS Professor will be named as a contributor to the report. In the details of the report, we will combine suggestions from all participants and share as group recommendations. If we include a quote of an exact statement you made, we will not include your name. If you disagree with any of the individual recommendations, you will have the opportunity to acknowledge your disagreement in the report.

Funding: This project is funded by the Pharmaceutical Research and Manufacturers of America (PhRMA).

University of Maryland
School of Pharmacy

Appendix C. Background meeting slides

The **PATIENTS** Program
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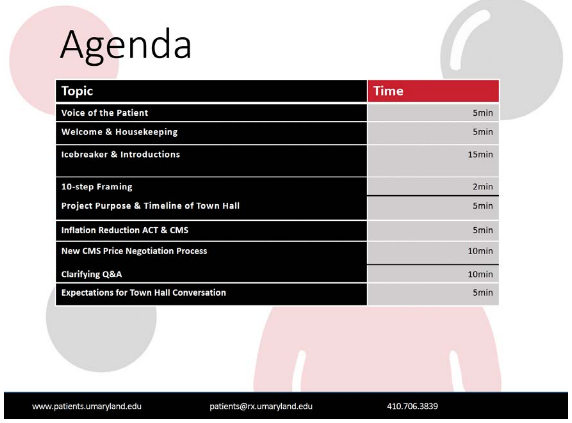
PATIENTS Professors

Background Session for CMS Town Hall

University of Maryland School of Pharmacy



Agenda

Topic	Time
Voice of the Patient	5min
Welcome & Housekeeping	5min
Icebreaker & Introductions	15min
10-step Framing	2min
Project Purpose & Timeline of Town Hall	5min
Inflation Reduction ACT & CMS	5min
New CMS Price Negotiation Process	10min
Clarifying Q&A	10min
Expectations for Town Hall Conversation	5min

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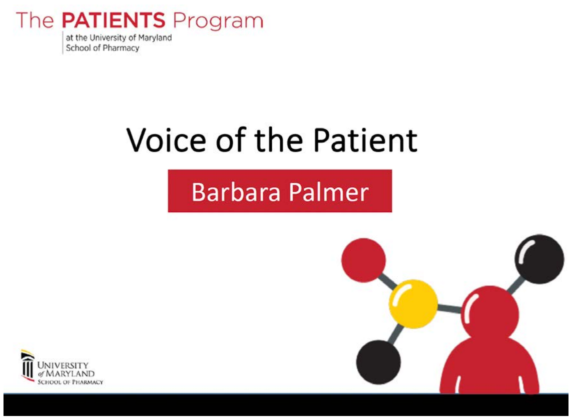

The **PATIENTS** Program
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Voice of the Patient

Barbara Palmer

University of Maryland School of Pharmacy

The **PATIENTS** Program
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Welcome & Housekeeping

University of Maryland School of Pharmacy

Introductions

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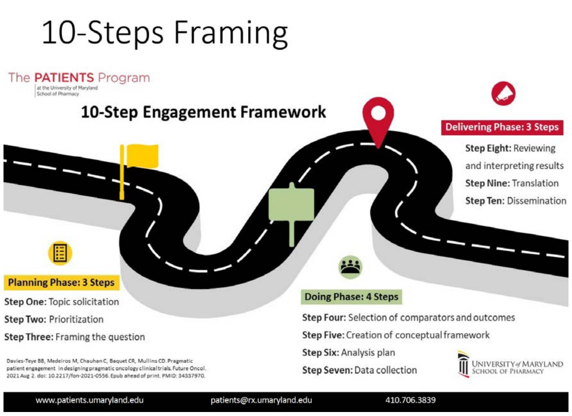

10-Steps Framing

The **PATIENTS** Program
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School of Pharmacy

10-Step Engagement Framework

Planning Phase: 3 Steps
- **Step One:** Topic solicitation
- **Step Two:** Prioritization
- **Step Three:** Framing the question

Doing Phase: 4 Steps
- **Step Four:** Selection of comparators and outcomes
- **Step Five:** Creation of conceptual framework
- **Step Six:** Analysis plan
- **Step Seven:** Data collection

Delivering Phase: 3 Steps
- **Step Eight:** Reviewing and interpreting results
- **Step Nine:** Translation
- **Step Ten:** Dissemination

Davies-Teye BB, Medeiros M, Chauhan C, Baquet CR, Mullins CD. Pragmatic patient engagement in designing pragmatic oncology clinical trials. Future Oncol. 2021 Aug 2. doi: 10.2217/fon-2021-0556. Epub ahead of print. PMID: 34337970.

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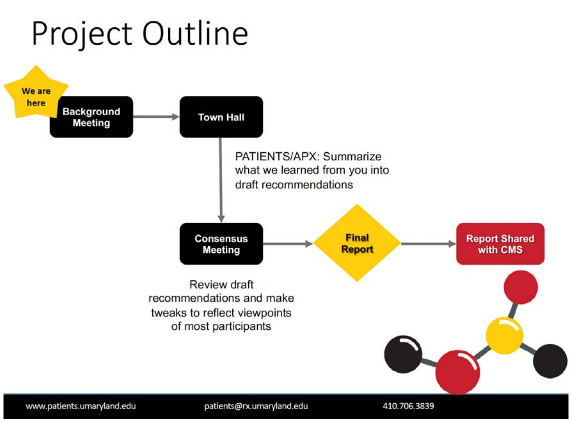
Appendix C. Background meeting slides



Project Outline

We are here

Background Meeting → Town Hall

PATIENTS/APX: Summarize what we learned from you into draft recommendations

Consensus Meeting → Final Report → Report Shared with CMS

Review draft recommendations and make tweaks to reflect viewpoints of most participants

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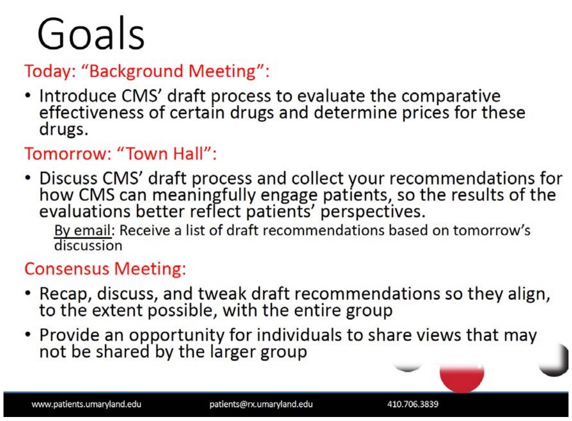

Goals

Today: “Background Meeting”:

- Introduce CMS’ draft process to evaluate the comparative effectiveness of certain drugs and determine prices for these drugs.

Tomorrow: “Town Hall”:

- Discuss CMS’ draft process and collect your recommendations for how CMS can meaningfully engage patients, so the results of the evaluations better reflect patients’ perspectives.
  By email: Receive a list of draft recommendations based on tomorrow’s discussion

Consensus Meeting:

- Recap, discuss, and tweak draft recommendations so they align, to the extent possible, with the entire group
- Provide an opportunity for individuals to share views that may not be shared by the larger group

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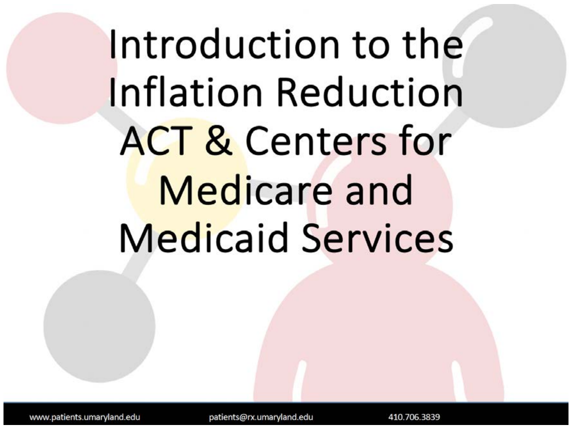

Introduction to the Inflation Reduction ACT & Centers for Medicare and Medicaid Services

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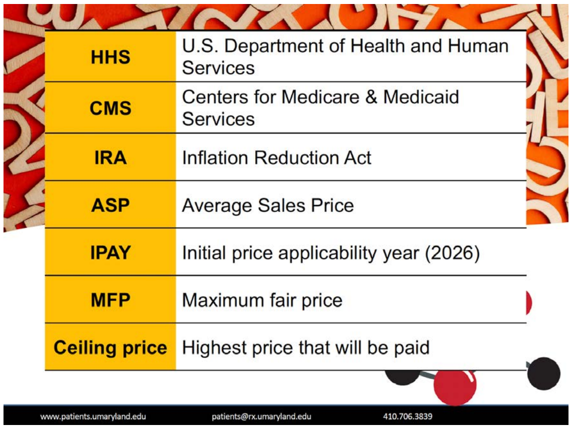

HHS	U.S. Department of Health and Human Services
CMS	Centers for Medicare & Medicaid Services
IRA	Inflation Reduction Act
ASP	Average Sales Price
IPAY	Initial price applicability year (2026)
MFP	Maximum fair price
Ceiling price	Highest price that will be paid

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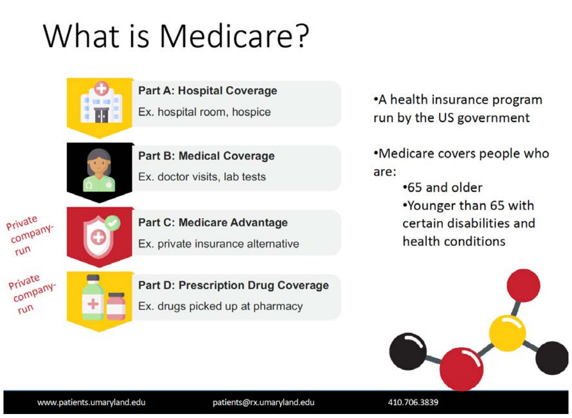

What is Medicare?

Part A: Hospital Coverage
Ex. hospital room, hospice

Part B: Medical Coverage
Ex. doctor visits, lab tests

Private company-run

Part C: Medicare Advantage
Ex. private insurance alternative

Private company-run

Part D: Prescription Drug Coverage
Ex. drugs picked up at pharmacy

- A health insurance program run by the US government
- Medicare covers people who are:
  - 65 and older
  - Younger than 65 with certain disabilities and health conditions

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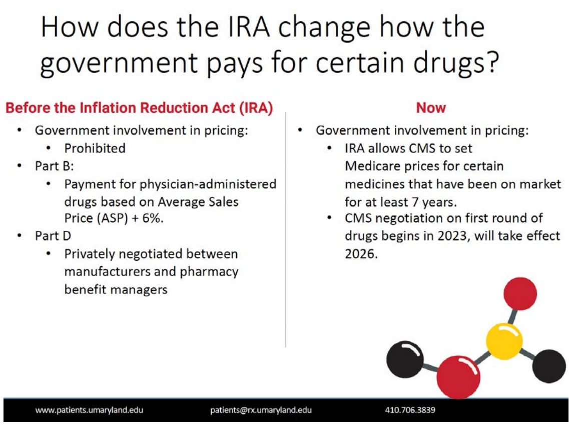

How does the IRA change how the government pays for certain drugs?

Before the Inflation Reduction Act (IRA)

- Government involvement in pricing:
  - Prohibited
- Part B:
  - Payment for physician-administered drugs based on Average Sales Price (ASP) + 6%.
- Part D
  - Privately negotiated between manufacturers and pharmacy benefit managers

Now

- Government involvement in pricing:
  - IRA allows CMS to set Medicare prices for certain medicines that have been on market for at least 7 years.
  - CMS negotiation on first round of drugs begins in 2023, will take effect 2026.

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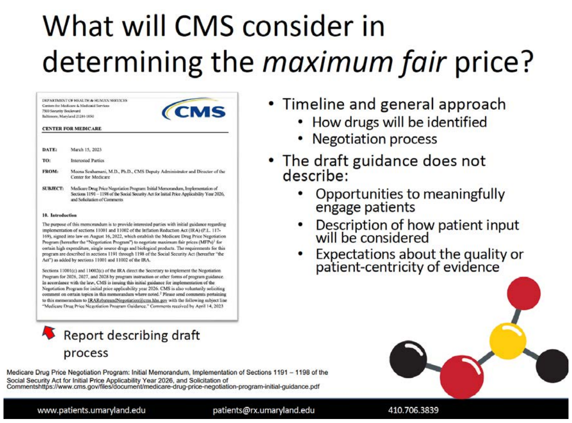
Appendix C. Background meeting slides



What will CMS consider in determining the *maximum fair* price?

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS

CENTER FOR MEDICARE

DATE: March 15, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

10. Introduction

The purpose of this memorandum is to provide interested parties with initial guidance regarding implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169), signed into law on August 16, 2022, which establish the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") to negotiate maximum fair prices (MFPs)¹ for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter "the Act") as added by sections 11001 and 11002 of the IRA.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this initial guidance for implementation of the Negotiation Program for initial price applicability year 2026. CMS is also voluntarily soliciting comment on certain topics in this memorandum where noted.² Please send comments pertaining to this memorandum to IRARebateandNegotiation@cms.hhs.gov with the following subject line "Medicare Drug Price Negotiation Program Guidance." Comments received by April 14, 2023

Report describing draft process

- Timeline and general approach
  - How drugs will be identified
  - Negotiation process
- The draft guidance does not describe:
  - Opportunities to meaningfully engage patients
  - Description of how patient input will be considered
  - Expectations about the quality or patient-centricity of evidence

Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Commentshttps://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

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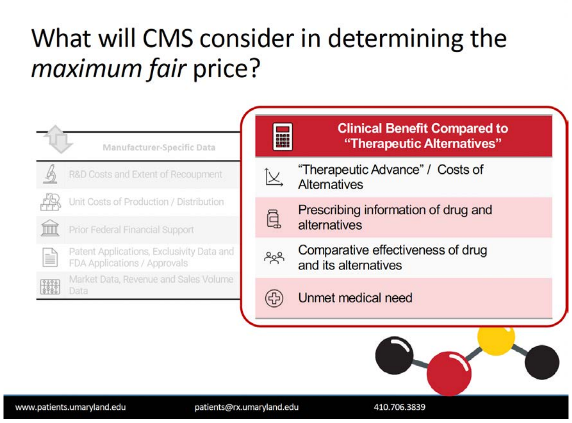

What will CMS consider in determining the *maximum fair* price?

Manufacturer-Specific Data
R&D Costs and Extent of Recoupment
Unit Costs of Production / Distribution
Prior Federal Financial Support
Patent Applications, Exclusivity Data and FDA Applications / Approvals
Market Data, Revenue and Sales Volume Data

Clinical Benefit Compared to "Therapeutic Alternatives"
"Therapeutic Advance" / Costs of Alternatives
Prescribing information of drug and alternatives
Comparative effectiveness of drug and its alternatives
Unmet medical need

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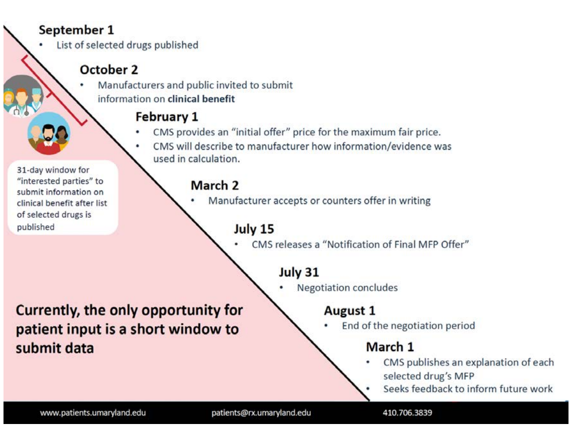

September 1
- List of selected drugs published

October 2
- Manufacturers and public invited to submit information on **clinical benefit**

February 1
- CMS provides an "initial offer" price for the maximum fair price.
- CMS will describe to manufacturer how information/evidence was used in calculation.

March 2
- Manufacturer accepts or counters offer in writing

July 15
- CMS releases a "Notification of Final MFP Offer"

July 31
- Negotiation concludes

August 1
- End of the negotiation period

March 1
- CMS publishes an explanation of each selected drug's MFP
- Seeks feedback to inform future work

31-day window for "interested parties" to submit information on clinical benefit after list of selected drugs is published

Currently, the only opportunity for patient input is a short window to submit data

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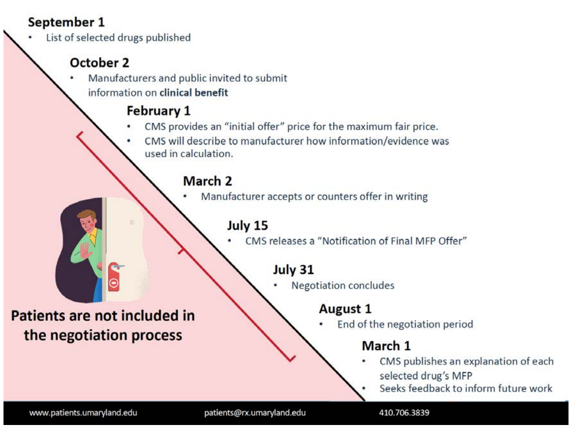

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Patients are not included in the negotiation process

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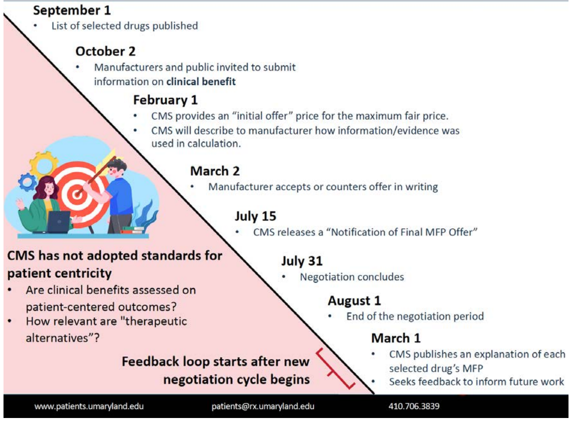

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- End of the negotiation period

March 1
- CMS publishes an explanation of each selected drug's MFP
- Seeks feedback to inform future work

CMS has not adopted standards for patient centricity
- Are clinical benefits assessed on patient-centered outcomes?
- How relevant are "therapeutic alternatives"?

Feedback loop starts after new negotiation cycle begins

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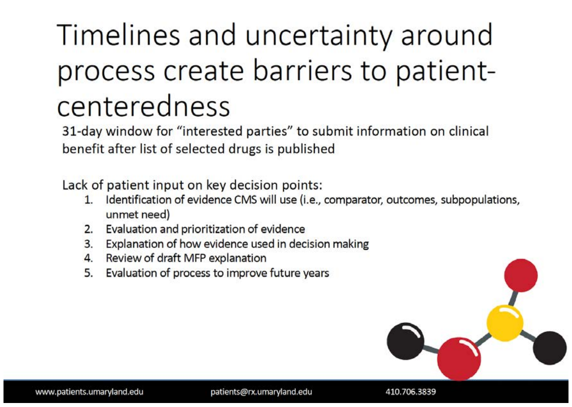

Timelines and uncertainty around process create barriers to patient-centeredness

31-day window for "interested parties" to submit information on clinical benefit after list of selected drugs is published

Lack of patient input on key decision points:
1. Identification of evidence CMS will use (i.e., comparator, outcomes, subpopulations, unmet need)
2. Evaluation and prioritization of evidence
3. Explanation of how evidence used in decision making
4. Review of draft MFP explanation
5. Evaluation of process to improve future years

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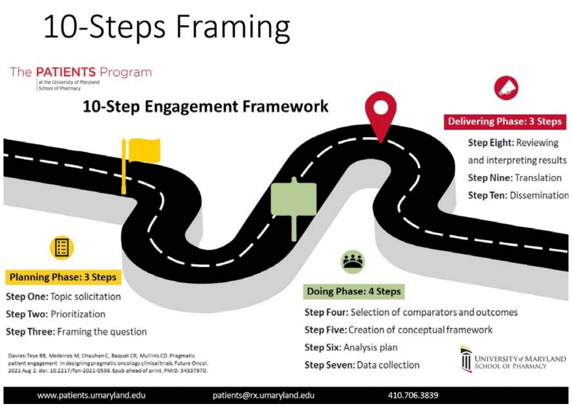
Appendix C. Background meeting slides



10-Steps Framing

The **PATIENTS** Program
at the University of Maryland
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10-Step Engagement Framework

Planning Phase: 3 Steps

Step One: Topic solicitation
Step Two: Prioritization
Step Three: Framing the question

Doing Phase: 4 Steps

Step Four: Selection of comparators and outcomes
Step Five: Creation of conceptual framework
Step Six: Analysis plan
Step Seven: Data collection

Delivering Phase: 3 Steps

Step Eight: Reviewing and interpreting results
Step Nine: Translation
Step Ten: Dissemination

Davies-Teye BB, Medeiros M, Chauhan C, Baquet CR, Mullins CD. Pragmatic patient engagement in designing pragmatic oncology clinical trials. Future Oncol. 2021 Aug 2. doi: 10.2217/fon-2021-0556. Epub ahead of print. PMID: 34337970.

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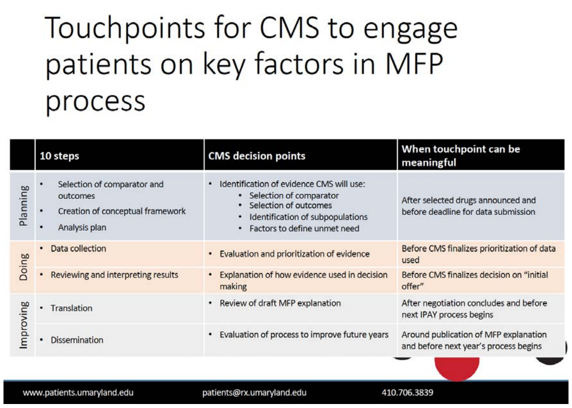

Touchpoints for CMS to engage patients on key factors in MFP process

	10 steps	CMS decision points	When touchpoint can be meaningful
Planning	• Selection of comparator and outcomes • Creation of conceptual framework • Analysis plan	• Identification of evidence CMS will use: • Selection of comparator • Selection of outcomes • Identification of subpopulations • Factors to define unmet need	After selected drugs announced and before deadline for data submission
Doing	• Data collection	• Evaluation and prioritization of evidence	Before CMS finalizes prioritization of data used
	• Reviewing and interpreting results	• Explanation of how evidence used in decision making	Before CMS finalizes decision on "initial offer"
Improving	• Translation	• Review of draft MFP explanation	After negotiation concludes and before next IPAY process begins
	• Dissemination	• Evaluation of process to improve future years	Around publication of MFP explanation and before next year's process begins

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Clarifying Q&A

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Town Hall Expectations

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Appendix D. Town Hall discussion questions

1. If you could wave a magic wand and change something about the CMS negotiation process, what would it be?
2. Are there touchpoints you would like to see built into CMS' process for the patient community to engage?
    a. Are there specific approaches you recommend?
3. How would CMS' timeline need to be modified to engage the patient community meaningfully and continuously?
4. How should the patient community be engaged as CMS assesses these specific elements of clinical benefit?
    a. Therapeutic alternatives (i.e., comparators)
    b. Therapeutic advance (i.e., improvement) compared to therapeutic alternatives
    c. Outcomes of interest
    d. Impact on subpopulations
    e. Addressing an unmet need
5. The decisions that CMS will make in the process currently occur behind closed doors. How do you believe this should evolve? What is important for you to know about the negotiations?
6. How should CMS inform stakeholders about the role patient input played? The role of other stakeholders?
7. Should CMS provide an opportunity for the patient community to provide feedback on the explanation if they have questions or disagree with something? Why or why not?
8. How can CMS ensure patients understand how their input is considered in the process?
9. Based on what you have learned and discussed over the past two days, what else would you like CMS to know as they implement this process?

Appendix E. Identified themes and additional explanatory quotes

Theme	Illustrative Quote
Continuous engagement is key	
	From the formulation of the question down to the dissemination of the results, the whole continuum, the patient should be involved in all of it.
	I think the patient is a stakeholder and should be engaged from the very beginning. So CMS should have had a collaborative relationship that meant everybody knows what's going on.
	[. . .] starting with the very beginning of the patient input on even the list of selected drugs, what, you know, what would benefit what drugs would benefit are most utilized would benefit the patient. I think just being a part of the entire process from the very beginning.
Patients and stakeholders should have equal role	I think they [patients] should both be equal members of whatever panels they're on equal to all the other panel members.
Other examples provide a pathway	I really like the FDA model. The FDA engages a patient actively, and a community representative actively. And I think if CMS looked at that approach. That is another way to get the whole community involved.
	Yeah, I think that it should not be a small timeframe. I think it shouldn't happen through the whole course. And the thing that I'm thinking of to use as an example is clinical trials. When a clinical trial is being done, it starts out with a certain amount of information in a certain plan. And as more information occurs, the plan may change based on that information. But through the course of the whole trial, it is open to receiving information that may change its course, I think we should use that model here. There should be an opportunity for public input through the whole process. And the process then evolves based on the receipt of that input.

Theme	Illustrative Quote
Continuous engagement is key	
Comprised of diverse stakeholder perspectives	This, then, would be. way of protecting the rights of Medicare met people who are recipients of the services through CMSs. So any change they would just like you would have to notify participants. If there's a change in the in the study as it was originally outlined, they would also have to update. But I'm suggesting that the members of our recipients of CMS services would also be updated in an ongoing basis after the review is done, and that someone in in these meetings who is considered a lay person or a person that's not employed by CMS, or has lower knowledge than someone who is actually a Provider or a CMS employee, or a Federal worker, or something in that sort."
Aides in dissemination and trust	What we were just talking about here almost like an IRB, But it's more community driven than it is scientists. And this issue here with CMS, it doesn't really require a lot of science per se behind this process that we're talking about. We're not breaking molecules here. We're talking about getting some information out to the community. So, it's it should. One would think it. It's like a no brain, it it's getting information to the community for the community. You would think that we would know to have the community somewhere playing a big part of this."
	I think a model we're using is. as you mentioned before, an IRB which has a nonscientist on it, who keeps confidential everything that is confidential. But the process requires them understanding and meeting would say, this was done. the according to the stay there that we've set up. But that idea of having a patient representative or multiple ones involved in the process from the whole way.

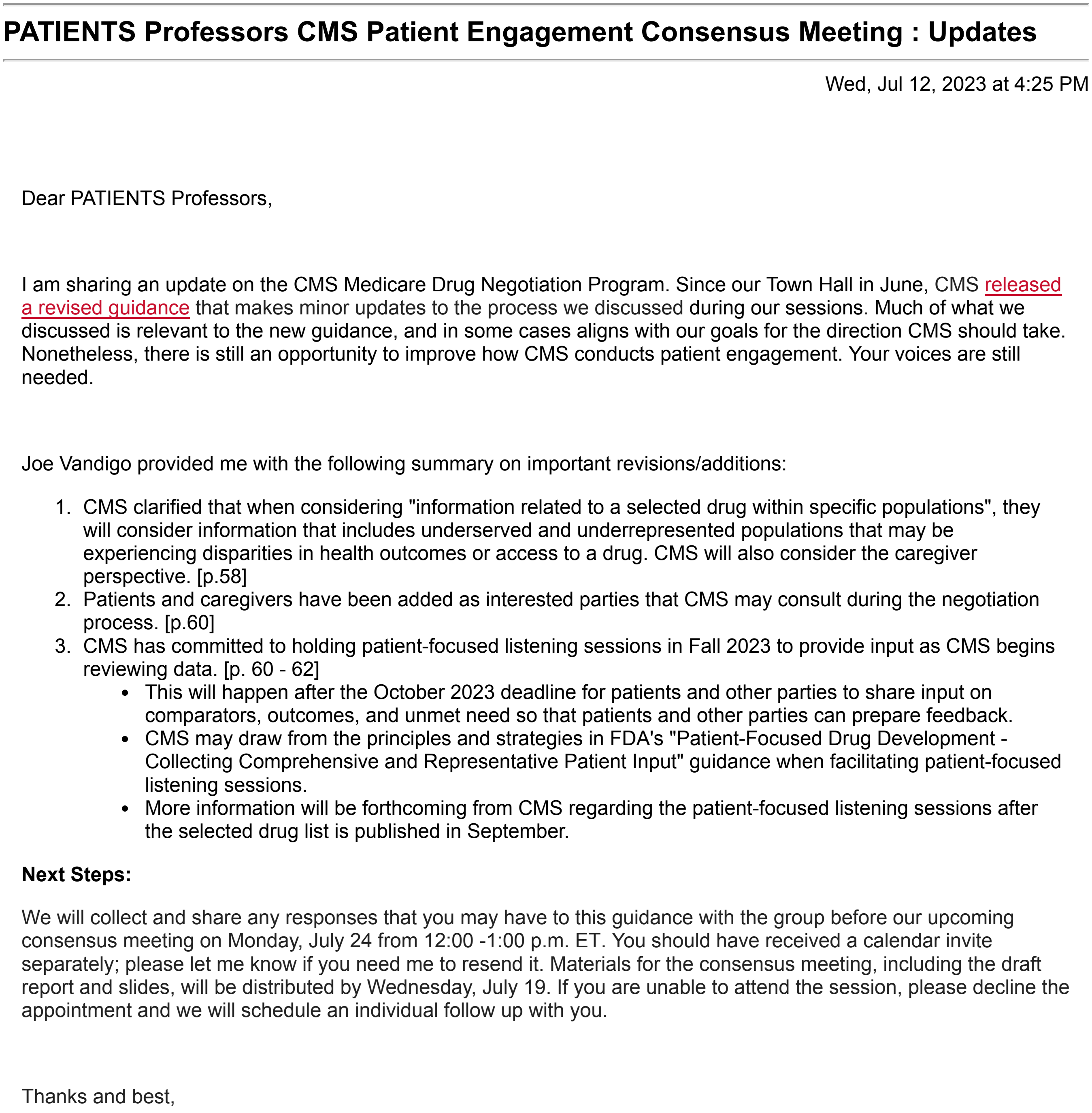
Theme	Illustrative Quote
Information collection should be proactive and inclusive	
Active data creation in addition to passive collection	And I don't think it's enough for the public to be able to submit information. I think the public needs to be not I don't know what the word is Canvas or reached out to that there needs to be a more active engagement of the public and an understanding that not everyone can do it in writing. That is a very elitist approach to me to say that it must be in writing, they really need to reach out and talk with people and transcribe what people say.
	So I think we need to look broadly at the ways and the areas where the population of interests might socialize or engage or are gathered so that we can address their needs or contact them directly. So that's just a thought.
	And also, like reaching out to people who, who English isn't their first language, I think those type population gets often left behind. And I think just having multiple languages for people who, whose English is not their first language. So like, for example, I come from an expat family. Most of my family does not speak English. However, there's a language barrier that needs to be considered, that needs to be looked at, if we want to provide meaningful engagement to various groups in our community.
Improvements to collect a broad range of perspectives	The public comment section, as it's set up, is only going to hear from the people that choose to answer, not the people that need to be hearing what the question is, but the people that can find the question, and will respond. Absolutely. And it's ignoring all the people. All the other things that causes you to get positive feedback only. And engineering will tell you positive feedback causes a system that go out of controls. So you need to just not definitely limit your input to justice people that will tell you what you want, which is what this seems to be

Theme	Illustrative Quote
Information collection should be proactive and inclusive	
	My concern is only using input electronically, leaves out a whole segment of important population. And they really need to look at a way to reach out to rural communities, to underserved communities, to get input in a very specific open, way that addresses the whole community.
Models for data collection	We use focus groups. we use like they, I use a model called the Yellow Table call, and I bring this to the community together. It's a senior community for the youth community, and whatever the topic is at hand. we build a discussion around that topic with not with the language that is not so broad that everybody's looking like what's going on. So you bring them in to help."
	We could look at old public health models. When the public health people went door to door, asked for information and to reach out to communities, much more sense of active engagement from the agency, rather than expecting the community, you do all the engagement.
	One of the specific approaches we could take is, again, hiring community health workers, they could hire community health workers to reach community leaders to disseminate the information that they that they want to disseminate and not just get a bunch of head nods, yeses, they can get a broad swath of people who are going to say yes, and gonna say, No, I'm going to put up some contention. But when you use the community health worker, as the bridge between CMS and the patient, then again, it makes more robust and you get, you get to have the real time feedback from the community
	Needs to be a multi-pronged approach. I think all of these ideas are great ideas. Some folks you're going to capture with the community health worker. And those are the folks that can get out that are mobile, and are aware of what's going on in communities, some, the hotline will be great, maybe for those who have mobility issues. But I think there needs to be resources allocated.

Theme	Illustrative Quote
Do not make engagement “check the box”	
“Check the box” engagement is not sufficient	I agree about being heard. But being part of the process. But what I worry about is being part of the process, and it’s just checking off a box. You gotta be part of the process and knowing that you’re listening to me, and I’m being heard, and thing and feedback come back to say, yes, I heard you. This is what happened, and this is, and we’re making it better because of what happened during this process. But just being heard, it is me being part of, not enough. Gotta be heard, and, and knowing what I say has relevant and benefit.
A continuous approach should have opportunities to check-in throughout the process	If there could possibly be a vote after every session every step has taken place, to make sure that patients are in agreement with moving forward to the next phase.
Process should allow for improvement	This is a new process, and it is new ideas that you’re putting out there new processes that you’re putting in place. Don’t you want people from the original cohort at least some to overlap into the next cohort, so that there is some consistency. There is some accountability from hey? This was the original idea. This was how it it fleshed out. This is what we did with it. And this is how we wanted it translated versus giving it to CMS and then maybe they say, Well, those are different people. They’re no longer here. We can just kind of, you know, finesse it in the direction that that we see to be important.
Importance of an accountability mechanism	What’s the accountability? Because typically we, we fall short of accountability. And from the hospital perspective, I can tell you, we fall short. I’m speaking for just a few hospitals in my rural area, of course. but I can tell you that collectively, the data will demonstrate that CMS put out incentives for hospitals to prove that they were giving quality of care. Well, those incentives are still in place, but we slacked, we slipped. There’s no accountability. or what if you don’t meet the measure, what if you don’t send the message back and forth?”

Theme	Illustrative Quote
Do not make engagement "check the box"	
	Probably the thing that I would think would provide value was that feedback, so people know what is being decided. Because once you have to tell what you've done, then you're more mindful of what you're doing. Hearing instead of going into the void of okay, we'll take your opinion, but didn't matter. But hearing back, having that feedback, engagement afterwards.
Transparency builds trust	
Highlighting impact of engagement	Not only should the patients be engaged, but that engagement should be highlighted in CMS's presentation of itself to the public and that would begin to speak to the patient as an equal partner, not a subject.
Broad dissemination of findings and impacts	And my main concern is, how is the public going to be notified?
Transparency creates trust	I think the value of having patients engaged in every step is it's no longer happens in a back room. But a patient shines a little bit of light. The analogy that I've used in another context is you turn rocks over and it's muddy and cruddy underneath. But all that dries up when it's shining the light on it, sunshine on it. So I think there's some value in not just the patients being heard, but the community hearing from a patient.

Appendix F. Letter to participants on June 30th guidance



PATIENTS Professors CMS Patient Engagement Consensus Meeting : Updates

Wed, Jul 12, 2023 at 4:25 PM

Dear PATIENTS Professors,

I am sharing an update on the CMS Medicare Drug Negotiation Program. Since our Town Hall in June, CMS released a revised guidance that makes minor updates to the process we discussed during our sessions. Much of what we discussed is relevant to the new guidance, and in some cases aligns with our goals for the direction CMS should take. Nonetheless, there is still an opportunity to improve how CMS conducts patient engagement. Your voices are still needed.

Joe Vandigo provided me with the following summary on important revisions/additions:

1. CMS clarified that when considering "information related to a selected drug within specific populations", they will consider information that includes underserved and underrepresented populations that may be experiencing disparities in health outcomes or access to a drug. CMS will also consider the caregiver perspective. [p.58]
2. Patients and caregivers have been added as interested parties that CMS may consult during the negotiation process. [p.60]
3. CMS has committed to holding patient-focused listening sessions in Fall 2023 to provide input as CMS begins reviewing data. [p. 60 - 62]
    - This will happen after the October 2023 deadline for patients and other parties to share input on comparators, outcomes, and unmet need so that patients and other parties can prepare feedback.
    - CMS may draw from the principles and strategies in FDA's "Patient-Focused Drug Development - Collecting Comprehensive and Representative Patient Input" guidance when facilitating patient-focused listening sessions.
    - More information will be forthcoming from CMS regarding the patient-focused listening sessions after the selected drug list is published in September.

Next Steps:

We will collect and share any responses that you may have to this guidance with the group before our upcoming consensus meeting on Monday, July 24 from 12:00 -1:00 p.m. ET. You should have received a calendar invite separately; please let me know if you need me to resend it. Materials for the consensus meeting, including the draft report and slides, will be distributed by Wednesday, July 19. If you are unable to attend the session, please decline the appointment and we will schedule an individual follow up with you.

Thanks and best,

Appendix G. Consensus meeting slides and polling questions

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PATIENTS Professors

CMS Recommendations Consensus Meeting
Monday, July 24
12 – 1pm EST

The PATIENTS Program at the University of Maryland School of Pharmacy

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Welcome Back!

Quick Housekeeping

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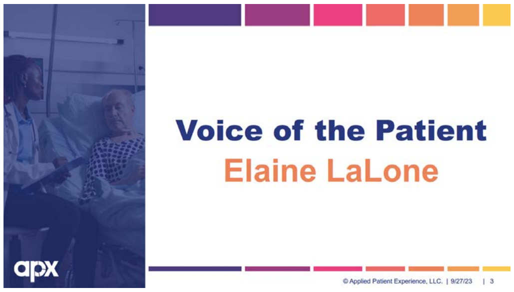

Voice of the Patient

Elaine LaLone

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Agenda

Topic	Time
Introductions/Housekeeping	2 min
Voice of the Patient	5 min
Overview	3 min
New Guidance	7 min
Theme overview	10 min
Recommendations Consensus	30 min
Conclusion/Wrap-up	3 min

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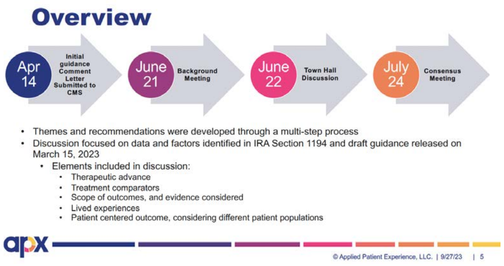

Overview

Apr 14 – Initial guidance Comment Letter Submitted to CMS
June 21 – Background Meeting
June 22 – Town Hall Discussion
July 24 – Consensus Meeting

- Themes and recommendations were developed through a multi-step process
- Discussion focused on data and factors identified in IRA Section 1194 and draft guidance released on March 15, 2023
  - Elements included in discussion:
    - Therapeutic advance
    - Treatment comparators
    - Scope of outcomes, and evidence considered
    - Lived experiences
    - Patient centered outcome, considering different patient populations

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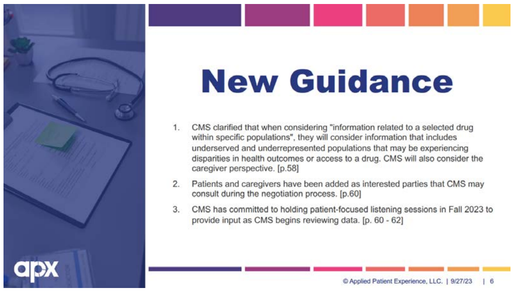

New Guidance

1. CMS clarified that when considering "information related to a selected drug within specific populations", they will consider information that includes underserved and underrepresented populations that may be experiencing disparities in health outcomes or access to a drug. CMS will also consider the caregiver perspective. [p.58]
2. Patients and caregivers have been added as interested parties that CMS may consult during the negotiation process. [p.60]
3. CMS has committed to holding patient-focused listening sessions in Fall 2023 to provide input as CMS begins reviewing data. [p. 60 - 62]

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Listening Sessions

Strongly disagree — Strongly agree

Hosting a patient-focused listening session adequately represents continuous patient engagement.

A listening session addresses concerns about the short submission timeframe in the process for CMS to receive input and information from patients.

A listening lesson addresses concerns about limited inclusivity in the process to receive input and information from patients.

Themes

Do not make engagement "check the box"

Continuous engagement is key	Information collection should be proactive and inclusive	Transparency using multiple communication channels builds trust

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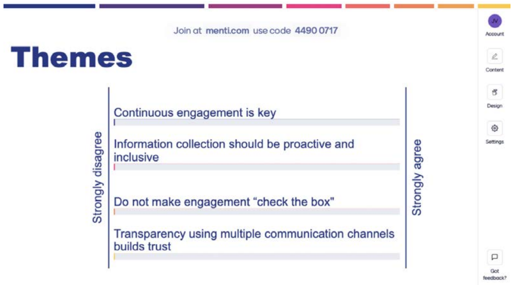
Appendix G. Consensus meeting slides and polling questions



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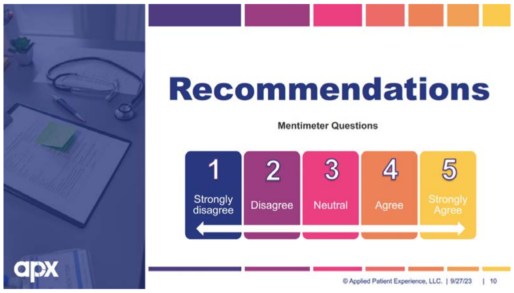
Themes

Strongly disagree — Strongly agree

- Continuous engagement is key
- Information collection should be proactive and inclusive
- Do not make engagement "check the box"
- Transparency using multiple communication channels builds trust



Recommendations

Mentimeter Questions

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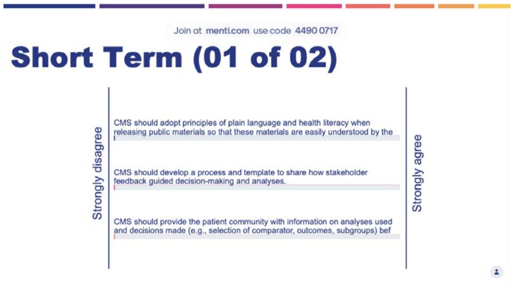

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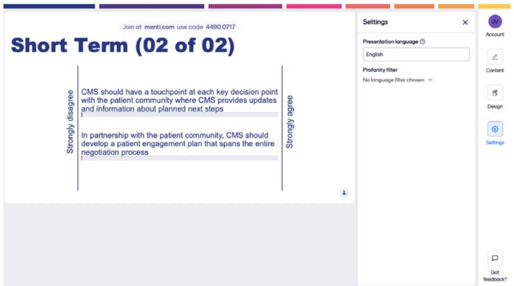
Short Term (01 of 02)

Strongly disagree — Strongly agree

- CMS should adopt principles of plain language and health literacy when releasing public materials so that these materials are easily understood by the
- CMS should develop a process and template to share how stakeholder feedback guided decision-making and analyses.
- CMS should provide the patient community with information on analyses used and decisions made (e.g., selection of comparator, outcomes, subgroups) bef



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Short Term (02 of 02)

Strongly disagree — Strongly agree

- CMS should have a touchpoint at each key decision point with the patient community where CMS provides updates and information about planned next steps
- In partnership with the patient community, CMS should develop a patient engagement plan that spans the entire negotiation process

Settings

Presentation language: English

Profanity filter: No language filter chosen

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Medium Term

Strongly disagree — Strongly agree

- CMS should implement a continuous patient engagement approach
- CMS should develop processes to train CMS staff in engagement throughout the negotiations process
- Develop a third-party evaluation of patient and stakeholder engagement to ensure transparency and accountability

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Long Term

Strongly disagree — Strongly agree

- Implement third-party evaluation to ensure transparency and accountability in patient engagement
- Prioritize evidence developed using principles of patient-centricity (i.e., 10-Step Framework, PCORI rubric)

Next Steps

Office Hours 01
Monday
July 31st
12 – 1pm EST

Office Hours 02
Monday
August 7th
12 – 1pm EST

Report Process

- Updated draft report by Friday, August 4th
- Return feedback before Friday, August 11th
- Report Returned to PhRMA by EOD Monday, August 14th
- Report sent to CMS before August 31st (*Planned*)

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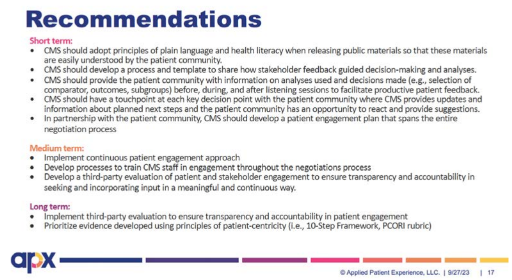

Recommendations

Short term:
- CMS should adopt principles of plain language and health literacy when releasing public materials so that these materials are easily understood by the patient community.
- CMS should develop a process and template to share how stakeholder feedback guided decision-making and analyses.
- CMS should provide the patient community with information on analyses used and decisions made (e.g., selection of comparator, outcomes, subgroups) before, during, and after listening sessions to facilitate productive patient feedback.
- CMS should have a touchpoint at each key decision point with the patient community where CMS provides updates and information about planned next steps and the patient community has an opportunity to react and provide suggestions.
- In partnership with the patient community, CMS should develop a patient engagement plan that spans the entire negotiation process

Medium term:
- Implement continuous patient engagement approach
- Develop processes to train CMS staff in engagement throughout the negotiations process
- Develop a third-party evaluation of patient and stakeholder engagement to ensure transparency and accountability in seeking and incorporating input in a meaningful and continuous way.

Long term:
- Implement third-party evaluation to ensure transparency and accountability in patient engagement
- Prioritize evidence developed using principles of patient-centricity (i.e., 10-Step Framework, PCORI rubric)

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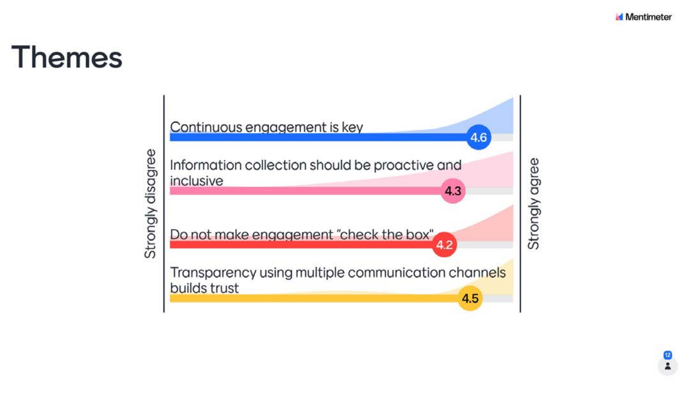
Appendix G. Consensus meeting slides and polling questions

Listening Sessions

Hosting a patient-focused listening session adequately represents continuous patient engagement.

A listening session addresses concerns about the short submission timeframe in the process for CMS to receive input and information from patients.

A listening lesson addresses concerns about limited inclusivity in the process to receive input d information from patients.



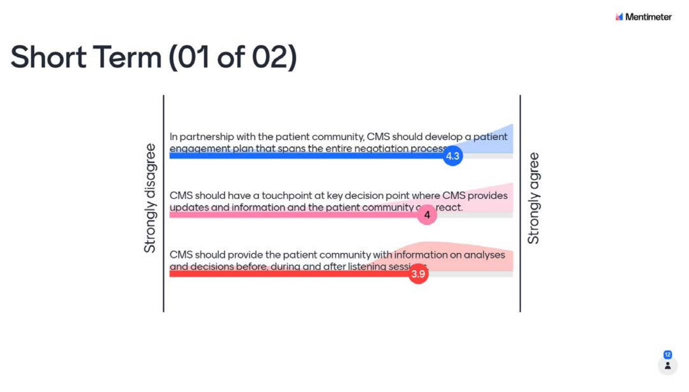
Themes

Continuous engagement is key

Information collection should be proactive and inclusive

Do not make engagement "check the box"

Transparency using multiple communication channels builds trust

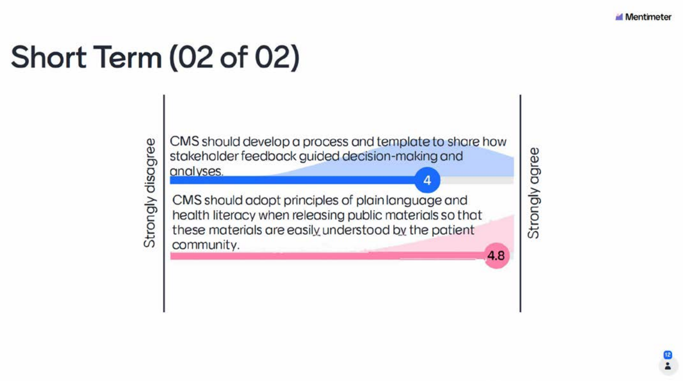


Short Term (01 of 02)

In partnership with the patient community, CMS should develop a patient engagement plan that spans the entire negotiation proces

CMS should have a touchpoint at key decision point where CMS provides updates and information and the patient community c react.

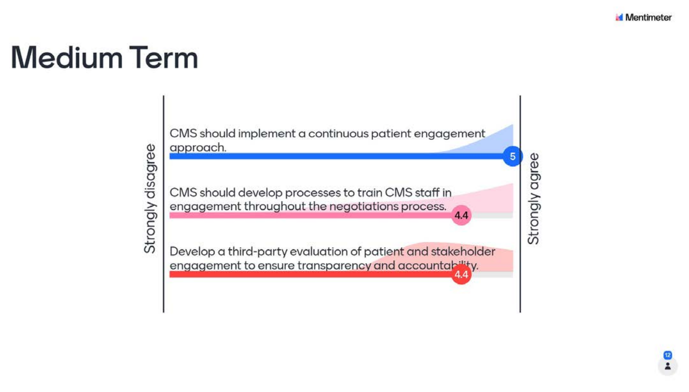
CMS should provide the patient community with information on analyses and decisions before, during and after listening sessi



Short Term (02 of 02)

CMS should develop a process and template to share how stakeholder feedback guided decision-making and analyses.

CMS should adopt principles of plain language and health literacy when releasing public materials so that these materials are easily understood by the patient community.

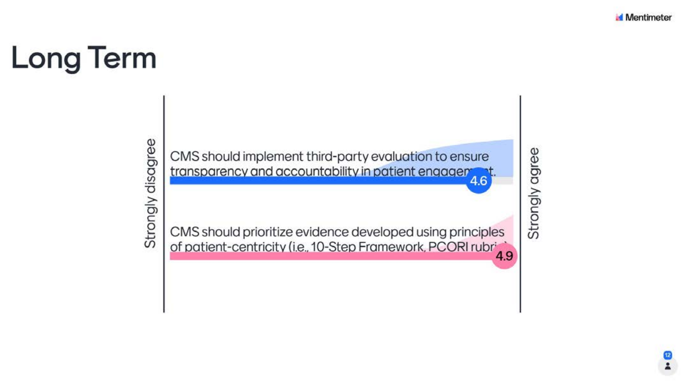


Medium Term

CMS should implement a continuous patient engagement approach.

CMS should develop processes to train CMS staff in engagement throughout the negotiations process.

Develop a third-party evaluation of patient and stakeholder engagement to ensure transparency and accountab ity.



Long Term

CMS should implement third-party evaluation to ensure transparency and accountability in patient engagem t.

CMS should prioritize evidence developed using principles of patient-centricity (i.e., 10-Step Framework, PCORI rubri

Appendix H. Themes and illustrative quotes (Patient-focused listening sessions)

Theme	Illustrative Quote
A component of continuous engagement, but not entirely patient engagement	I mean, they're, it's all a start. But listening sessions are not true patient engagement. They are the first step to adequate ongoing patient engagement.
	Too little if I mean if that's all there is, no, it's not enough. But if it's the first step, then yeah, let's go with it.
Positive direction but want more information	I just want to say that it's quite encouraging to see that CMS is wanting to engage patients more. The only thing I'm concerned right now is we'll see CMS holding subsequent patient focused listening sessions beyond the fall. That's what I'm concerned about right now. But it's really encouraging to see that they're taking the steps to assure patient engagement.
	Also, is it me or? And maybe I just need a little clarification. But it seems vague, the new guidance seems vague, almost not not detailed as to how they're going to do this. So are they going to determine that from these fall sessions? To see you know, what the feedback is, but then, you know, be more specific about, you know, how are they going to further engage patients and caregivers? You know, they say they're going to do but they don't say how they're going to do it. Other than the, you know, the townhall meetings?
Ensuring accessibility for participants	The other thing that I'm thinking about because I live in the middle of nowhere, is them reaching out to the underserved populations that are not electronically connected, and don't live in major areas. How are they planning to reach out because that's where a lot of the underserved people are. And it can't all be electronic and be true. And it can't all be just in person in Washington, DC and be true.