20230919 House Hearing, CMS and Innovation

Unofficial Auto Transcript
https://www.discoveriesinhealthpolicy.com/2023/09/september-19-2023-congress-holds.html

AI AUTO SUMMARY (FIREFLIES.AI)

PART ONE

AI meeting summary:

- Part 1 of the transcript discusses the need to update Medicare to meet the needs of seniors and lower drug costs. It highlights specific bills that aim to increase access to innovative medical technologies, improve coverage determination processes, and address chronic disease management. The importance of balancing innovation with budgetary implications is emphasized. Both Democrats and Republicans present their perspectives on improving Medicare coverage for drugs and devices, but differ in their approach.
- Democrats are committed to opposing any cuts to Medicare benefits, raising the retirement age, or increasing beneficiary contributions. They have proposed bills that would reduce cost sharing and extend funding for low-income beneficiaries, but these bills were rejected by the majority. However, they are pleased that HR 5380 Copays Act was included in today's hearing as it would eliminate copays for generic drugs for low-income beneficiaries. They also aim to address unfair pharmacy benefit manager practices and prioritize lowering costs for patients. The witnesses discussed the Centers for Medicare and Medicaid Services' work on ensuring timely coverage of innovative treatments and medical technologies for Medicare beneficiaries while maintaining rigorous evidence standards. CMS uses various pathways, such as national coverage determinations (NCD) and Coverage with Evidence Development (CED), to make coverage decisions. They are also developing a revised approach to NCDs that will provide greater transparency and consistency. Additionally, they introduced the Transitional Coverage for Emerging Technologies (TSET) pathway which offers an efficient review process for eligible breakthrough devices authorized or cleared by FDA.
- Dr. Hughes and CMS are discussing the need for transparency and accessibility of drugs for Medicare beneficiaries. They review formularies to ensure all necessary drugs are included and investigate complaints when contractors make decisions that go against evidence-based practices. They also discuss the limitations on coverage pathways for new medical devices and the importance of balancing patient access with fiscal realities. There is a focus on monitoring formularies to prevent discrimination against beneficiaries, especially regarding expensive drugs, and CMS agrees to reconsider recommendations made by

GAO. The transcript also touches on challenges in accessing innovative treatments in rural areas, particularly for Alzheimer's drugs, due to reimbursement issues. Finally, remote patient monitoring is highlighted as a valuable tool in healthcare accessibility during the COVID-19 pandemic, but there is a need to reevaluate minimum required durations for monitoring periods.

- CMS is working to improve access to early cancer diagnosis technologies for Medicare beneficiaries. They provide coverage for medically reasonable and necessary technologies on a claims by claim basis through local coverage determination and national coverage determinations. The multi-cancer early detection technology aims to address disparities in routine screening, especially among black Americans. HR 247, the Nancy Gardner Sewell Medicare multicancer Early Detection Screening Coverage Act, aims to increase timely access to this technology. There is concern about patients having to pay more at the pharmacy counter due to higher rebates required by PBMs from drug manufacturers. Greater scrutiny over these rebates could bring more fairness for patients. CMS has taken steps to increase transparency on fees charged by pharmacies and level the playing field for providers. The TSET Rule establishes a pathway for emerging technology to be covered under Medicare, with specific timelines and commitment from CMS. The Ensuring Patient Access to Critical Breakthrough Products Act allows temporary Medicare coverage for designated medical breakthrough devices, improving access and saving lives.
- The transcript discusses various issues related to Medicare coverage and access to medical innovations. Dr. Hughes emphasizes the need for Medicare beneficiaries to have full access to items and services that meet statutory standards. The discussion highlights the challenges faced by seniors on fixed incomes who are paying more for drugs compared to insurance companies, as well as the concentration of unbalanced rebate dynamics among certain types of patients with specific diseases. There is also a focus on CMS's evaluation process for new medical products in the context of the unique characteristics of the Medicare population. Additionally, there are discussions about creating a coverage pathway for breakthrough medical devices, improving access to home infusion services, and encouraging greater utilization of generics through reduced copays for low-income seniors.

Action items:

- From the transcript, the following tangible action items can be identified:
- Dr. Dora Hughes:
    1. Work with Congress to improve the transparency and timeliness of the National Coverage Determination (NCD) process.

    2. Review the decisions made by CMS contractors and address any issues where the process was not followed properly.
    3. Monitor the effective rebates on Part D formularies and their impact on Medicare and beneficiary spending.
    4. Work with Congress on proposals to address unfair pharmacy benefit manager practices.
- Mr. John Dickon:
    1. Work with Congress to improve the transparency and timeliness of the National Coverage Determination (NCD) process.
    2. Review the decisions made by CMS contractors and address any issues where the process was not followed properly.
    3. Monitor the effective rebates on Part D formularies and their impact on Medicare and beneficiary spending.
    4. Work with Congress on proposals to address unfair pharmacy benefit manager practices.
    5. Work with Congress on legislation to encourage greater generic utilization and save money for low-income seniors.
    6. Review recent experiences related to home infusion therapy and work with Congress to address any challenges faced in this area.
- Overall, the action items are focused on improving access to innovative medical technologies, ensuring transparency in coverage determinations, addressing issues related to rebates and formularies, and promoting affordable and quality coverage for Medicare beneficiaries.

Outline:

- Chapter 1: Opening Statements
- 01:25 - The chair recognizes himself for five minutes for an opening statement.
- 06:09 - The Chair now recognizes the Ranking Member, the Gentle Lady from California, for five minutes for her opening statement.
- 11:07 - The Chair will recognize the Chair of the full committee, Chair Rogers, for five minutes for an opening statement.
- 19:14 - We'll have our witnesses' opening statements today.
- Chapter 2: Witness Testimony
- 19:17 - The witness is introduced and given five minutes for an opening statement.
- 23:10 - Dr. Dora Hughes discusses the new Transitional Coverage for Emerging Technologies pathway (TSET).
- 24:11 - Dr. Hughes concludes her testimony.
- 24:20 - The chair now recognizes Mr. [unknown name] for his testimony.

- 25:40 - A summary of key findings and recommendations from a recent Geo report is presented.
- 29:23 - The witnesses conclude their prepared statements.
- 29:31 - The committee moves to members' questions.
- Chapter 3: Members' Questions
- 29:39 - The Chair recognizes himself for five minutes to ask questions.
- 30:31 - The Chair discusses working on improving transparency and timeliness of the NCD process.
- 33:39 - The Chair asks Dr. Hughes about the TSET pathway.
- 35:32 - The Gentle Lady from California asks questions.
- 36:49 - The Gentle Lady discusses investigating at their level.
- 39:01 - Mr. [unknown name] expresses his intention to send questions after the hearing.
- 41:01 - Mr. [unknown name] asks Dr. Hughes a question.
- 46:31 - Mr. [unknown name] mentions having more questions for the record.
- 51:10 - Mr. [unknown name] asks Dr. Hughes about implementation timelines for the TSET Rule.
- 55:45 - Dr. Hughes agrees with a statement made by Mr. [unknown name].
- 56:29 - Mr. [unknown name] asks a question.
- 57:48 - Dr. Hughes discusses implementation timelines and transparency.
- 59:21 - Mr. [unknown name] emphasizes the importance of meeting deadlines.
- 1:01:36 - The Chair asks questions.
- 1:01:43 - The Chair picks up where a colleague left off.
- 1:02:12 - The Chair asks Dr. Hughes about clear and accountable timelines for review and coverage decisions.
- 1:02:36 - The Chair requests specific commitments to timelines.
- 1:03:09 - Dr. Hughes agrees to provide more transparency and deadlines.
- 1:06:02 - Mr. [unknown name] discusses rigorous evidence review.
- 1:11:18 - Mr. [unknown name] expresses appreciation for the witnesses' opinions and expertise.
- 1:13:02 - Dr. Hughes is asked about the need for quicker decisions.
- 1:14:40 - Dr. Hughes highlights the commitment to transparency and deadlines.
- 1:14:55 - The next question is directed to Mr. [unknown name].
- 1:16:16 - The Chair recognizes Ms. [unknown name] for questions.
- 1:18:32 - Ms. [unknown name] mentions challenges and working together.
- 1:20:06 - Dr. Hughes agrees to work on the issues.
- 1:21:32 - Ms. [unknown name] expresses willingness to work together.
- 1:23:17 - The Chair recognizes Dr. [unknown name] for questions.
- 1:24:59 - Dr. [unknown name] mentions the need to review comments and evidence.

- 1:25:10 - The topic switches to other legislation.
- 1:25:16 - Mr. [unknown name] asks Dr. Hughes about a specific bill.
- 1:26:29 - Dr. Hughes states she may not be able to answer quickly.
- 1:26:54 - The Chair recognizes Dr. [unknown name] for questions.
- 1:27:03 - Dr. [unknown name] expresses appreciation for the witnesses' testimony.
- 1:27:42 - The discussion about digital technologies is highlighted.
- 1:28:49 - The Chairman and Ranking Member are thanked for including the topic.
- 1:32:06 - The Chair recognizes Dr. [unknown name] for questions.
- 1:32:09 - The Chair accepts a statement of support.
- 1:32:16 - The Chair recognizes Dr. [unknown name] for questions.
- 1:32:21 - Dr. [unknown name] expresses gratitude for the witnesses' opinions and expertise.
- Chapter 4: Closing Remarks
- No specific timestamps indicate the conclusion of the hearing or closing remarks.
- Note: The chapter titles are based on the content and context of the transcript but may not accurately represent the actual topics discussed.
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- **PART TWO**

AI meeting summary:

Summary:

- The transcript includes discussions about the significant error in estimated and observed spending in Medicare, the impact of Medicare Part D on reducing costs and disease burden, the need for long-term preventive health savings, the importance of transparency in Medicare Advantage plans' supplemental benefits, and concerns about coverage with evidence development (CED) requirements limiting patient access to FDA-approved items. The transcript also mentions several bills related to increasing patient access to innovative therapies and improving coverage determinations.
- CMS took five years to agree to cover a certain medical treatment, but in the meantime, the company provided it for free to Medicare patients. The speaker acknowledges that this is not the fault of the person they are addressing, but states that it needs to be addressed for the broader CMS audience. They express the need for more retired NCDs and mention bills aimed at improving Medicare coverage. One bill focuses on eliminating copayments for low-income patients using generic drugs. The speaker asks if increasing generic drug utilization will reduce overall drug spending and if eliminating copayments will encourage more people to use generics. The transcript then moves on to discuss changes in Part D benefits under the Inflation Reduction Act and their impact on

low-income beneficiaries. The timeframe for implementing a cap of $2,000 out-of-pocket expenses for prescription medication is mentioned as 2025. Another representative discusses a bipartisan bill called Protecting Patients Against PBM Abuses Act that aims to address high drug prices caused by pharmacy benefit managers (PBMs). A GAO report found that PBMs do not pass savings onto beneficiaries and may disadvantage lower-cost drugs due to rebate practices. The representative urges cooperation on this critical legislation from both witnesses present at the hearing.

- In another part of the transcript, concerns are raised about registry requirements imposed by CMS for access to FDA-approved Alzheimer's treatments through coverage with evidence development (CED) programs. These requirements could create barriers for underserved populations such as low-income seniors, rural seniors, Black Americans, and Hispanic Americans seeking treatment options.
- The witness responds by stating that CMS has made efforts to ensure easy access through an online registry available on their website which takes approximately five minutes to fill out. They also mention other organizations interested in starting their own registries where providers can have choices.
- There is discussion about tracking concerns or complaints from individuals experiencing difficulties accessing treatments or facing barriers due to geographical location or socioeconomic status.
- Overall summary: This part of the transcript covers concerns about delayed coverage decisions, bills aimed at improving Medicare coverage and reducing drug costs, issues with pharmacy benefit managers (PBMs), and challenges faced by underserved populations in accessing Alzheimer's treatments under CED programs.
- Dr. Hughes discusses the need for timely access to innovative treatments for Medicare beneficiaries and emphasizes the importance of adhering to a consistent and transparent timeline for coverage decisions. A bipartisan bill called the Access to Innovative Treatments Act is introduced to address bureaucratic delays in accessing proven treatments. Other bills are also mentioned, such as the Find Act, which aims to improve payment policies related to diagnostic radiopharmaceuticals, and the Timely Access to Coverage Decisions Act, which seeks timely local coverage determinations. The transcript also highlights bills that focus on expanding access to life-saving medications and treatments for seniors under Medicare, such as HR 2407 (Multi-Cancer Early Detection Screening), HR 40818 (Treat and Reduce Obesity), and HR 3842 (Expanding Access to Diabetes Self-Management Training). Additionally, concerns are raised about CMS's proposed exclusion of diagnostic lab tests from coverage pathways under TCET. The need for increased access to obesity

medications is emphasized, along with opposition towards minimum staffing ratio requirements for nursing homes due to existing staffing challenges.

- The transcript discusses the shortage of healthcare staff in nursing homes and long-term care facilities, as well as the challenges they face in complying with increasing staffing requirements. The discussion also touches on penalties for non-compliance.
- Additionally, there is a conversation about Medicare coverage pathways for innovative drugs, medical devices, and technologies. The need to improve access to these treatments is highlighted, particularly in Massachusetts where medical innovation plays a significant role.
- The transcript further includes discussions on the proposed transitional Coverage for Emerging Technologies (TSET) guidance and its limitations in expanding patient access to innovative medical devices due to resource constraints.
- There are also conversations about improving Medicare patients' timely access to medications through mail delivery or family member pick-ups post-public health emergency. Concerns are raised regarding CMS rules that restrict such deliveries based on self-referral laws.
- Lastly, the conversation shifts towards creating coverage parity for Medicare patients by aligning reimbursement policies with those of private insurance plans. This would ensure that seniors have equal access to safe and effective innovations regardless of their insurance type.
- Overall, the transcript covers topics related to staffing shortages in healthcare facilities, improving Medicare coverage pathways, expanding patient access to innovative treatments and medications, addressing reimbursement disparities between different insurance types, and promoting cost savings through biosimilars utilization.
- Dr. Hughes discusses the need to enhance access to biosimilars in order to reduce drug spending for the government and beneficiaries. He expresses interest in working on a proposal related to this issue.
- There is concern about the lack of coverage pathways for innovative diagnostic tests under Medicare, and Dr. Yuse explains that local Medicare administrative contractors play a role in reviewing these tests.
- The lack of coverage pathways for FDA-approved devices with breakthrough designation under Medicaid is highlighted as an issue, particularly affecting pediatric patients. CMS is working on prioritizing the needs of pediatric beneficiaries in Medicaid.
- The Treat and Reduce Obesity Act aims to improve obesity treatment coverage under Medicare by enhancing access to intensive behavioral therapy and allowing Part D coverage for anti-obesity medications. CMS expresses willingness to work on this proposal.

- The Share the Savings with Seniors Act, which includes rebate pass-throughs for chronic condition medicines, is mentioned as a positive development.
- Concerns are raised about high out-of-pocket costs for beneficiaries despite rebates received by Part D plans. The need to address PBM malfeasance is discussed, and Dr. Hughes commits to working on proposals related to lowering patient costs.
- Digital therapeutics are recognized as potentially beneficial for mental health services among Medicare beneficiaries, especially underserved populations. CMS acknowledges their potential but seeks more information before incorporating them into existing benefits.
- Off-label treatments remain inaccessible for Medicare patients outside of cancer care where compendia inclusion allows coverage decisions between doctors and patients without intervention from CMS or other agencies.
- Expanding remote monitoring access through digital health technology is viewed as valuable in rural communities with provider shortages like rural Appalachia, Ohio. HR 5394 proposes extending coverage of remote monitoring at two days per month while long-term billing thresholds are developed.

Action items:

- From the transcript, the following tangible action items can be identified:
    1. Dr. Hughes (CMS):
        - Work with the committee on expanding access to remote monitoring, including discussing the proper billing threshold.
        - Work with the committee on expanding coverage for artificial intelligence in FDA-approved devices and software.
        - Work with the committee on expanding coverage for innovative diagnostic tests.
        - Work with the committee on addressing the coverage and payment for digital therapeutics.
        - Work with the committee on updating coverage policies for obesity treatments.
        - Work with the committee on addressing the rebate issue for pharmaceuticals.
    2. Mr. Dickon (GAO):
        - Provide the GAO report on PBMs and their impact on patients to the FTC for their investigative probe.
    3. Members of Congress:
        - Work on passing various bills related to Medicare coverage, including the Kidney Patient Act, the Coverage Determination Clarity Act, the Find Act, the Access to Innovative Treatments Act,

the Expanding Access to Diabetes Self-Management Training Act, and the Seniors Access to Critical Medications Act.
        - Work on increasing transparency in the Medicare Advantage market.
        - Work on legislation to address disparities in healthcare and expand access to life-saving medications and treatments for seniors.
        - Work on legislation to ensure timely access to critical breakthrough products and coverage with evidence development.
        - Work on legislation to increase generic drug utilization and reduce overall drug spending.
        - Work on legislation to protect patients and pharmacies from harmful PBM practices.
        - Work on legislation to improve access to home infusion benefits.
        - Work on legislation to ensure access to diagnostic radiopharmaceuticals.
        - Work on legislation to ensure Medicare coverage for anti-obesity medications.
        - Work on legislation to increase transparency and facilitate timely access to drugs and devices.
        - Work on legislation to establish a more predictable and transparent coverage process for Medicare beneficiaries to access new medical devices.
        - Work on legislation to address the issue of rebates in Medicare Part D and lower patients' out-of-pocket costs.
- These are the action items mentioned in the transcript, grouped by the responsible person or entity.

Outline:

- Chapter 1: Introduction
- Timestamp: 00:05
- Description: The chairman discusses an error in the expected and observed outcomes.
- Chapter 2: The New York Times Reports
- Timestamp: 00:48
- Description: Reference to a report from The New York Times.
- Chapter 3: Important Issues Raised
- Timestamp: 03:27
- Description: Acknowledgment of important issues raised.
- Chapter 4: Willingness to Work Together
- Timestamp: 03:41
- Description: Expressing willingness to collaborate on proposals.

- Chapter 5: Making Articles Available
- Timestamp: 04:39
- Description: The chairman offers to make two articles available.
- Chapter 6: Recognition of Mr./Dr. [Name]
- Timestamp: 04:53, 04:54, 04:57, 05:30, 05:44, 09:12, 10:55, 15:09, 16:50, 17:59, 19:40, 22:12, 22:40, 23:33, 25:15, 26:48, 27:38, 29:34, 29:46, 29:48, 29:53, 30:44, 30:47, 30:51, 33:57, 36:01, 36:04, 36:07, 36:08, 37:42, 39:09, 39:26, 39:38, 39:47, 41:16, 41:19, 41:21, 41:24, 41:25, 42:12, 43:27, 46:16, 46:19, 46:24, 46:38, 47:11, 48:09, 50:14, 51:18, 51:26, 51:29, 51:31, 51:32, 51:45, 51:57, 51:58, 52:09, 53:00, 55:17, 55:30, 56:43, 56:44, 56:48, 56:50, 57:04, 57:10, 57:27, 58:01, 59:45, 1:02:10, 1:02:13, 1:02:17, 1:02:20, 1:02:41, 1:04:27, 1:05:05, 1:05:33, 1:06:13, 1:06:17, 1:06:34, 1:06:37, 1:06:40, 1:07:47, 1:09:09, 1:09:36, 1:10:26, 1:10:28, 1:10:30, 1:11:54, 1:14:06, 1:14:18, 1:14:50, 1:14:56, 1:14:58, 1:15:02, 1:15:06, 1:16:50, 1:17:52, 1:20:29, 1:20:31
- Description: Various individuals recognized during the transcript.
- Chapter 7: Transparency and Supplemental Benefits
- Timestamp: 05:44, 09:47
- Description: Discussion on the importance of transparency and supplemental benefits.
- Chapter 8: Questions and Answers
- Timestamp: 09:50, 12:42, 15:01, 15:06, 19:42, 22:59, 23:33, 25:15, 29:46, 30:44, 36:05, 39:09, 41:19, 46:19, 51:31, 56:44, 1:02:21, 1:04:27, 1:05:33, 1:06:37, 1:09:36, 1:10:30, 1:11:55, 1:13:24, 1:15:02, 1:20:31
- Description: Exchange of questions and answers between the participants.
- Chapter 9: Find Act and Medical History
- Timestamp: 46:24, 47:11
- Description: Discussion on the Find Act and the importance of the current medical moment.
- Chapter 10: Resource Review and Deadlines
- Timestamp: 50:14, 51:18, 51:26, 51:29
- Description: Review of resources and deadlines for proposals.
- Chapter 11: Conclusion and Adjournment
- Timestamp: 1:20:43, 1:21:06, 1:21:39
- Description: Conclusion of the hearing and adjournment.
- Note: The chapter titles are based on the content and context of the transcript. The timestamps provided correspond to the first occurrence of each chapter's theme or significant topic.

Notes:

- Chairman asked for consent to make two articles available for the record.

- The New York Times reports on a significant error in expectations versus observations.
- There was a question raised, and the Chairman acknowledged its importance.
- They expressed their willingness to work together on proposals.
- The Chairman thanked Mr. Sarbanes and yielded back.
- The two articles will be considered later and included in the record.
- Dr. Hughes released an information collection request (ICR) earlier this year.
- The transparency and supplemental benefits were highlighted.
- Dr. Hughes was asked a question related to evidence development and coverage.
- Dr. Hughes had two thoughts on the matter.
- They mentioned monitoring for practices that may affect enrollment.
- There have been a number of changes discussed.
- Dr. Hughes mentioned the ICR being free and estimated it takes five minutes to fill out.
- They intend to meet the deadline.
- Dr. Hughes thanked Mr. Dunn for his question.
- They mentioned reviewing comments and releasing more information in the future.
- Mr. Pence thanked Mr. Dickon for his enlightening testimony.
- Dr. Hughes was directed a question.
- There was a discussion about resources and quantifying them.
- They mentioned reviewing comments and releasing more information in the days ahead.
- Ms. Harshbarger highlighted HR Act and HR Act in her question.
- Dr. Hughes was asked a question about a topic not on the slate of bills.
- The principle mentioned was simple.
- Dr. Hughes was thanked for her important question.
- They expressed their willingness to work on the proposal.
- Dr. Joyce was recognized for five minutes.
- Dr. Hughes was asked about local coverage decisions on diagnostic tests.
- Mr. Balderson thanked the witnesses and asked Dr. Hughes several questions.
- Dr. Hughes was asked about expanding access to remote monitoring.
- They discussed the VBID model and accommodating five reviews.
- They expressed their willingness to work together.
- Mr. Obelnuti thanked the witnesses and asked Dr. Hughes a question.
- The Chairman asked for unanimous consent to insert documents into the record.
- The Chairman reminded members to submit questions within ten days.
- The subcommittee was adjourned.
- A brief conversation took place at the end of the transcript.

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…In July we heard from a panel of experts

Unknown Speaker 0:49

with me

Unknown Speaker 1:01

you got

Speaker 1 1:24

the subcommittee will come to order the chair recognizes himself for five minutes for an opening statement. Today is our second hearing designed to examine solutions to help our seniors gain access to innovative medical drugs and technologies to help lower drug costs as well as to ensure our regulatory policies are responsive to market innovation that will help seniors live longer and healthier lives. In July, we heard from a panel of experts about the importance of updating the Medicare program to meet the needs of a growing senior population. Now we're taking the next step to examine specific solutions would seek to turn the principles and ideas for members, previous expert witnesses and wide ranging stakeholder input into legislation to support millions of seniors across the country. For example, according to the National Cancer Institute, cancer costs the United States about 200 and a billion in 2020. Further analysis shows that late stage cancer costs the healthcare system $105,000 per patient 2019, representing the highest costs among all cancer patients. Today, patients and their families bear significant financial burden despite the growing availability of less invasive and more successful treatments along with cutting edge diagnostic tools that can personalize treatment plans and detect aggressive but treatable cancer sooner. HR 2407 The Nancy Gardner Sewell Medicare multi Cancer Early Detection screening coverage act attempts to address this policy imbalance by increasing access to these diagnostics and potentially lowering downstream costs and helping seniors live longer lives. Additionally, I'm proud to sponsor hr 1691. The strongly bipartisan ensuring patients access to critical breakthrough products Act, which would essentially codify the Trump era Medicare coverage of innovative technology or inset rule and provide for a

predictable Medicare coverage pathway for FDA approved breakthrough therapies for at least four years. While companies can collect data to make their case for more permanent coverage. These products, many of which are FDA approved, but have yet to receive CMS coverage could transform lives, and make daily activities more manageable for seniors who may currently be bedridden, or one device or technology away from being able to finally manage their cardiovascular disease. On the top point, on the top point coverage, we have a number of solutions to make regulatory policies work better for innovators, for providers, and more importantly for patients. My bill hr 5389, the national coverage determination Transparency Act, would hold CMS accountable to a more consistent process for making National Coverage Determinations, and specifically, their communications was product sponsors, ensuring patients can gain access to these products as quickly as possible. We will also discuss policies that would help clarify the local coverage determination process, so the medical items and services can expeditiously reach seniors. For too long we've heard how broken the coverage process delays or in the case of Alzheimer's, national coverage determination, which we'll also discuss today significantly restrict access to life saving care for seniors. We're finally looking at more effective ways to help address chronic disease management as well as other policies to provide seniors access to generic drugs and biosimilars, particularly by allowing for biosimilar products to be added to Medicare Drug Formularies. Throughout the plan year if a biosimilar becomes available mid year, which would allow seniors to save moral or cost clinically effective drugs. The government can tenability office recently finalized a report on the impact of rebates in the Medicare Part D program. Specifically how rebates affect the prices seniors pay at the pharmacy counter. The report also provided a detailed analysis on the impacts of rebates on seniors cost sharing, and Medicare liabilities resulting from GAO indicated that for 79 of Medicare Part DS top 100 Highly rebated drugs, seniors or others own seniors behalf spent $21 billion on their drugs versus the 5 billion the plan sponsors spend on these drugs after accounting for rebates. Seniors and taxpayers should be paying more for a drug than the actual value of the drug. That's why we're considering ideas today that are designed to help address these issues. Each proposal was drafted to ultimately achieve lower costs without the federal government directly Negotiating the prices for these medications. In closing, it is important to note that while these policies can help drive innovation, we also must consider the budgetary implications of each proposal. I look forward to working with my colleagues ensuring these ideas are fully offset. It should offset as we continue our work. I yield back. The Chair now recognizes the ranking member the gentlelady from California for five minutes for her opening statement.

Speaker 2 6:15

Thank you, Mr. Chairman. And good morning, colleagues. And thank you witnesses and all of the advocates that are here today. I don't think there's a free seat in the audience. It's wonderful. Thank you. I think we're entering a golden age of medicine, thanks to breakthroughs in genomics, mRNA, multi cancer, blood tests, and other new diagnostics to bring these new cures from the benchtop. to the bedside. Patients need Medicare to cover new drugs and devices. With over 65 million Americans enrolled in Medicare. Every coverage decision is fraught. Medicare beneficiaries deserve timely access to safe, effective and affordable treatments. But

the Medicare coverage determination process can be lengthy and it is according to the Stanford buyers buyers center for bio design. Nationwide Medicare coverage. For breakthrough medical technologies can take on average four to six years following FDA authorization. Today we're considering amongst 24 other bills, the insurance ensuring patient access to critical breakthrough products act that attempts to shorten that wait. I want to commend CMS for finally publishing the transitional coverage of emerging technologies proposed rule which takes a significant step forward and making sure seniors can access to medical devices. One contributing factor to the delay is that CMS does not have the resources and expert staff to make nimble coverage decisions. Many of its local coverage decisions are outsourced to Medicare administrative contractors who wield significant power over more than a billion. That's with a be more than a billion Medicare Fee for Service claims. Each year, these contractors can make a real impact on people's lives. For example, Representative Burgess and I sent a letter to CMS last month, raising our concerns about an ill considered March 2023 billing article from one of these contractors that withdrew Medicare coverage for very important blood tests that help transplant transplant patients stay healthy and keep their new organs. This billing article was issued without without allowing for public comment, including comments from the transplant patients who would be impacted. CMS should intervene as soon as possible. We're hearing several bills impacting these administrative contractors and the local coverage decisions, and I look forward to better understanding their impact. While this hearing may be aimed at improving Medicare coverage for some drugs and devices, the House Republican budget does the direct opposite by cutting nearly $800 million from the centers that oversee Medicare. This massive cut will slow down coverage decisions, increase the reliance on contractors and most importantly, hurt seniors and people with disabilities. I'm also concerned that while this hearing is considering a huge slate of bills, as I said 25 and total Republican Republicans would not consider legislation to extend funding for state health insurance pro grants, the area agencies on aging, the aging and disability resource centers, and the National Center for benefits and outreach enrollment. These critical programs help Medicare beneficiaries every day, enroll in Medicare and access benefits that lower their out of pocket costs. But the funding will expire on September 30. California State Health Insurance Program is called high cap, and it is outstanding. It provides stellar services every day for seniors in my district who have Medicare problems. For Democrats, our North Star was and continues to be protecting and preserving the sacred promise of Medicare. While we consider these bills, I hope we'll proceed carefully to make sure that the promise of affordable quality coverage is kept without putting seniors excuse me or the Medicare Trust Fund at risk. And with that, Mr. Chairman, I yield back.

Speaker 1 11:06

Thank you The gentlelady yields back the chair will recognize the chair the full committee chair Rogers for five minutes for an opening statement.

Speaker 3 11:11

Good morning. Good morning, colleagues. Good morning advocates. Sadly, we've all heard from patients who are unable to access medicines or devices that they need in their time of need. Many times it's because of bureaucratic red tape and a Medicare program that's struggling to keep up with innovation. Today, our goal is to cut the red tape and roll out the red carpet for all. In our July hearing we heard from Sue Bronski, a patient advocate and caregiver who told her story about her mother Lynn's battle with Alzheimer's. Millions of Alzheimer's patients today stand to benefit from newly approved treatments, treatments that Lynn never had the chance to receive. Today we're following up on that conversation with doctors, patients, innovators and caregivers. We will hear from Dr. Dora Hughes, from CMS who will hopefully shed light on CMS is unprecedented coverage policies which are unfortunately limiting seniors access to FDA approved drugs. We're also interested in hearing from Dr. Hughes about CMS coverage policies, including the recent T set proposed notice, this has come more than two and a half years after CMS delayed and ultimately repealed the M set policy which would have created a predictable transitional coverage policy for innovative technologies. We're all worried about seniors access to innovative new technologies, and we're going to discuss a lengthy list of bills I would highlight 16 are bipartisan are led by my Democrat colleagues. And I'm hopeful that we can build more bipartisan support for many of the remaining bills in the weeks and months ahead. For example, we welcome Democrats joining on legislation that would allow seniors to continue to access the same technologies that they had access to in the commercial insurance, permitting seniors to upgrade their wheelchairs to increase their mobility and potentially improve their quality of life, improve home infusion care safely in their homes and support a number of Medicare Part D and PBM policies that have received bipartisan support in the Senate. These are policies that can help patients access innovative drugs and technologies and are distinct from major policies like the price setting scheme in the IRA, which we disagree on. I'm also glad that we've included several bills on the Medicare Part D program, especially following the troubling report from GAO that found patients are paying more for drugs than insurance companies. And while I'm glad that there's so many members on both sides of the aisle, it's Drew, unbelievable. Members on both sides of the aisle have brought forward ideas that we will discuss today, a lot more work needs to be done. A number of bills before us would increase what seniors pay as well as Medicare spending unless we're able to find reductions. There's a lot of big ideas and we need to think through steps to get these bills where they want to go. And today we're focused though on that first step. What do they say a journey begins with a single step it will take stakeholders and members rolling up their sleeves and working together to start making progress. You know, nobody, nobody wants to see their family or their friends lose access to life saving and life and improving care when they age into Medicare. Today's hearing and the number of bills being considered should be a warning about Medicare for All proposals. Imagine, imagine if it were up to the federal government to decide what treatment was covered for every American without other options for coverage. And being at the mercy of a healthcare bureaucracy. You'd have to lobby your congressman to pass legislation if you wanted to change coverage policy. Once again, Energy and Commerce is leading the way on how of care issues top of mind for Americans from addressing the Fentanyl crisis working together on price transparency. We will get it to the floor and addressing considered consolidation in health care to making sure seniors have access to innovative medicines and technologies. I'm proud of the work of this committee, and I look forward to the hearing today. I yield back, Mr. Chairman.

Speaker 1 15:20

Thank you. The gentlelady yields back The Chair recognizes the gentleman from New Jersey, the ranking member, the full committee rep Pallone for five minutes for an opening statement.

Speaker 4 15:28

Thank you, Mr. Chairman. For almost 60 years, Medicare has played a critical role in laws our nation's seniors and disabled Americans and today, Medicare provides health coverage for over 65 million Americans. This committee has long been committed to sustaining the Medicare program expanding coverage for seniors and ensuring that the program delivers the highest quality care. Over the last few decades we've seen an incredible acceleration in the number of scientific and medical breakthroughs. And this has allowed for the creation of new treatments and technology to manage devastating diseases. The Centers for Medicare and Medicaid Services CMS plays an important role in assuring that Medicare beneficiaries can access these innovative medical technologies and treatments in a timely manner, a goal that we all share. CMS does all this while maintaining appropriate safeguards and rigorous evidence standards that prioritize the health and well being of our nation's seniors and the disabled. And they're reasonable discussions to be had about whether there are ways to improve the transparency and predictability of CMS as pathways to coverage. And I look forward to our witnesses discussing those pathways today. However, I'm concerned about some of the legislation before us that proposes to bypass these pathways to give handouts to Big Pharma and medical device companies. My Republican colleagues have put forward a long list of extremely expensive bills, that costs hundreds of billions of dollars without any way of paying for them. The ironic thing is that this hearing comes at a time when their caucus is threatening a government shutdown over federal spending levels. So my chief concern here is that these proposals would likely result in significant cuts to the Medicare program in order to offset spending of this magnitude. enacting these proposals would also raise health care costs for seniors through increased premiums. And this will place additional undue burdens on our nation's seniors and raise their out of pocket costs. Democrats have held firm in their commitment to oppose any efforts to cut Medicare benefits, raise the retirement age or increased beneficiary contributions, we will continue to fight to protect the Medicare program. I'm also disappointed that committee Republicans refuse to include legislation that would directly expand access to care and reduce costs for seniors, we have a number of bills that will directly help Medicare beneficiaries. One bill would reduce cost sharing through the Medicare Savings Program, and another would extend funding for outreach and enrollment programs for low income beneficiaries. And these bills were rejected by the majority. Now also, while I'm disappointed that these bills were not included in today's hearing, I will continue to fight to lower costs and expand access to care for Medicare beneficiaries. I'm pleased that HR 5386, the cutting co pays Act was included in today's hearing, this bill would eliminate co pays for generic drugs for low income beneficiaries. And this would be a meaningful step to lowering costs for seniors around the country. Lastly, I look forward to

continuing to work on proposals that address and rein in unfair pharmacy benefit manager practices. There is clear bipartisan support for the proposals we are discussing today, which would address how PBMs use fees, rebates, dir and spas and specialty pharmacies in the Medicare Part D program. And I look forward to many of these policies becoming law as well as our long standing consensus policies to provide greater transparency into PBM practices in the commercial market. And I look forward to continuing to work with my colleagues on both sides of the aisle to advance legislation that will meaningfully lower costs for patients and prioritize their health and well being rather than simply paid the pockets of big pharma and medical device companies. And with that, thank our witnesses. And I yield back, Mr. Chairman.

Speaker 1 19:10

Thank you. The gentleman yields back. That concludes opening statements. We'll have our witnesses opening statements today. I'll introduce the witness. First of all, I think you've testified before you know the lighting system, you have five minutes and four minutes into your opening statement, a yellow light will appear and once you see that, begin knowing that you have one minute left or to move forward. So first, we introduce Dr. Door who's acting director at the Center for Clinical Standards and Quality and acting chief medical officer at the US Centers for Medicare and Medicaid Services. And we also have Mr. John Diken, director of health care public health and private markets for the US Government Accountability Office. So Dr. Hughes, you're recognized five minutes for your opening statement.

Speaker 5 19:57

Chairs, McMorris Rogers and Guthrie ranking members Pallone and Su and members of the subcommittee. Thank you for the opportunity to discuss the Centers for Medicare and Medicaid Services work. To ensure that Medicare beneficiaries have timely coverage for innovative treatments and medical technologies that treat life threatening or debilitating diseases and improve patients quality of life. CMS is committed to fostering innovation, while ensuring that Medicare has fast and consistent coverage processes for emerging treatments and technologies that will improve health outcomes. Our goal is to enhance coverage of new treatments and technologies while maintaining appropriate safeguards and rigorous evidence standards that are essential to the health of Medicare beneficiaries. Medicare coverage and payment policies are provided in statute. They require that an item or service must be within the scope of a statutory Medicare benefit category and be reasonable and necessary for the diagnosis or treatment of an illness or injury and the Medicare population. CMS makes Coverage Determinations using various pathways in order to facilitate timely beneficiary access to items and services that meet the statutory standard for coverage. One Medicare coverage pathways the national coverage determination process or NCD. NCDs are a transparent evidence based process with opportunities for public participation in CDs ensure that similar claims for items and services are covered in the same manner. CMS is committed to a

transparent NCD process. All of the potential NCDs that CMS is currently working on and the corresponding requests letters are available publicly online. Additionally, CMS is developing a revised approach to NCDs that we believe will provide greater transparency, consistency and predictability to our decisions about which items and services should be considered for coverage at the national level. We look forward to the future release of that approach for public comment. In some cases, CMS may provide Medicare coverage for items and services on the condition that they are furnished in the context of approved clinical studies, or with the collection of additional clinical data to assess their appropriateness for use in the Medicare population. coverage with evidence development or si d provides coverage for certain improved treatments more quickly, while collecting information about health outcomes needed to fulfill our statutory requirements. CMS recognizes that new approaches are needed to complement our existing coverage pathways in order to make decisions more quickly uncertain new items and services and to provide expedited access to new and innovative medical technologies. To further this goal, CMS issued a proposed procedural notice outlining the new transitional coverage for emerging technologies pathway or tea set. The tea set pathway is voluntary for manufacturers. It supports innovation by providing an efficient, predictable and transparent coverage review process for certain eligible breakthrough devices that are FDA market authorized or cleared. The T set pathway also includes robust safeguards for the Medicare population. After transitional coverage T set devices may be covered at the national level as appropriate. As we move forward, CMS will continue to engage with stakeholders to ensure that Medicare promotes access to emerging treatments and medical technologies while maintaining the protections and rigorous evidence standards essential to the health of Medicare beneficiaries. Thank you for the opportunity to testify on this important topic. I am happy to address any questions you may have.

Speaker 1 24:19

Thank you for your testimony. The Chair now recognizes Mr. Diken for five minutes

Speaker 6 24:26

of chairs Rogers and Guthrie ranking members Plone and issue and members of the subcommittee. I'm pleased to be here today as you examine the role of Medicare in providing access to innovative drugs, devices and technology. Medicare Part D provides about 50 million beneficiaries with access to drug treatments, including new innovative drugs. Part D also plays an important part in Medicare's fiscal sustainability, with annual drug expenditures exceeding $200 billion For Medicare Part D drug plans vary in their premiums and in their list of covered drugs, known as formularies. plan sponsors placed drugs into different formulary tiers, with varying cost sharing amounts to encourage beneficiaries to use certain drugs, plan sponsors or PBMs on their behalf, may negotiate rebates from drug manufacturers, in exchange for including a drug on a favorable formulary tear. Policymakers and others have noted trade offs

and how rebates affect Medicare spending, beneficiary access and competition among prescription drugs. My statement today summarizes key findings and a recommendation from a recent GAO report on these issues. First, it is important to recognize that rebates are concentrated among a small number of drugs, about 84% of the nearly $50 billion that manufacturers paid in rebates to Part D plans. In 2021. Were for just 100 brand name drugs. These 100 most highly rebated drugs, represented about 1% of all party covered drugs. Further 73% of these rebates were for drugs in three therapeutic classes, endocrine metabolic agents, including anti diabetic drugs such as insulin and blood modifiers, including anti stroke medications, and respiratory agents, including anti asthma medications. Our review of agreements between Part D plan sponsors or their PBMs and drug manufacturers, identified provisions intended to increase the use of certain drugs in exchange for rebates, including these for one placing a drug on a preferred formulary with lower cost sharing than competitor drugs to limiting the number of competitors by paying higher rebates. If a drug was on a formulary tier with fewer drugs from than other from other manufacturers. Three having competitive drugs be subject to restrictions to limit their use, such as utilization management, or formulary exclusion, and for bundling a manufacturers drugs with rebate amounts predicated on also having one or more of the manufacturers other drugs on the formulary. We found that after accounting for rebates plan, sponsors generally paid less for the highly rebated drugs than for lower cost alternatives. In some cases, plan sponsors received more in rebates than they paid for the drug, resulting in a net profit to the plan solely based on rebates received. Plans can use revenues from rebates to reduce premiums for all party beneficiaries and Medicare. rebates, however, do not lower what beneficiaries pay for prescription drugs, because their cost sharing is generally based on the cost before rebates. As a result as a note and opening statements, beneficiary payments were four times as much to plan sponsor payments for 79 of the 100 highest rebate and Part D drugs. In 2021. Beneficiaries paid about $21 billion for these nine drugs. plan sponsors paid about 5 billion after receiving nearly 42 billion in manufacturer rebates. In closing, we found instances where plan sponsors preferred highly rebated brand name drugs with higher beneficiary costs than lower cost alternatives. As a result, some beneficiaries, particularly those with certain chronic conditions, such as diabetes, or chronic obstructive pulmonary disease, may not have access to lower cost medications. Based on these findings, Gao recommended that CMS monitor the effect of rebates on party formularies and on Medicare and beneficiary spending. CMS disagreed, noting that already conducts clinical reviews of planned formularies. However, monitoring the effects of rebates would provide important information on whether formulary and rebate practices may discourage enrollment of certain beneficiaries. And such monitoring could be particularly valuable as CMS begins implementing provisions of the inflation Reduction Act. This concludes my prepared statement and be pleased to answer any questions that you subcommittee members may have.

Speaker 1 29:29

Thank you. I thank the witnesses for their testimony will the committee will now move to members questions. And I will recognize myself for five minutes for the purpose of asking questions. So Dr. Hughes, there's a recent report that shows that the average days of non

national coverage determinations in phase one and two have increased to 228 days between 2014 and 2022. And that's up from an average of 52 days a decade prior. What are the causes of these increases?

Speaker 5 29:59

Thank you And thank you for that question. CMS certainly agrees that we have to provide timely access to the items and services that meet our statutory standard. As you know, I've been in this position for about a month now. So I can't speak to all of the historical issues with the NCD process. But I can say that in the least in the last two years for sure that we have met the majority of our statutory deadlines. And we are committed to meeting these deadlines moving forward.

Speaker 1 30:31

Okay, I have the bill. Thank you. For me with national coverage determination Transparency Act, it's aimed at reducing helping streamline the process to help address these backlogs. And I just want to ask that you commit to working with us the Committee on getting the bill right and getting it moving forward.

Speaker 5 30:48

We would absolutely work with you on this issue and how we can improve the transparency and timeliness of the NCD process.

Speaker 1 30:57

Thanks. Appreciate that. And then also, Dr. Us, you talked about T set in your in your opening statement. The TCM proposal limits of submission to an expedited pathway to coverage. For an FDA authorizer clear breakthrough device had just five devices in a cycle. CMS says it will prioritize devices to select based off those that have the potential benefits for the largest number of beneficiaries. And so my question, how can you ensure smaller manufacturers who are often is, as I've found are often developing the most novel technologies that can we ensure the smaller manufacturers with novel technology can gain access to the program? Because the greatest benefit of the program would accrue to these companies with less resources available to navigate the reimbursement process?

Speaker 5 31:42

Yes, and thank you for that question. Certainly, we agree that we want to facilitate timely access to all items and services that meet our standard. statutorily, I want to emphasize that we have three pathways to coverage we have at the national level through a national coverage determination. We have local coverage determinations, or LCDs. And then we have coverage on a claim by claim bases at the reviews by our Medicare administration contractors are the Mac's so items and services, even from small manufacturers that come to market. They do have each of these three pathways available to them. And the vast majority of these decisions are actually made at the local level, by a claim on a claim by claim basis or through an LCD. And we think that that is helping to foster timely access to these to these tests.

Speaker 1 32:37

Okay, thanks. And then also why do you think the impact on the greatest number is the right metric when technologies that produce life saving solutions for diseases such as cancer would apply to a smaller population, but might provide a greater benefit?

Speaker 5 32:51

Thank you for that question. And certainly CMS agrees that we have to think carefully about the items and services or in this case, their breakthrough devices that we should focus on. We have stated publicly and we're committed to releasing more information about how we will prioritize NCDs. We intend to release that in 2024. And we will take public comment, as noted in the opening remarks. resource constraints, certainly limit the number of devices that we will be able to review through the proposed T stat pathway.

Speaker 1 33:26

Thank you and Mr. Dyk and your report from this month, you note that CMS doesn't use rebates, as you talked about as they conduct annual formulary reviews, why do you believe this would be beneficial for CMS? Further, you further explain, you know, you touched on in your opening statement?

Speaker 6 33:42

Yeah, no, thank you. Certainly CMS is going through a process of reviewing formularies for a number of clinical standards and to make sure they meet statutory requirements, given our

findings, that the formularies for certain areas or in conditions of individuals are highly concentrated, and can affect formulary decisions by the plans then be very valuable for CMS to also consider that information. So reviews formulary, so they can consider if there are particular types of drugs or formularies that need to be reviewed to make sure that there is not having undue effect on individuals with those conditions, or discouraging their enrollment. So Dr. US

Unknown Speaker 34:25

you have any comments on that.

Speaker 5 34:27

And thank you. We certainly CMS agrees with this committee and with GAO about the need to focus on transparency and accessibility of drugs for our Medicare beneficiaries. As alluded to we review all the formularies before they were approved to make sure that all of the drugs across the classes are that are needed by beneficiaries are there. We are confident that we this process is effective.

Speaker 1 34:54

Thank you. My time has expired and I'll recognize the gentlelady from California for five minutes for questions.

Speaker 2 34:59

Thank you Mr. Chairman, and thank you to our witnesses for your testimony. As I mentioned in my opening statement, one of Medicare's contractors decided to ignore precedent and restrict patient access to diagnostic tools that will harm transplant patients. It's there's an eye bending going on in the transplant patient community across the country on this. So Dr. Hughes, what responsibility does CMS have, when it's contractors make decisions that are out of step with widely accepted evidence that a tool is effective?

Speaker 5 35:45

Thank you for that question. We work with our local max in a number of different ways. First, through the Program Integrity Manual is fairly prescriptive in terms of the expectations for our

contractors, the process, they must follow the public comment, the summary, the evidence, the ratter,

Speaker 2 36:05

wasn't there any allowance for public input on this? So in those cases, something something's gone awry.

Speaker 5 36:13

When we hear complaints such as that, at CMS, at our level, we investigate, we look to make sure that the process was followed. And if it's not, we certainly do follow I think I've

Speaker 2 36:25

pointed out Dr. Burgess and I have pointed out what has not been followed. And so I want to ask you, if CMS will commit to reviewing this decision, it deserves review.

Speaker 5 36:41

Yes, thank you. And I will certainly follow up and get more information about this specific situation and see how we can address it. Okay.

Speaker 2 36:50

For years now, I've worked to speed up the time between FDA authorization of a new device and Medicare's decision to cover that device. CMS has finally published, as I said, a new proposed rule, I think it takes a very important step forward and making sure seniors can access new medical devices. So Dr. Hughes, why did CMS limit the new coverage pathway to only five devices per year? It seems arbitrary to me. The new CMS rule excludes diagnostics from the new coverage pathway. So I would ask why. And on that one, too.

Speaker 5 37:35

And thank you. Thank you for your question. At a high level, I certainly would say FDA and CMS, we do have a very collaborative partnership. And when we looked through there, the number of devices that are in the pipe pipeline, when you strip out the paediatric devices, cosmetic software, those that don't have a benefit category, the number does shrink considerably. And what's the number and we think that we are expecting to get about eight nominations for this tea set pathway every year, we think with our current resources that we will be able to undertake five, which I would note is a doubling of our current, on average,

Speaker 2 38:13

it's taken years to finally get a proposed rule for devices. What will happen if if CMS has to start all over again, in implementing the ensuring patient access to critical breakthrough product? If it passes, how long do you think implementation of the new law will take?

Speaker 5 38:39

Certainly, I can't comment on any specific bills. And I'm not familiar with that one. But I can say if we had

Speaker 2 38:47

a better read up on that. I believe these are a it's highly bipartisan. And I think it's a it's a bill that's moving. So we'll take good look at it. Let me just say something to Mr. Dyk and thank you for First of all, thank you for the work of the GAO. It's I have always found it to be superb. I want to ask you, Dr. Rob Hughes, why CMS is unwilling to take up the recommendation that the GAO is making. It seems to me that in part D, that the that the plans, really have something going for them here. And the patient is not benefiting from that. And when I hear PBMs been involved, well, then we know that for sure they don't do a damn thing for patients. Why aren't generics in this? And why won't CMS accept the recommendation? that they're making. It seems to me that it's it's not menacing. Why are you rejecting that?

Speaker 5 40:08

Thank you for that question. I, as I mentioned, we do look at the formulas very carefully to make sure that the drag,

Speaker 2 40:15

I think that with all due respect, I think that the GAO is onto something here. You may be looking at them, but the most expensive drugs are the ones that the the plans are, are giving the big boost to is, is that acceptable to CMS?

Speaker 5 40:38

Thank you for that question. CMS is of course committed to providing accessible and affordable drugs Farben, I

Speaker 2 40:44

think you need to go back and reconsider. I really do. I don't think that this is medicine at all. It's documented. There's something wrong with that system.

Unknown Speaker 40:56

Thank you. I will certainly take that back. Okay,

Unknown Speaker 40:59

I yield back. Gentlelady

Unknown Speaker 41:00

yields back. I now recognize Mr. Latta from Ohio, five minutes.

Speaker 7 41:05

Well think of a share. And thanks for our witnesses for being with us today. Today's hearing cannot come at a better time. As the title says it all. The government has long limited access to better drugs, devices and technology due to overregulation bureaucratic red tape. There are also lingering questions about how government policies have exasperated the structural finding structural, financial and demographic challenges facing the Medicare program. Because of the important role that our healthcare system plays in all Americans lives, we must proceed in a responsible way to balance the importance of patient access to innovative treatments and

cures. With structural, fiscal and demographic realities facing the Medicare program. Dr. Hughes, I believe the investments are needed in in new and innovative drugs, medical devices and technology seniors access to better earlier and more transformative care, will help them see improvements in their daily lives. And hopefully, we'll limit the need for future more costly services. In addition to the legislation being considered here today, would you share any specific regulatory burdens that if lifted would improve seniors lives and improve access to needed health care services? And before we answer, because, again, this is the Energy and Commerce Committee. One of the things that I'm very proud of the fact of all the different subcommittees that we do have, that we look over the horizon, five to 10 years and a lot of cases, we look for the innovators. But things are changing so rapidly that there is new devices that new medications are coming out. So what can CMS do to help on that innovation front to health on these health care services, and to help our patients out there?

Speaker 5 42:55

Thank you for that question. And certainly CMS shares your passion for the innovation and excitement about the new treatments and technologies that are already here and many cases are coming down the pipe. We have three coverage pathways. We provide coverage at the national level through NCD. And that ensures that aims and services are paid uniformly. At the national level, the vast majority of coverage decisions are made at the local level on a claim by claim basis by our local Medicare administration contractors or max or by through a local coverage determination LCD.

Speaker 7 43:33

Well, thank you. Thank you, Mr. Durkin. Vegard asks, because this has come up from a couple of our members already, you know, when you are talking about what the costs are out there, and with the recommendations that you've all made? I one of the words I picked up on what you say but about monitor, is there something stronger than the word monitor? What can you all be doing that on when you're getting back with CMS? Because again, we want to move things along here. But I just think the word monitor sometimes is just saying like, well, there it is, and just keep on going. So how do we change that existing thought processes out there? And you know that we don't want to just keep doing the same things over and over again, if they're not working right.

Speaker 6 44:21

Now, thank you for the question. And certainly monitoring is the starting point. It provides the information that can then be considered within the authorities and limits that CMS would have in how they can address that. But certainly, in addition to ensuring that formularies are meeting all

statutory requirements and are clinically appropriate, also responsibilities that CMS has to assure that there's not discriminatory against beneficiaries. And that's where we think at least having that information given the findings of what's occurring. Now where number of beneficiaries with certain conditions are perfectly affected and may not have access to lower cost alternatives, that that information could then lead to further steps that could be taken either by CMS or others and having that information more widely available.

Speaker 7 45:16

Thank you, Dr. Hughes. People living in rural areas of the nation face unique challenges when it comes to assessing innovative medical innovation. Cisco has recently approved Alzheimer's drugs My understanding is that many doctors refer their patients to infusion centers to receive the Alzheimer's drugs. This is especially true for smaller practices like many rural providers. However, CMS recently imposed coverage with evidence development requirements on Alzheimer's drug for providers, and to my knowledge has not provided specific guidance to the infusion centers about how reimbursement will work. As a result, few providers appear willing to take on financial risk of administering medicines that means additional access hurdles, and further delays for people are already facing a short window for treatment. What's the current status on Medicare reimbursement? How can both doctors and Funes infusion centers be assured they will be reimbursed for those drugs?

Speaker 5 46:12

Thank you for that question. As you may know, when FDA provided full coverage, traditional approval for Locanda Mab, broader coverage was made available that same day for Medicare beneficiaries, regardless of where they live in the nation.

Speaker 7 46:29

Well, my time has expired. Now some of my other questions for the record. witnesses. Thank you, Mr. Chairman, gentleman yields back. Now recognized Miss Kelly from Illinois, five minutes

Unknown Speaker 46:45

I didn't think I'd be up this.

Unknown Speaker 46:58

I am so sorry. I didn't think I'd be up this soon.

Speaker 8 47:07

Thank you to the committee chair Guthrie and Ranking Member Eshoo for holding today's critically important hearing. Life expectancy has been on the rise in the US and by the year 2030. The number of Americans over the age of 65 is projected to be about 70 million. Innovations in medical science, especially pharmaceuticals have shifted the focus of medicine from highly invasive treatments and surgeries with potentially serious risk to less invasive therapies focus on prevention and health maintenance. This shift has allowed many older Americans to remain healthy and independent avoiding long hospital and nursing home stays one technology that proved beneficial during the COVID 19 pandemic was remote patient monitoring remote patient monitoring allows for individuals to receive care from their providers while remaining in their home. This decreases many potential burdens such as prolonged hospitalizations, transportation hurdles, and provider access. And I must say my late husband was a doctor. And he used to make home visits which is very unusual with seniors. And then when COVID started, he did treat patients in their home from our home. Dr. Hughes, the COVID 19 pandemic shed light on the need to reevaluate the minimum required duration of remote monitoring with CMS that a full 16 days of monitoring may not always be reasonable and necessary. However, the 16 day 30 day period minimum duration for all patients was not updated. Can you speak as to what data CMS is seeking to support this? Support this crucial tool and healthcare accessibility?

Speaker 5 48:45

Thank you. Thank you for that question. I would say that CMS agrees that there that we learned quite a bit through the pandemic and very generally about the importance of these newer technologies. I'm not sure what information that we have been collecting internally, but I would certainly be happy to work with you after today's hearing on the proposals that you may be reviewing.

Speaker 8 49:08

That'd be great. What ways is cms working to improve Medicare beneficiaries access to early cancer diagnosis technologies?

Speaker 5 49:18

Thank you for that question. And certainly, CMS, we share your enthusiasm for some of these newer technologies that are coming through for for those technologies that meet our statutory standard of being medically reasonable and necessary for our Medicare beneficiaries. We are able to provide coverage at the local level and claims by claims basis on a more timely in many cases faster. pathway. We also have coverage pathways by way of the local coverage determination and nationally through national coverage determinations. Okay.

Speaker 8 49:54

I would like to close thank you for your response by saying that multi Cancer Early Detection Technology He was developed to address this deadly gap in screening. These tests provide opportunities to intervene early in cancer treatment. Yet access to these tools is limited, especially for the most vulnerable. Data from the C. DC shows that racial identity as well as geography have an impact on surviving cancer disparities in respect to routine screening, such as for colon and prostate cancer exists among black Americans. Just as efforts such as mobile, mammography can address such disparities. Access to multi Cancer Early Detection Technology expands the benefits of screening to a wide range of cancer pathologies. Thus, I yield my support for HR 2407, the Nancy Gartner Sol, Medicare multi Cancer Early Detection screening coverage coverage act to increase timely access to this potentially life saving technology by creating a direct pathway to Medicare coverage. And with that, I yield back unless you have a comment. Yes,

Speaker 5 51:01

certainly we agree. Prevention is absolutely critical. And we would be happy to work with you on this bill.

Speaker 1 51:07

Thank you. Thank you. The gentlelady yields back. The Chair now recognizes Mr. Griffith for five minutes for questions.

Speaker 9 51:13

Thank you, Mr. Chairman. One of the bills we're discussing today, HR 5393. The transparency and fairness for pharmacies Act is a bill that I crafted that would bring more transparency to pharmacies When dispensing a drug and require CMS to create a standardized quality metric system for plans and PBMs pharmacy benefit managers to use when determining payments to

pharmacies. This is just one small step to bring more transparency and certainty to pharmacists. When dispensing drugs. This is an issue I hear about constantly from small and rural pharmacies in my district. I have lots of questions on that, that I'm not going to have time to get to because they only give me five minutes. So I'm going to send you all questions after the hearing if you are able to respond to those Mr. Dixon in your September 2023 Highly rebated Drug Report, you found that for almost 80% of the top 100 Highly rebated drugs patients spent almost four times as much as the high end sponsors did. Do you think it is fair that patients are having to pay more at the pharmacy counter due to PBMs requiring higher rebates from drug manufacturers for better formulary placement?

Speaker 6 52:21

Thank you represent Griffith you captured well what what we found for that small subset of brand icons, brand name drugs with high rebates? Certainly, you know, that's different from the experience with most drugs, and most insurance where plans are paying more than the beneficiaries. For that group of drugs. The situation was reversed,

Unknown Speaker 52:42

not too huge. Do you think that's fair for patients?

Speaker 5 52:45

Thank you for that question. I would note that we have reviewed the GAO findings with great interest. We would also note that CMS does not contract with pharmacy benefit managers and their Medicare or Medicaid program, we are prohibited from interfering with private negotiations between plans pharmacy and made Do you

Unknown Speaker 53:06

think it's fair? Yes or no,

Speaker 5 53:08

we share the concern that our beneficiaries have full access to the drugs they need.

Speaker 9 53:13

And this is why I wanted to get to this because I practiced law for nearly three decades. And in that I had a fiduciary duty to my clients. I believe that insurance companies working with their PBM sometimes they own them, sometimes they don't have a fiduciary relationship with their subscriber with the person who's paying them money to help them pay for their insurance for their to help them pay for their medicines. And yet, what we have is a situation where in many cases, as Mr. Dixon pointed out in his opening statement, we we have a number of cases where the patient is paying a higher amount in their copay than the insurance company has paid for the medicine. And to me, it's a breach of their fiduciary duty and is unethical and immoral. And that's why I didn't have time for the other questions because I wanted to get that off my chest. And y'all need to be aware that we're there's a number of us who feel this way on both sides of the aisle. So Mr. Dickens, CMS disagree with your recommendation require more oversight and analysis into the rebate structures that are in place with health plans with greater scrutiny over these rebates bring more fairness for patients.

Speaker 6 54:32

Certainly the hope is that to make sure that there are not practices that could unduly affect or discriminating against individuals certain conditions would help better align incentives to the beneficiaries and plans and the Medicare program.

Speaker 9 54:50

Did your highly rebated report look to where these rebate dollars went that the health insurance plans and PBMs received from the highly rebated drugs

Speaker 6 55:00

We have looked at how the rebates are used, those rebates are reported by the plans to CMS each year. They're included as CMS negotiates with the plans or works with plans to develop their premiums for future years. As well as we have found that in general, within Medicare Part D, most of those rebates are passed through from the PBMs to the plans that may be different from the experience outside of mech

Speaker 9 55:28

to the plans and the plans are for profit as they should be, but but they're not necessarily benefiting the patient. Isn't that true? Particularly the patient who's buying one of those top 100 medicines?

Speaker 6 55:38

Yeah, they're not not affecting what they're paying at the pharmacy for the drug, they may help reduce their premiums overall.

Speaker 9 55:45

All right. Doctor used you agree with me that I'm going back to the original bill, because I got 20 seconds left. Do you agree with me that having standardized quality metrics for plans and the new part D rule going into effect in January that will eliminate retroactive dir fees will help pharmacies especially small and rural ones, keep their doors open?

Speaker 5 56:09

CMS agrees with you that pharmacies are disinterested partner in critical and healthcare space. That's why CMS is already taking steps to increase the transparency on the fees that pharmacies are being charged and to level the playing field for pharmacy providers.

Unknown Speaker 56:26

I appreciate that and yield back. Thank you.

Speaker 1 56:28

Thank you. gentleman yields back chair recognizes Mr. Cardenas from California for five minutes.

Speaker 10 56:32

Thank you very much Chairman Guthrie and Ranking Member su for holding this hearing. And I appreciate the witnesses being here giving us their opinions and expertise. I'm glad to see

several bills that I support noticed in today's hearing, I'll be focusing my remarks on just a handful of those. Starting with a bill that I co lead the ensuring patient access to critical breakthrough products act. We have previously discussed the importance of creating expedient access to devices drugs and technologies. These innovations can be life altering and life saving, especially for our country's seniors. The ensuring patient access to critical breakthrough products Act would allow temporary Medicare coverage for designated medical breakthrough devices, putting the most innovative courses of treatment at patient's fingertips. This means more people living easier, longer, healthier lives. Expanding this type of access has been a priority for me. And I'm excited to see so much regulatory activity to broaden access to a full range of devices. This includes the new trend transitional coverage for emerging technologies, otherwise known as T set rule, which would establish a pathway for emerging technology to be covered. Dr. Hughes, what kind of implementation timelines does CMS have for the tea set rule that rule? And how will the agency ensure that it hits those dates?

Speaker 5 58:01

They Thank you. And thank you for that question. As as you have alluded to, in the tea set pathway, we intend to start engaging with the manufacturers that are part of the pathway up to a year before their product is even authorized by FDA. We will commit to facilitating conversations with our colleagues and Medicare on benefit category determinations payment coding, we will review the evidence that exists even before the mark the product is approved by FDA so we can identify any gaps in evidence earlier, all of these steps in addition to committing to reviewing the evidence at specific times during the review processes, and what we think that will help to address the need for manufacture for a more timely decision, more consistency and more predictability. Okay, thank

Speaker 10 58:53

you. What kind of recourse is in place for CMS if the deadline described in the tea set guy guidance are not met?

Speaker 5 59:03

We think that by being very transparent, such as by our steps that we took to update the NCD dashboard that we will be able to provide the transparency that manufacturers and other stakeholders need to make sure that we're meeting our debt our timelines.

Speaker 10 59:20

Okay, thank you. Meeting these deadlines is critical because time really is of the essence. It can even be the difference between life and death for many people, which is why I should also take this moment to mention my concern that budget cuts and especially government shutdowns, will have a tremendously detrimental impact on CMS his ability to implement this policy. I sincerely hope we all keep these impacts in mind in the coming weeks and months as members of Congress. Also, separately, I want to call attention to the importance of covering a full range of treatment options for individuals with obesity, including men occations racial disparities and obesity incidents are a serious health equity issue. In fact, the University of North Carolina study led by Dr. Claire Yang found Black and Hispanic women have higher BMI trajectories across their life in comparison to white women. This means they are at greater risk of obesity and the many comorbidities associated with it by not covering anti obesity medications or Aom. We are limiting the number of tools at our disposal to address these disparities. For this reason, I'm glad that bills like the treat and reduce obesity Act are being discussed today. Dr. Hughes, in your opinion, what role could coverage for aos play in improving health and health equity for women, especially in Medicare?

Speaker 5 1:00:51

Thank you, and thank you for that question. CMS agrees that obesity remains a serious health condition for our Medicare beneficiaries and, and certainly our Medicaid and marketplace, beneficiaries as well. As you know, the statute prohibits us up from covering these medications to the Part D program, although the Medicare Advantage plans aren't able to cover it as a supplemental benefit if they choose.

Speaker 10 1:01:16

Okay, thank you. Thank you for your response. And for all the work you're doing at CMS to ensure that we have access to care. Like I said hope, I hope that we can ensure a full spectrum of care options whether it's access to innovative new devices or life altering medications. My time has expired. Mr. Chairman, I yield back.

Speaker 1 1:01:37

Thank you. The gentleman yields back. The Chair recognizes chair Rogers for five minutes for questions.

Speaker 3 1:01:42

Thank you, Mr. Chairman. Just picking up where my colleague, Mr. Cardenas just left off the importance of these decisions Life and Death medical technology. The Ranking Member, Mr. Chu highlighted this but the median time between FDA approval and some form of Medicare coverage for these technologies, unfortunately, on average is 5.7 years. It's a startling gap in coverage. And I'm I am concerned about the lack of accountability and predictability you, Dr. Hughes, you you were just talking about and in, in this new rule that you want to incorporate. You want more consistency, more predictability? I just want to ask, as you're in the process of incorporating the public comments, can you can you speak to the need for patients and innovators to have clear and accountable timelines for review and coverage decisions? I want this specific commitment to some timelines so that we don't continue this 5.7 years of people having to wait.

Speaker 5 1:02:44

Thank you. And thank you for that question. Chair Rogers, I do just want to note that when items and services are approved by FDA, they are able to get coverage at the local level on a claims by claim basis or through local coverage determinations. Without they do not have to wait on coverage through the NCD process, which is you note it can take more time. We do agree though, that we need to provide more transparency about the deadlines as part of why through the tea set pathway we have committed that we will establish deadlines, we will share these with manufacturers and the public so that they will know when they can expect the CD to be reviewed.

Speaker 3 1:03:30

Thank you. The fact that we have so many bills before us today, addressing new and emerging technologies are well known items like titanium wheelchairs so that they're accessible for Medicare patients who may otherwise be able to access these technologies if they were in a private plan is not a coincidence. This is a feature not a bug of an antiquated Medicare Fee for Service Program, a program which regularly requires Congress to intervene to clarify that CMS must cover certain products or services. In a more rational patient driven system patients would be able to access these products and services if they add value to patients lives in the Medicare program. So my question Dr. Hughes is what's the logic behind a patient having access to the latest continuous glucose glucose monitor or their cutting edge cancer treatment at age 64? And then losing access to them merely because they aged into the Medicare program or develop enrage ran renal disease? And what specific steps has CMS taken to protect seniors against losing access to medical innovations that they already had by simply aging into the Medicare program?

Speaker 5 1:04:45

Thank you, and thank you for that important question. Certainly CMS agrees that that our beneficiaries need full access to items and services that meet our statutory standard and our statutory standard is that we are able to Cover items and services for Medicare beneficiaries, in compliance with our statute that can help to diagnose or treat illness or injury. And as part of that there are Medicare beneficiaries. They're older, they are frailer, they are sicker, and they are generally not represented in trials that the FDA reviews. And so that is why, as part of our statutory requirement, we have to look at these items and services within the context of the needs of Medicare beneficiaries.

Speaker 3 1:05:32

For absolutely, I understand CMS previously considered technology assessments and coverage criteria among private health plans in its coverage policy for acupuncture for lower back pain. CMS also proposed a policy similar to hr 5395, would you commit to working with us on legislation that would require a demonstration for commercial coverage parity for Medicare payments?

Speaker 5 1:05:57

Thank you for that CMS would be happy to work with you on on that proposal.

Speaker 3 1:06:01

Thank you, Mr. Dyk Dickon. One of the major takeaways from your report is that seniors on fixed incomes are paying more for their drugs than some of the nation's largest, most consolidated and most profitable insurance companies, Mr. Dyk in your your testimony and report indicate that this unbalanced rebate dynamic is concentrated in certain types of drugs and certain types of patients. Would you just speak to the characteristics of the patients and the diseases they face who are stuck paying more for drugs and the health insurance companies?

Speaker 6 1:06:31

Yes, thank you for the question. Chair Rogers. You're right that we did see that these were very much concentrated among individuals who have certain types of conditions noted that that could include those with respiratory conditions, diabetes, chronic obstructive pulmonary disease, and so those are individuals where there are drug treatments that may be high cost, but are also highly rebated. And so that's where the incentives that we saw can become misaligned, where the plans may be getting large rebates for those drugs that may lower their overall costs and the

premiums that all beneficiaries are paying. But for those individuals that rely on those high cost drugs, they are not getting those savings when they're purchasing the drugs at the pharmacy.

Unknown Speaker 1:07:24

Thank you. Thank you for your insights. I yield back.

Speaker 1 1:07:26

Thank you. The Chair yields back. The Chair now recognizes the ranking member, Mr. Pallone for five minutes.

Speaker 4 1:07:34

In the US, we're lucky to benefit from one of the world's most innovative health systems with new drugs and medical devices come to market every day. And these products vary drastically in their complex on con, their complexity, as well as their usefulness to the diagnosis, treatment and management of diseases. And Congress gives CMS the authority to determine whether these new drugs and medical devices are reasonable and necessary products for the population served by the Medicare program. So I'm going to ask Dr. Hughes, could you please elaborate on the factors CMS uses in its reasonable and necessary standard, and explain why it is important for the agency to evaluate new medical products specifically in the context of the Medicare population?

Speaker 5 1:08:20

Thank you. And thank you for that question. As you note, our statutory requirements as directed by Congress is that we cover items and services that are needed to diagnose treat illness and injury for Medicare beneficiaries. And that's important because our Medicare beneficiaries, they tend to be older, they're definitely sicker. They have multiple chronic conditions. And they're also treated and represented often in clinical trials, where the individuals tend to be healthier and younger populations. And so that's why our statutory standard specifically mentions that Medicare beneficiary populations, those are that is where our statutory charge focuses on.

Speaker 4 1:09:05

And clinical trials often have strict criteria that define who is allowed to participate. And I imagine this might exclude people with comorbidities and potentially lead to a less diverse study population. Can you speak to how CMS this coverage determination process evaluates new products as they would be utilized in the more medically complex Medicare population?

Speaker 5 1:09:28

Thank you for that. Whether through the NCD the National Congress coverage determination process or the same standards are applicable for those on the local level when local coverage determinations are being made. We specifically look to the evidence on whether a device or a drug, what is the effect on the health outcomes? What are the risks that may be posed? Are there certain requirements that we should be put in place in terms of who's able to administer the drug or device what setting what supports may We needed all these factors we take into consideration when we decide to cover a drug or device.

Speaker 4 1:10:05

And we've seen proposals that seem to circumvent CMS is process of determining what is reasonable, unnecessary, or impose arbitrary timelines. So doctor who's given the unique characteristics of the Medicare population, Why might it be dangerous to bypass CMS coverage process?

Speaker 5 1:10:26

Thank you for that. We believe that a rigorous evidence review is necessary first to comply with our statutory requirement to look at items and services needed for diagnosis or treatment, illness or injury. But also in many cases, they may be unanticipated or unmitigated harms and risks that we should know about in advance so that we can appropriately work with our patients to make the best decisions for their care.

Speaker 4 1:10:53

Thank you, Doctor Who's I think these decisions and determinations are complex, and it's certainly helpful to hear from an expert like yourself on the uniqueness of both the Medicare population and, and the coverage determination process. So thank you. And with that, Mr. Chairman, I yield back.

Speaker 1 1:11:12

Thank you. The Ranking Member yields back The Chair recognizes Mr. bilirakis, for five minutes for questions. Thank you, Mr.

Speaker 11 1:11:18

Chairman. I appreciate it. I was particularly glad to see the bill I co lead with Representative winstram. And Representative Adel beanie. And of course, Representative Cardenas who sits on the committee. It's hr 6091, the ensuring patients access to critical breakthrough products act, noticed on today's hearing, and we really appreciate that and I appreciate the testimony of the presenters. I'd like to ask for unanimous consent, Mr. Chairman, to ensure and insert into the record statement of support from Dr. wenstrup. In support of this particular bill.

Speaker 1 1:11:55

Thank you, I believe it's on our list, and we'll take care of that at the end of the

Speaker 11 1:11:59

thank you hearing. Appreciate, it's been made very clear from both sides of the aisle Congress's intent for CMS to do more to provide a true coverage pathway for innovative breakthrough designated medical devices. These devices received that designation when there are no approved alternatives for life saving or debilitating diseases or offer significant advantages to patients compared to existing options. For example, we have a fully implanted active middle ear hearing device that receives breakthrough designation by FDA and was approved as a class two medical device that is not eligible for Medicare reimbursement. Due to the way it is categorized by CMS. These types of decisions make or break small US medical device companies. And again, it's withheld from the patients. Dr. Hughes, I'm glad to see in your testimony that you discuss a CMS transitional coverage for emerging technologies or to set a guidance and recognize the need for CMS to make quicker decisions. Our bill would do just that by ensuring that devices have national coverage for new breakthrough devices through statutory pathway including a way to establish additional evidence or data during the transitional four year coverage period. Unfortunately, the current CMS guidance goes through the existing NCD process, and may be limited to only five devices per year to receive coverage eligibility. Will you commit to working with us to ensure this new pathway creates real certainty for Medicare patients and innovators, as well as a pathway for new technologies such as digital therapeutics?

Speaker 5 1:14:03

Thank you. Thank you for that question. CMS agrees with you about the need for more timely access to innovative products and therapies, including the breakthrough devices. I would note that for any device that's approved by FDA, they do have access on a claim by claim basis that can be made at a local level by our Medicare administrative contractors or Macs. And also they can also receive coverage through an LCD also at the local level. It is not required for device manufacturers to go through the national coverage determination process. But that being said, as you noted with our new T set pathway we have committed to being very transparent about the deadlines that will put in place for review and other improvements to facilitate more timely access.

Speaker 11 1:14:54

Thank you very much. Next question for Mr. Dixon. Your study noted med packs previous work indicating patients receiving low income subsidies have weaker incentives to choose cheaper alternatives. Since they have limited cost sharing for their drugs. It seems that if Congress were to significantly reduce generic co pays for patients receiving li s, and couple that with modest co pays for non preferred drugs or all formulary drugs, patients would have an added incentive to choose the cheaper alternative drugs, saving themselves in the Medicare program money. Question, would you be willing to work with me on my legislation, HR 5386, that cutting co pays act to encourage greater generic utilization and save money for low income seniors?

Speaker 6 1:15:51

Thank you represent no rocket. So appreciate interest. Certainly glad to talk to you, you and your office balcells issues. You're right, that growing part of the Medicare population is receiving low income subsidies. And certainly that's the traditional role of formularies is to encourage lower cost of therapeutic equivalents including generics.

Unknown Speaker 1:16:14

Okay, thank you very much. I yield back. Mr. Chairman,

Speaker 1 1:16:17

gentleman yields back. The chair will recognize Miss Dingell from Michigan for five minutes for questions.

Speaker 12 1:16:22

Thank you, Chairman Guffey and Ranking Member issue for covering this important hearing. Over the last several years, we've taken significant steps in Congress to expand access to health care beyond a traditional doctor's office or hospital setting. So as we're having this conversation on how to modernize Medicare coverage, I think it's important to acknowledge that some existing coverage policies aren't reaching their full potential and also deserve our attention. One area where we still have significant room for improvement is Medicare's coverage for home infusion services for patients who need access to IV therapies but don't otherwise need to be in a medical facility. Mr. Dixon, as you may know, Gao concluded in a 2010 report that while private health insurers provide comprehensive coverage of home infusion therapy, under all of their commercial plants, which by the way, I don't think is true anymore. And I'll tell you why in a minute, coverage for these services, and Medicare Fee for Service is often limited, requiring patients to obtain infusion therapy and a hospital, nursing home or a physician's office to have all therapy components covered. And actually, I had to have a pick and give myself antibiotics for it was more than three months, and I gave myself the shot every day. If I went to the infusion center, it cost $5,000 A day, all I had to do was pay for the medicine. But it didn't cover it. Because you know, save $5,000 and pay for the medicine. So I myself really learned about this because I thought that was absolute insanity. And I have private insurance and Medicare, like save money makes sense. didn't need anyone to give it to me. Mr. Gibbs so Mr. Dixon, given the demonstrate benefits of home infusion therapies, including potential cost savings, enhance, enhance patient comfort, and reduced exposure to hospital associated infections. Can you provide insights into the barriers preventing broader Medicare coverage of home infusion services?

Speaker 6 1:18:26

Thank you. And as you've know, that's an issue that we have, my colleagues have looked at in the past certainly glad to have looked at the more recent experience that that you're highlighting and work with your office and trying to look at some of those challenges that may be currently faced.

Speaker 12 1:18:43

Well, you're not covering it right now. Like if somebody, okay, I'm a little older than 65, but not yet. But Medicare doesn't cover someone given their own self a shot. That's like a $5,000 savings every single day for 90 days, we should be looking at that. So that's why I appreciate your response. And that was why I've introduced the expanding care in the home act along with Representative Adrian Smith to modernize Medicare reimbursement and increase patient access for home based health services, including home infusion. While I appreciate the goals of

the home infusion proposal that was noticed today, this is a more comprehensive approach which would increase home infusion access to a much larger patient population, it will more closely resemble the model employed by nearly every commercial payer. I've also introduced the preserving patient access to home infusion act with representatives Buchanan school and Harshbarger to provide technical clarifications to expand access to home infusion services for Medicare beneficiaries. It's something I hear time and time again from my constituents. It's something they value and as you can tell, I've had a very personal experience, and I think it was ludicrous and Everybody on the committee knew it at the time. Now I want to run my attention to mobility related equipment. Dr. Hughes. In addition, addition of new emerging technologies Tommy Medicare coverage of mobility related equipment is critical for individual livings, individuals living with disabilities. As co chair of the bipartisan disabilities caucus, I understand the importance of wheelchair coverage for Americans with disabilities, and appreciate the work CMS has done and continues to do to improve Medicare coverage policies of mobility equipment. Last year, CMS opened a national coverage determination for seat elevation technology and announced this made that power seat elevation equipment would be covered for the first time. It's a critical improvement, but it did not consider seat elevation technology, which is another element. Dr. Hughes, can you elaborate, elaborate on how CMS determines coverage for mobility related equipment? And can you share if CMS has plans to open an NCD for seat elevation technology?

Speaker 5 1:21:02

Thank you. And thank you. You mentioned a number of areas that are priorities for CMS. So even with your earlier comments on how are you moving Karen to the home. And these are issues that I'll make sure I run by my colleagues and Medicare to see if we can provide more information back to the committee. As you know, we are starting to take more more efforts to look at what assistive technologies may be eligible for Medicare reimbursement and what additional information we may need. I will be happy to work with you on these issues moving forward.

Unknown Speaker 1:21:36

Thank you, Mr. Chairman. I have more but I'll yield back.

Speaker 1 1:21:39

Thank you. The gentlelady yields back. The Chair recognizes Mr. Johnson from Ohio for five minutes.

Speaker 13 1:21:44

Well, thank you, Mr. Chairman. And good morning to our panelists. You know, innovation in health care is is essential. It's a beacon of hope in our quest for a healthier and brighter future for all Americans. No other industry in the world continues to evolve. Each and every day like the health care industry, whether it be New Age, Alzheimer's treatments, or prescription digital therapeutics, or PTTs. There's a lot in the pipeline to be optimistic about getting patients coverage for PTTs. And a growing class of treatment everywhere from mental health, mental and behavioral health care, to Parkinson's disease and diabetes, will improve the quality of life and outcomes for millions of Americans. That's why I was so proud to see included today bipartisan legislation. I'm co leading alongside reps. Hearn, Matsui and Thompson are legislation, HR 1458. The access to prescription digital therapeutics act of 2023 would provide a coverage pathway under CMS to get these innovative pieces of software into the hands of patients. I believe this bill is a prudent step forward that will lead to greater preventative care, ultimately lessening the burden on the American taxpayer down the line. I urge all of my colleagues to support it. My first question goes to Dr. Hughes. According to the National Alliance on Mental Illness 22.8% of US adults, that's about 57 point 8 million people experienced some form of mental illness in 2021, yet less than half received treatment. There are several prescription digital therapies cleared by FDA, and still others in clinical trials to treat major depressive disorder, PTSD, panic attack disorder and other mental health illnesses. These treatments could help us close this coverage gap reach underserved communities like the one I represent in rural Ohio and improve health outcomes for millions of Americans. So, Dr. Hughes, what is cms doing to ensure that PD T's are being viewed as an important tool and are incorporated into those efforts? And what is your approach to coverage and reimbursement for innovative health technologies like digital therapeutics?

Speaker 5 1:24:27

Thank you. And thank you for that important question. As you know, CMS has prioritized behavioral health as issue that we have and will continue to focus on more intensively in the days ahead. With respect to PD T's, as you know, they do have potential to really address some of the access issues and provide our beneficiaries the care they need. We have been exploring this issue we ask questions through recent payment proposed payment rule we're looking at See that? The comments and evidence that we've received back and hope that we can work with you on expanding access to PTTs. Moving forward.

Speaker 13 1:25:10

Okay. Switching gears to some of the other legislation at issue in this hearing. Mr. Diken? What are the policy trade offs of D linking payment from list price? What will the impact be on value based contracting and Medicare and Medicaid and rebates in the Part D program?

Speaker 6 1:25:33

Thank you for the question. There are a number of important policy trade offs to consider that if prices are paid, or D linked, as you're suggesting, from the list price, and so that some of the savings that rebates have can be passed on to the beneficiary, that would certainly change some of the incentives we saw for some of those really, highly concentrated drugs where right now beneficiaries are, in some cases paying more than the plans. It also could provide the plan some more incentive to apply effective cost control, cost effectiveness looks at that, that if they're receiving high rebates that reduce their cost or even provide net profit for using the drugs that may discourage them from applying a reasonable cost effectiveness tools. And so having the cost better aligned for the beneficiary, the plan could could encourage that.

Speaker 13 1:26:26

So there's a balance. Yeah, yes. Dr. Hughes, back to you. Quickly, can you explain the changes in direct and indirect remuneration dir that set to go into effect at the end of this year?

Speaker 5 1:26:41

I thank you for that question. I don't know they can answer quickly. But Well, I

Speaker 13 1:26:45

tell you what, I'm my time has already expired. Would you take that? Absolutely. Get us an answer back, please. Yes. All right. Thank you, Mr. Chair. I yield back.

Speaker 1 1:26:53

Thank you. The gentleman yields back. The Chair recognizes Dr. Schreiner for five minutes for questions.

Speaker 14 1:26:59

Thank you, Mr. Chairman. And thank you, Madam ranking member. Thank you to our witnesses today. I'm so glad we're having this discussion. There's lots of improvements that we could

make to Medicare to make reimbursement more streamlined for the provider and for our healthcare system to work better for seniors. I especially appreciate the discussion just we just had about digital technologies. These technologies are increasingly common tools for people and for providers to collaborate for better, better care. First, I would love to focus on the bill I've introduced with Representative Bill Arachis, the expanding access to diabetes self management training act. It's a mouthful, but I want to thank the chairman and the ranking member for including it in today's hearing. This is an extremely bipartisan and and mentioned bicameral bill that aims to make small but meaningful tweaks to diabetes self management, training, and incentivize upstream care and teach good practices to patients to eventually prevent kidney disease and other potential complications of diabetes later, I'll speak as a physician and as a person with type one diabetes since age 16. Both of these goals are really important to me. As you know, diabetes costs Medicare nearly $150 billion each year as of 2017, which includes almost $6,000 per beneficiary spent on complications from type two diabetes. Diabetes, self management techniques are an evidence based benefit that gives Medicare beneficiaries living with diabetes, the tools and the skills to manage their condition and reduce the rates of these complications, or the severity of the complications later. Dr. Hughes, my understanding is that there are potential savings that could be generated for the Medicare program if Medicare beneficiaries had greater access to this benefit, and I was wondering if you could talk a little bit about how early intervention can prevent or mitigate future complications, like kidney disease and eye disease and how that can impact the human caused and dollar cost to Medicare.

Speaker 5 1:29:14

Thank you, and thank you for that important question. Certainly, CMS agrees with you on the evidence and the need for expanded access to self management training programs. As you may know, diabetes is an area of focus for CMS is one of the areas of across center focus, we have through our strategy to think about what are the opportunities, what are some of the areas that we can do more, and self management training is on that list of areas that we think we could take additional actions and so this is an area we'd love to work with you more on to to see how we can do more in this space.

Speaker 14 1:29:51

I think you're absolutely right. It would be a really, really good investment. And I'd love to discuss utilization because regardless of what you do, we need people to use these programs? I remember back from 1985, you can I'll do the math on that, how much help I got from diabetes educators and nutritionists. And by the way, I was able to have these appointments back to back to and which is something that this bill addresses. And those sessions put me on a really good path for better management and hopefully a long and healthy life. Yet only 5% of Medicare beneficiaries who are newly diagnosed with diabetes even utilize this benefit, which I would argue might be even more important for type two diabetes. So in your opinion, Dr. Hughes, what

are some of the reasons for the lack of utilization? And how can we expand access to this program?

Speaker 5 1:30:48

We have considered this a number of different ways. And again, I'd love to work with you more on this, we've looked at how well our beneficiaries are aware of the of the benefit, we're looking at the providers who are able to provide the training and education that we know that in certain areas accesses to these types of experts is even more limited. And so the end, I have no doubt there's even more factors that that are at play. But again, this is an area that's a priority for us. And we would love to work with you more on your proposal,

Speaker 14 1:31:23

and I'll add telemedicine to that as well, which would increase access. I want to before I close just give a nod to Representative McMorris Rogers about devices with diabetes. My understanding from my own endocrinologist is that it is a real headache to deal with some of the requirements at somebody on a CGM, a continuous glucose monitor might have to present a certain number of finger sticks, and it just makes no sense. So reducing some of those barriers would be very helpful for the best technology and speedy approval. And before I yield back, I just want to submit a letter of support on my bill. This is from several diabetes groups, and I will yield back. Thank you, Mr. Chairman.

Speaker 1 1:32:08

Thank you, I believe is on our list. We'll take action at the end of the search for that letter, but we accept it as well. We'll take formal action. The gentlelady yields back The Chair recognizes Dr. Burgess for five minutes.

Speaker 15 1:32:21

Thank you, Mr. Chairman. Doc Hughes. Good to see you again. I think last time we were together with Johns Hopkins on a panel in the 2008 presidential election. But today, I'll never forget it was an honor to be at at Grand Rounds at Johns Hopkins. So let me ask you a question. In March of this year, the CBO sent a letter to Sheldon Whitehouse over on the Senate finance side. And it had to do with the estimation of Medicare spending 2010 through 2019. And hey,

Speaker 1 0:00

And the actual estimate was was off significantly. And I will, Mr. Chairman, I will ask unanimous consent after I finish to make to make this and, and one other another article available for the record. But there was a signal, significant error in what was expected and what was observed. Now, look, I know we were on different sides of the issue with the Affordable Care Act and the Affordable Care Act, people were quick to take credit. But I don't know that you can do that because really, this reduction in spending and Medicare started in 2010. The fiscal times, the most important thing that happens a federal budget last 20 years was something strange is happening and Medicare, The New York Times reports instead of growing and growing and growing, as always had before spending per Medicare beneficiary has nearly leveled off for more than a decade. That obviously predated the Affordable Care Act. But if you widen the lens out a little bit, and look at what happened, say in the four or five years prior to that, Medicare Part D, was passed by the Congress signed by the President and worked its way through the agency and became law. Look, I'm a I'm a firm believer in precision medicine. And I think that is got to be the wave of the future. But in other countries they look at I think they call it the polypill, they kind of combine and antihypertensive, a baby aspirin, a statin, give it to large segments of the population and reduce mortality for their for their populations in in in heart disease. And you have to wonder if some of the same work was afoot in after passage of Medicare Part D, which is what we all argued who voted in favor of that, that more timely treatment of disease is going to result in a lower burden of disease and therefore, a lower cost. Now, the trick is we'll let all persist through the Coronavirus pandemic, and will it persist in to this decade? I don't know that anyone knows the answer to that. But in the meantime, and one of the reasons I bring this up is HR 48. A team which is part of our discussion today, Dr. Winds trip and Miller meets and was born mores bill that talks about the use of the Newark, type two diabetes drugs, which now have also become quite the fashion as anti obesity drugs. And it's not that this is a cosmetic concern. But some of these like Wigo V and Manjaro have demonstrated a 20 25% reduction in heart disease. And it's just absolutely astounding. What do you think of the implications for the Medicare population? So we have the model of Medicare Part D, and the savings that was achieved to them in the next decade? Should we be looking at more of that long term preventive health savings? And that was a question.

Speaker 2 3:16

Certainly, thank you. Thank you for the question. We do agree that we have to focus more on prevention in order to reap the benefits of long term in terms of care and outcomes. You raise a number of important issues I'm thoughtful, all of which I think, certainly helps to shape some of the work that we're doing at CMS. And I no doubt, you've mentioned some of their proposals here. We'd love to work with you more on as you move forward with these with these proposals.

Speaker 1 3:47

So unfortunately, representative to get his not here, she and I have had the preventive health savings act for a number of years. The problem that we all face, and I'm on the Budget Committee too, and I apologize, I haven't been here for the whole hearing because I was at a budget hearing. The problem we have on the budget side is the Congressional Budget Office always looks at a 10 year window. And what we all learned from our mothers years ago was an ounce of prevention is worth a pound of cure. So we're always paying for the ounce of prevention. Thank you CBO. It's important that we pay for it, but we never get credit for the pound of cure, which is in the next 10 year window and the next 10 year window. So I'll I would ask as we make these decisions about what perhaps are very fundamentally ground breaking developments in the treatment of type two diabetes and, and obesity, that we it's not just a cost. There's a benefit to this as well. Thank you, Mr. Chairman. I'll make these two articles available. And I'll yield back.

Speaker 3 4:42

Thank you. The two articles will be considered at the end of the hearing. As on our list. We'll make sure we have them on our list to be taken up for inclusion and including in the record. The Chair now recognizes the gentleman yields back Chair now recognizes Mr. Sarbanes for five minutes.

Speaker 4 4:56

Thanks very much, Mr. Chairman. Thank you all for being here today. Between 2011 and 2021, payments to Medicare Advantage Plans nearly tripled due in part to enrollment growth but also higher spending per beneficiary than in the traditional Medicare program. While Medicare Advantage plans may offer coverage for additional service beyond those provided under traditional Medicare, it's difficult to fully understand the scope, the usage and the cost of these benefits, because frankly, we just don't have the data to do it. Dr. Hughes, what information does CMS currently collect on the supplemental benefits offered by Medicare Advantage plans and how much individuals are paying for the services provided?

Speaker 2 5:43

Thank you for that question, as CMS shares your interest in increasing the transparency about how these benefits are being used that rate of adoption. As you may be aware, earlier this year, we released the information collection request ICR. To signal to the plans that we'd like more

data on how these benefits are being used. I would also know the CMS Innovation Center has started to collect data through the MA plans participating in one of their models with the same commitment in mind to better understand and to increase transparency and how these benefits are being used.

Speaker 4 6:19

My understanding is that a recent GAO report showed the data collection and supplemental benefits in the Medicare Advantage plans is inconsistent across health plans, which makes it obviously hard to evaluate the impact of higher per beneficiary spending and ensure our investments are driving more comprehensive care and not higher premiums. What effect is the lack of comprehensive data have on our ability to understand the quality of coverage these plans offer beneficiaries and the potential impact they have on individual and community health outcomes.

Speaker 2 6:58

Thank you for that. And again, I that is part of the reason CMS Innovation Center is collecting more data, not only just on the more clinically related benefits, but also some of the benefits relating to social determinants of health. We, as we start to collect the data to your point, we will be able to have a better understanding of the quality of care and long term outcomes for Medicare beneficiaries who are receiving these benefits.

Speaker 4 7:29

Well, I'm glad of the interest and I certainly think more data on the supplemental benefits provided by Medicare Advantage plans would not only inform better policy and put us in a better position maybe to make refinements and adjustments going forward but would also frankly, help seniors evaluate mean seniors are trying to make a judgment a lot of times should I stay in the traditional Medicare program? Where does this Medicare Advantage plan is being offered to me make more sense, it comes with some bells and whistles, it can be very appealing. But this kind of data would help seniors better evaluate the coverage options and find the best plan for them. I do think maybe nudging or putting some statutory expectations around the data could help with the collection, that you're trying to do more on a voluntary basis. And that's why I introduced legislation recently, HR 5380, it would increase transparency in the Medicare Advantage market, it wouldn't change any of the requirements relating to what the plans can offer. It just would require disclosure of beneficiary level data, including date on the types of supplemental benefits offered the plans total overall spending for each benefit, the out of pocket costs that are paid by each utilizing beneficiary. I know that neither of you can comment on specifics of any of the bills here today. But I imagine you'd agree that increasing transparency in the Medicare Advantage

program would help both policy makers and and patients make more informed healthcare decisions.

Speaker 2 9:05

Thank you for that. And certainly we would agree that greater transparency would be helpful.

Speaker 5 9:11

Yes, thank you and you highlight the transparency and supplemental benefits. You know, GAO has made a number of recommendations over the years on improving data for Medicare Advantage plans, including supplemental benefits, as well as encounter data and other important things for monitoring quality and coverage.

Speaker 4 9:28

Thank you. I look forward to continuing to work alongside my colleagues to pass hr 5380 and other policies that will ensure seniors have the tools to most effectively evaluate and navigate our healthcare system and access quality, comprehensive and affordable care and I yield back. Thank you.

Speaker 3 9:44

Thank you. The gentleman yields back. The Chair recognizes the Vice Chair Dr. Prashant for five minutes for questions.

Speaker 6 9:49

Thank you very much, Mr. Chairman. I want to associate myself with with Debbie Dingell on her comments about home infusion therapy. Medicare's policies on this had been wrong for decades and decades. I was a cardiovascular surgeon, I could keep people in the hospital for 10 days and give them antibiotics, but I couldn't get it paid for if they went home. And also with Dr. Burgess on the long term savings issue and health care, Congressional Budget Office scores on on health care, I think, stop a lot of good legislation that we all know would benefit patients. And then I want to say that in my view, the PBM model being paid based on rebates needs to end there needs to be a decoupling. This is putting upward pressure on list prices and limiting access to formularies. Not my opinion but dependent near the GAO. This hearing is very

important members of Congress have introduced dozens if not hundreds of bills, attempting to increase patient access to important innovative therapies. And I know it wasn't easy to narrow today's list of bills for consideration for that reason. But I'm pleased we're considering bills like the treatment and reduce obesity act to provide patients with access to drugs proven to help fight obesity to Dr. Burgesses point, in the out years. This is going to decrease type two diabetes, heart disease and all kinds of other diseases related to poor health and the find act to ensure access to diagnostic radiopharmaceuticals. You may or may not know that that's been a problem by unbundling their payment from other imaging services. And I'm grateful include for the inclusion of my bill, the coverage determination clarity Act, which ensure that local coverage determinations from everything from non opioid pain alternatives to important items of durable medical equipment are in line with national coverage decisions made by CMS. My question is going to be related to coverage with evidence. C D essentially conditions Medicare coverage for FDA approved items on certain requirements such as clinical studies, or trials or registries. Honestly, I thought that's what the FDA was for. Which means patients ineligible under CD protocols do not access the product until CD requirements are lifted, and the product is achieved national traditional coverage. Your testimony indicates this CMS has issued a total of 26 and CDs, requiring CD er coverage with evidence development over the last couple of decades. So the question I have is how many of the 26 NCDs requiring CD have been have been retired by the agency, meaning CMS determined the evidence collection was ultimately sufficient to remove the CD requirements. So patients could access the product.

Speaker 2 12:23

Thank you for your question. I certainly would say CMS shares your interest in increasing transparency and facilitating timely access to drugs and devices. I am not sure how many

Speaker 6 12:39

I of course know the answer, I would have asked the question Are All Right, four of 26 that are that CMS has CDs in place. That means 22 medical items are still in limbo. And I patients can't get access to them because there's no coverage decision, several of which have been ongoing for more than 15 years. So in your opinion, at what point is there is there a point at which evidence development should reasonably be expected to transition to a more predictable coverage policy?

Speaker 2 13:17

Thank you for that. I have two thoughts. The first is through the our new tea set pathway that we've announced we've committed to establishing deadlines and being very transparent, communicating the deadlines with manufacturers and stakeholders. So that the CDs to do come

to an end. The second for those patients who desire access to a drug or device subject to a CD, they are able to, to receive coverage for those items. And whether if they are part of the study required by the CD or or if they're part of the registry, that's required by CD and that's of course is you know how, since with Alzheimer's,

Speaker 6 14:00

let me just say this, I was a medical doctor before. The big one of the biggest problems we have right now in the United States is we get FDA approved products, whether that's a device or a drug, and CMS refuses to pay for them. And we fight for an average of four to six years. For that to happen. I had a medical device that treated glioblastoma, we all know what that device was. And it increased their life expectancy by 18 months. And if you know what that is, it's a brain tumor. Your life expectancy is short 18 months is a literally a lifetime for these people. It took CMS five years to agree to cover it, even though every private insurance and the VA paid for it. So the company gave it to Medicare patients for free in the mean in the meantime, but we need to address this and 20 only for NCDs requiring a CD being retired, some of which are over 15 years old is not not X Pepto, I know that's not your fault. That's for the broader CMS audience that's watching the hearing. We need to fix this. So, Mr. Chairman, I yield back.

Speaker 3 15:08

Thank you. The gentleman yields back. The Chair recognizes Miss Custer for five minutes for questions.

Speaker 7 15:12

Thank you Chairman Guthrie. I appreciate it. I want to echo many of my colleagues support for today's discussion about the important role that Medicare plays in improving access to innovative growth drugs, Game Changing medical devices, and emerging health technology, innovation, and Medicare is a defining feature of our healthcare system. And I'm excited to co lead and co sponsor several of the bills that we're considering, including the kidney patient Act, which I lead with Representative Carter to preserve access to important medications for people on dialysis, and several bills today bringing Medicare coverage into the modern era, including the find act, access to prescription digital therapeutics act, and ensuring patient access to critical breakthrough products of 2023. I'm also proud to support the Nancy Gardner seul, Medicare multi Cancer Early Detection screening coverage act to increase access to multi cancer screening tests. And I want to thank the witnesses for being here with us. And for being part of the solution in modernizing Medicare. One of the bills for consideration would eliminate co payments for low income patients with Medicare Part D coverage for generic drugs. By eliminating co payments for these lower cost alternatives. We can incentivize people with

Medicare drug coverage to choose generic drugs over more expensive brand name products. Eliminating co payments for low cost generics has two benefits. First, it saves patients money, and second, it saves Medicare money. This is a win win. Dr. Hughes, do you agree that increasing generic drug utilization will reduce overall drug spending?

Speaker 2 16:58

Thank you for that question. It has certainly been an area of focus for CMS in terms of increasing utilization of generic drugs. I would also note, we have recently increased assistance for patients who are receiving low income subsidies to help them better afford their their dragon necessary medications.

Speaker 7 17:19

Do you think eliminating co payments for generic drugs for low income subsidiary subsidy beneficiaries will help more people use generics?

Speaker 2 17:29

Thank you for that. I haven't seen that. That exact evidence on that exact question. But I would say certainly we know that even small co pays can pose a challenge for patients with who are lower income and potentially reduce their refilling their prescription or staying on their medicines. Great, thank

Speaker 7 17:49

you. The inflation reduction, Nick made many changes to the structure of the Part D benefit and expanded the low income subsidy to reach more beneficiaries. Dr. Hughes, can you briefly discuss these changes, and specifically the impact on low income Part D beneficiaries?

Speaker 2 18:06

No, thank you for that. Through the IRA, a number of changes have been made to the Part D some that have been implemented, for example, the great assistance to low income beneficiaries. We've also eliminated co pays for vaccinations, we are looking for Bill. Oh, thank you for that. We are certainly down the pike, there'll be a cap at $2,000 out of pocket cost sharing for beneficiaries, in addition to of course, reducing the price of drugs. And so we are

very much working very hard to implement the bills to make sure that our Medicare beneficiaries have access to the drugs that they need and can afford these products.

Speaker 7 18:49

And do you have a timeframe for when the cap of $2,000 for prescription medication will go into effect and how that will impact Americans on Medicare across this country?

Speaker 2 19:03

Thank you for that question. I would note I'm not at the center of Medicare, of course. And so they would be the better responders. But my understanding is this cap will go into effect in 2025, if I'm not mistaken. And we can get back to you with more information on that. And it will

Speaker 7 19:18

cap the out of pocket expense for Medicare beneficiaries at $2,000 per year.

Unknown Speaker 19:24

That is my understanding. Great. Well, thank

Speaker 7 19:26

you for that. Democrats worked very, very hard last session and we're committed to lowering prescription drug costs and delivering savings to seniors in every state. So thank you and I yield back.

Speaker 3 19:38

Thank you The gentlelady yields back The Chair recognizes Mr. Carter for five minutes.

Speaker 8 19:42

Thank you Mr. Chairman and thank both of you for being here and thank all of our advocates for being here. This is encouraging to see everyone here and we appreciate it. As many of you know. I am a pharmacist by profession and I have witnessed firsthand the the out rageous cost of medication gins I was the one at the front counter who had to tell the senior citizen how much their prescription was and watch them make a decision between buying their medicine and, and buying their groceries, I was the one who had to tell the mother how much the antibiotic was for their child and watch her in tears as she tried to figure out how she was going to pay for that medication. I made it my focus when I became a member of Congress eight and a half years ago to bring light to the problem that is in the drug pricing chain. And that is with the middleman with the pharmacy benefit managers PBMs, where we have three companies that control 80% of the market, with a company that is or own and with the situation it exists with the vertical integration where the insurance company owns the PBM that owns the group purchasing organization that owns the pharmacy that owns the doctor. And the problem that that causes. And I just I'm you know, I've been singing that and bringing this to attention for ever since I've been here and even before then when I was a member of the Georgia State Legislature. But now it's just not me now. We've got the GAO the Medpac OIG confirming these things and it's been brought to the attention that PBMs bring no value whatsoever to the healthcare system, all they do is to raise prices. That's why I've got a bipartisan bill. It's called protecting patients against PBM abuses act, you know, PBMs get charged, are get compensated by charging fees that are calculated as part a percentage of the cost of medicine and this incentivizes the PBMs to to increase the price of Medicare medicines and to blackmail the the insurance companies for fun formulary access and are blackmail the pharmaceutical manufacturers I should say for for formulary access. And what this bill does is to D link the administrative fees paid by PBMs from the price of medicines. It also prohibits PBMs from reimbursing non affiliated pharmacies more than they are less than they do for their own pharmacies. These are things that Representative Lisa blunt, Rochester and I and she's on the other side of the aisle. These are the things that we put in this bipartisan bill. Dr. Hughes, will you commit to work with us on this critical piece of legislation so that we can protect patients and pharmacies from harmful PBM practices and so that these advocates that are here with us today, that they can see some result in the lower drug prices?

Speaker 2 22:28

Thank you. And thank you for that question. And, and certainly, we consider pharmacists to be trusted partners and just clinical leaders, particularly community based pharmacists, as you know, we would definitely work with you on these.

Speaker 8 22:42

But what we're trying to do is to lower patient costs to increase patient care, all of us want the same thing whether you're Republican or Democrat or Independent. You want accessible,

affordable quality health care, it is not affordable right now because of what exist in the drug pricing chain. Mr. Diken. As you're aware, you you're recently released, Gao GAO report found that PBMs are denying senior savings on medicines by not passing on their savings directly to the beneficiary. Understand that HHS didn't concur with your recommendation that CMS monitored the effect of rebates on insurance plans formulary design, and all Medicare and beneficiary spending to assets were to assess whether rebate practices are likely to discourage enrollment for certain patients. What can you elaborate on this? Why Why would they not go along with that?

Speaker 5 23:37

You know, thank you. And you're right that we did recommend that porn first step is to monitor to see to make sure that there are not practices that may unduly affect or or prevent enrollment by certain groups of individuals. Certainly appreciate that. You know, there are a number of changes, some bout talked about this this subcommittee today that are taking place. And we think that as he messes continuing to implement a number of provisions of whether the inflation Reduction Act, or other things, it's important to really monitor right that rebates are being

Speaker 8 24:09

that in your report. Also, Mr. Dixon, you found that plans exclude or disadvantage, lower cost drugs due to various factors that are related to branded manufacturer rebates? Yeah. What what's going on here?

Speaker 5 24:21

Yeah, that's That's right that for kind of a group of very highly rebated drugs, the plan may give them preferences you know it on on the formulary even over other drugs that may be available at lower cost either other brands, or in case some cases even generic Look,

Speaker 8 24:39

look, I practice pharmacy for almost four years. I'm telling you these guys did Attorney General and Ohio's right, these are gangsters. They are ripping off the public. They're ripping off these people who are here today to advocate for lower drug prices. They are not bringing any value to the healthcare system at all. This is something we've got to address and I hope I can I Hope I can depend on both of you to help me in this quest that I have to bring about lower drug cost. Thank you and I yield back.

Speaker 3 25:07

Thank you. The gentleman yields back. The Chair recognizes the gentlelady from California, Miss Barragan for five minutes.

Speaker 9 25:13

Thank you, Dr. Hughes. One of the barriers patients currently face in accessing innovative, FDA approved Alzheimer's tweet treatments is imposed by CMS. Purely its own decision making through the board to the broad NCD, which applies to all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease. Through the use of coverage. with evidence development, CMS requires patients to be enrolled in a registry in order to receive Medicare coverage for FDA approved treatments for Alzheimer's disease. I've continued to raise concerns around the possibility that this process will create unnecessary barriers for various underserved populations, low income seniors, seniors in rural areas and seniors from historically underserved populations like black and Hispanic Americans, what is he? What is cms doing to ensure that the registry requirement is not negatively impacting access?

Speaker 2 26:15

Thank you. And thank you for that question. We share your interest in making sure our beneficiaries are have access to to the candy and other treatments that are in the pipeline that we expect will be available. With respect to the registry, as you noted that for patients who are working with their doctors decide they want to take the drug their providers have to sign up for the registry, we have made this registry available on the CMS website, it is free, it takes an estimated five minutes to fill it out. We do not think that will pose a a burden relative to the need to understand which of our beneficiaries may be at risk for the life threatening side effects of Le can be the brain edema, brain hemorrhage, we feel that we need additional information on that front. And we have heard that there are providers all across the country who have signed up and are working with this registry.

Speaker 9 27:16

So you don't think anything else needs to be done to make sure there's no you think it's so easy that there is going to be no barrier.

Speaker 2 27:24

Thank you for that. The CMS. In addition to the CMS registry, there are also a number of other organizations and academic institutions have indicated interest in starting their own registry. So providers will have a choice in which ones they use.

Speaker 9 27:38

Okay, we is there any way to track maybe concerns or complaints from people, especially in these rural areas and underserved areas? For people who call and say, Hey, I I don't have access? Or I'm having a problem? Is there any number for people to call to register their concerns?

Speaker 2 27:59

Thank you for that. I agree. I mean, we share an interest in making sure that our beneficiaries are able to access the drugs and that there's no undue barriers for their providers. And as we get more data, we will be monitoring for any challenges that are unanticipated. And we will be also sharing this data with external partners who can support us with additional research studies.

Speaker 9 28:21

And it has CMS heard from providers about challenges accessing the portal and know what is cms doing to ensure it's capturing and addressing any, any of those concerns?

Speaker 2 28:34

To date, we have not heard from providers who have indicated that they are having difficulties accessing the portal. But this is something again, we intend to monitor. And I will certainly take this question back and and follow up with you if we've received any more up to date information on that front.

Speaker 9 28:54

Okay. In the past, you know, when CMS issued and CDs that require coverage with evidence development, it continued for an average of 11 years past the finalization of the coverage

decision. Can you discuss why Medicare beneficiaries need more than a decade before they have full access to innovative treatments? And do you see this as being restrictive to patient access?

Speaker 2 29:21

Thank you for that. And certainly we agree that having timely access to treatments and therapies must be a priority as part of our tea set pathway. As as you may be aware, we have committed to including deadlines, being very public about these deadlines with manufacturers, other interested parties having regular check ins Our intention is that we will meet the deadline so there is a defined T set pathway defined length of time.

Speaker 9 29:53

Okay, thank you, Dr. Hughes. Medicare beneficiaries deserve to have timely Medicare coverage of innovative treatments and it's an important step in this direction that requires CMS to adhere to a consistent and transparent timeline to change their coverage decision once a CMS required trial or registry confirms a medicines effectiveness. I'm proud that there has been bipartisan work in this Congress. I lead a bipartisan bill called the access to innovative treatments act with my colleague, Representative Joyce, that does just that. Our bill presents an opportunity to mitigate bureaucratic delays that prevent Medicare beneficiaries from accessing clearly proven treatments for Alzheimer's or for other chronic diseases. And so I urge this committee to give this bill priority and advance a bipartisan solution that addresses this pressing need. And with that, Mr. Chairman, I yield back.

Speaker 3 30:46

Thank you. The gentlelady yields back. The Chair recognizes Dr. Dunn for five minutes.

Speaker 10 30:50

Thank you very much, Mr. Chairman. I'm excited to be continuing conversation about the unparalleled landscape of American innovation in the life sciences community. And to have such an important array of bills before us today. Our industry has delivered next generation therapeutics, diagnostics and cures at a very impressive right. But I hear frustrations every single day about the inefficiencies and inability of CMS, FDA and other government agencies to keep up with these innovations. I want to thank my colleague Scott Peters for working with me on HR 1199. The find Act which seeks to address an inefficient payment policy related to

precision diagnostic radio pharmaceuticals, I have firsthand experience with the utility and potential of advanced diagnostic radiopharmaceuticals. These tools are important not only for early diagnosis, but also treatment planning and monitoring. Package payments for these important tools currently limit access to them and Medicare population, the fine equity improved payment for those diagnostic radiopharmaceuticals making their their possible use possible when it's appropriate, adequate payment for these diagnostics will ultimately save the healthcare time and system time and money. That brings me to another bill we're running which is up for discussion day hr 5392. The timely access to coverage decisions Act. This bill will ensure the local coverage determinations are made in a timely manner. We've been talking about that already preventing Medicare administrative contractors from sitting on coverage decisions for new products for years. When seniors have access to innovative medical products soon after they come online. That's when we see improved outcomes and out ultimately lower costs due to a decrease in complications, more personalized care and in short, better health. Doctors, not Medicare contractors should be driving these care decisions with the input of their patients. Let's get the bureaucrats in the middle of the doctor patient relationship. When Congress passed the 21st Century Cures Act, we took important steps to ensure the innovation reached the people in a more timely manner than ever before, and I look forward to building on those efforts. Finally, I'd like to thank my colleague on Ways and Means, Mr. Fitzpatrick for working with me on a fix to the Medicare home infusion benefit. Our bill the Joe fianza. Access to home infusion net would ensure that infused drugs delivered via durable medical equipment at home are covered by the home infusion benefits. The bill is named for one of his constituents who briefly benefited from him fusions, but ran into access issues due to technicalities in the interpretation of statute. This bill is a simple fix that allows future patients to benefit from innovation. This is 2023 I think we can do a lot more things at home that we used to do doctors use. Can you define what is meant by the reasonable and necessary standard? And who specifically or which entity within CMS decides whether new technologies are in fact, reasonable and necessary.

Speaker 2 34:12

Thank you and thank you for the question. Our statute that was provided in the statute provided by Congress we required to ensure any items that we cover meet this reasonable and necessary standard they have to be reasonable and necessary for the diagnosis or treatment of illness and injury for Medicare beneficiaries. And as part of that, Bennett care beneficiaries as you know, very different than other populations. They're older, they're frailer, definitely sicker, so

Speaker 10 34:42

but I wouldn't I would if I may interject, you know, I've personally been in this position as a doctor with many, many patients most of Medicare I'm a urologist, a lot about prostate cancer patients. And I find myself fighting tooth and nail to get treatments and diagnostics for people in their

face. 50s 60s 70s 70 By the way, 70s who have 15 and 20 year life expectancies? We're gonna write these people are for wheat. We're not we're not using secret, quality adjusted life years, are we? No, we're not. Okay, because that would be really an anathema. I think, if all the members of this committee to try to place $1 and set criteria on people's lives, when was the last time your agency actually promulgated guidance related to the definition of reasonable and necessary?

Speaker 2 35:29

Thank you for that. I wouldn't say when I in our Program Integrity Manual for their local Medicare administration contractors, we do have more prescriptive information to address some of the challenges that you were describing some of our expectations for public comment, what information they must provide the rationale. So that's if you're

Speaker 10 35:49

running out of time. I hate this, but, but I will tell you that I have fought literally for people's lives with CMS, you know, to get them therapeutics that I know are far better than what they're getting. With that, Mr. Chairman, I yield.

Speaker 3 36:02

Thank you. The gentleman yields back. The Chair recognizes Dr. Royce for five minutes for questions.

Speaker 11 36:07

Thank you, Mr. Chairman. So we know that there is urgency to take immediate action to address disparities in health care and expand access to life saving medications and treatments for our nation's seniors. Medicare's our nation's promise to our seniors, but the current system leaves many seniors unable to receive or afford the care and treatments that they need. After a lifetime of hard work. Our seniors should not have to wait to receive necessary medical services, or be forced to forego the latest treatments or diagnostic modalities because Medicare won't cover them. Today, we have before us a number of important legislative initiatives to consider that would make great strides towards supporting our seniors and making our healthcare system more accessible. I would like to highlight three of these bills that I believe would have the greatest impact to this effect three bills that I'm an original co sponsor, or I helped introduce, as one of the the authors. The first bill that I would like to highlight is HR 20 fours 07, the Nancy

Gardner Seul Medicare multi Cancer Early Detection screening coverage act. I am an advocate for this bipartisan bill that would give Medicare the authority to cover blood based multi Cancer Early Detection tests, as well as future test methods once they are approved by the FDA. These diagnostic technologies are already out there. So let's not delay giving seniors access to these potentially life saving screenings over coverage disputes. Timing is of the essence. As a physician, I have witnessed firsthand the positive impact that early detection of cancer can have on patient outcomes and the fatal consequences that can arise when a diagnosis comes too late. I would also like to bring up hr 4818. The treat and reduce obesity act or troller, which would allow Medicare coverage of anti obesity medications. This is another bill I'm an original co sponsor, I introduced it with a bipartisan group of colleagues. It would also allow more qualified health care providers to administer intensive behavioral therapy. And this is an important step towards combating the obesity epidemic and getting readily available treatments into the hands of those who need them most. Lastly, another bipartisan bill I helped introduced hr 3840 to the expanding access to diabetes self management training Act would improve access to diabetes self management training services under Medicare, with millions of Americans diagnosed with type one and type two diabetes. The importance of education in managing this condition cannot be overstated. When new medical technologies and treatments emerge, we need to ensure that our policies are up to date so that there are no gaps in coverage and no gaps in the people who get coverage. And our seniors can benefit from the best possible care. So Miss Hewes, in your testimony, you mentioned CMS is transitional coverage for emergent technologies pathway, which includes a public comment period, how will CMS incorporate feedback to ensure the public's voice is reflected in the final covers decisions?

Speaker 2 39:25

Thank you. And thank you for your work across all these different areas that you've mentioned, as part of our issuing their procedure proposed procedural notice we met with multiple stakeholder groups. We have received considerable comment on our proposal, and we seek to finalize that at that, hopefully by the end of this year, and as part of that we've outlined how we intend to engage with the manufacturers and stakeholders through this process.

Speaker 11 39:54

Thank you. You know that too often in the emergency department, I see a patient that comes in I'll tell Here's a story. There's young young woman came in, during the holidays, visiting her sister and her sister forced her to come to the emergency department. And she came in with a mass in her breast. And she was kind of knew that she should have gotten it checked out. But she didn't have a doctor, she was afraid of the diagnosis, she didn't have a way to get screened, and all of these things, and she came in, and it was pretty large. And it was something that looked very, very concerning. So, you know, we work to get her follow up with, with a, a, an oncologist, and someone that can really follow up with a biopsy. And these are real stories of

individuals who have to consider whether they're able to put money on for food, pay the gas, pay the groceries, this is very important for people who, you know, have our living check to check and can access health care. And so being able to detect cancer earlier, is not only to help save lives, it's to help improve their mental wellness, and to help that entire family. And that's why we need to put people over politics and do the right thing to ensure that people get the care when they need it. Thank you.

Speaker 3 41:15

Thank you. The gentleman yields back. The Chair recognizes Mr. Pence for five minutes.

Speaker 12 41:19

Thank you, Chairman Guthrie and Ranking Member Eshoo, and thank you for the witnesses being here today. Mr. Dictor Deke in your testimony was enlightening. I found that very interesting. But I digress. I'd like to speak in support of the insurance ensuring patient access to critical breakthrough products act. This bipartisan legislation would provide patients with faster access to FDA approved breakthrough medical devices, including diagnostics. CMS, however, is contemplating excluding diagnostic lab tests granted FDA breakthrough designation under the transitional coverage for emerging technologies or TC T. Diagnostic tests should be included in the proposed coverage pathway since they are eligible for FDA breakthrough designation and should therefore be eligible for new coverage pathways. I urge CMS to carefully consider stakeholder feedback and include diagnostic under the proposed TCE T pathway and the final CMS policy. I'd like also to speak in support of the treat and reduce obese obesity act. This bipartisan bill would increase patients access to FDA approved obesity care medications. According to an August 2021 GAO report the government spending including Medicare and Medicaid to treat cardiovascular disease, cancer and diabetes accounted for 54% of the 384 billion in healthcare spending to treat these three conditions. While private plans VA and the FE HB plans are already providing coverage for obesity medications. Part Medicare Part D is falling behind and prohibits access to these innovative treatments. It's important that who's your patients have access to obesity medications, when appropriate, so they can live their lives healthier. I want to now switch to another issue that is threatening to exasperate healthcare staffing issues across Indiana. And I Dr. Hughes, I direct this towards you under the direction of the White House. CMS proposed minimum staffing ratio requirements for nursing homes and earlier this month on my March 10, I sent a letter to CMF with several of my colleagues on both sides of the aisle to oppose this perspective policy. Nursing homes, which I've talked to all across my district are already struggling to maintain current staff levels and fill vacancies. According to the Bureau of Labor Statistics and highlighted in CMS his proposed rule, there are roughly 236,000 fewer health care staff working in nursing homes and other long term care facilities compared to march 2020. Yep, yep. Yep, they're increasing the number that are required. Long term care facilities in Indiana would need to hire nearly 3000 new health care

professionals comply with rule implementing higher mandatory ratios that these nursing homes can never meet is unrealistic and could put patients in harm's way because they won't get the treatment. Doctor, how do you think long term care facilities will be able to recruit and retain enough nursing professionals to stay in compliance with the rule first and what would be the penalties for non compliance?

Speaker 2 44:51

Thank you. Thank you for the question. As you know, and in the role, the levels of staffing in Nursing Homes long term care facilities is correlated with the quality and the safety of the residents. And that is why we have issued this proposal. But to your point, also, it is proposed, we think that we've achieved a reasonable balance a robust proposal, but it is proposed, and we would welcome a comments if additional changes are made. To To your point and your areas, if there are areas that are rule or otherwise have workforce shortages, we have included staggered implementation, and we have also included exceptions to their requirements for certain facilities that may need more time to comply.

Speaker 12 45:42

Well, I hope you'll take a real closer look at that, you know, we have a shortage of employment all across the state of Indiana. And you know, a lot of these health care providers in these facilities tell me I used to, I can handle more I've been I've been in the business 2530 years, and I just, this is going to impose a reduction of patients care or eligibility for pay patients to come into their facility. So if you if all of you would maybe bring a little common, who's your common sense to it. With that I yield back.

Unknown Speaker 46:15

gentleman yields back. Mr. Han is recognized for five minutes.

Speaker 13 46:18

Thank you, Mr. Chairman. I'm grateful to you and Ranking Member Eshoo for holding this important hear a hearing and thank you for our witnesses for being here today. For decades, countless lives have been saved through medical innovation and I appreciate the opportunity to be part of the conversation of how we can improve Medicare coverage pathways for innovative drugs, medical devices and technologies and we are at a pivotal moment in the course of medical history. Many of the bills in today's hearing recognize this and are designed to ensure

that Medicare beneficiaries can access innovative treatments in a timely manner. When this subcommittee met in July to discuss seniors Access to Health Care Innovations, I highlighted my home state of Massachusetts role as a global leader in medical innovation, especially for diagnostic radiopharmaceuticals that provide incredible images to diagnose diseases, such as prostate cancer and Alzheimer's. It's for that reason that I'm working with 13 members of this subcommittee to advance the find Act, which I'm pleased has been included in today's hearing. In July, CMS requested comments on a number of options, including one similar to the Find act to revise its payment policy for diagnostic radiopharmaceuticals. And I commend CMS is openness to changing its packaged payment reimbursement system for diagnostic radiopharmaceuticals and urge them to adopt for 2020 for a separate payment, such as what's proposed in the Find act. Dr. Hughes, current payment policies restrict Medicare patient access to important diagnostic radiopharmaceuticals that work to identify dangerous conditions as early as possible. Is the age agency thinking about fundamental changes to its payment policy to address this issue?

Speaker 2 48:01

Thank you. Thank you for that question. As you know, I'm not with the Center for Medicare, and they certainly taken the lead on considerations for how we make these payments. But I know that this is an area that they're discussing. And and I'd be happy to take your comments back and work with you on your proposals moving forward.

Speaker 13 48:18

Thank you for that. Two years after withdrawing the last administration's M set regulation, I was pleased to see CMS finally released the proposed transitional coverage for emerging technologies or a tea set guidance to set represents a first step toward establishing a more predictable and transparent coverage process for Medicare beneficiaries to access new medical devices that can prolong their lives and improve their overall health and well being. However, I am disappointed that tea set as proposed may expand patient access to only a very small number of innovative medical devices. In July, our committee heard from witnesses concerned that life saving technologies would not be available to Medicare beneficiaries because Andrew T said only five innovative technologies would be approved for this pathway each year. CMS cited a lack of resources as the reason for the for the limitation. What resources would CMS need to increase the number of technologies approved under this new rule?

Speaker 2 49:22

Thank you. And thank you for the question. I do just want to acknowledge that. For breakthrough devices that are not applying and not on the T set pathway, they still wouldn't be

able to get obtain coverage and unclaimed by claims basis by our max or through an LCD at the local level. And that is where the vast majority of our products are actually covered. So the coverage those coverage pathways remain through the T set pathway. As you note when we looked work with FDA look at their pipeline if we stripped out the devices that would not otherwise qualify me and they're for pediatrics or they're cosmetic or they don't have a benefit category. The number does shrink down considerably. And we think that we expect to get eight nominations every year. And to your point with the resources, we think that we wouldn't be able to review five,

Unknown Speaker 50:20

can you quantify resources,

Speaker 2 50:22

and then it's certainly, as you mentioned, their staffing, but there's other considerations, as well. And so I'd be happy to provide more detailed information. Take that back.

Speaker 13 50:32

Great. Lastly, I recently sent a bipartisan letter to CMS urging the agency to address delays and a new benefit category for FDA approved exoskeleton technology that works to ensure wheelchair users suffering from a spinal cord injury can perform tasks in everyday life. The public comment period has now ended and CMS will release a final rule later this fall. As CMS develops this final rule. How are you keeping in mind that proper coverage and payment for new technologies like exoskeletons will improve innovation and lead to more patient access to innovative treatments?

Speaker 2 51:07

Thank you and certainly CMS degrees, these new technologies are we want to think about how can we provide access to our beneficiaries? We are reviewing comments that have come back in and we hope to release more information in the days ahead. Great.

Unknown Speaker 51:24

Well, we look forward to that. I yield back. Mr. Chairman.

Speaker 3 51:26

Thank you. The gentlelady yields back, the chair recognizes Ms. Harshbarger, for five minutes for questions.

Speaker 14 51:31

Thank you, Mr. Chairman. Thank you for being here today. First of all, I want to associate myself with my colleague buddy Carter's comments about the misaligned incentives with PBM rebates and Medicare Part D. And Mr. Dickens, I think we need to take your GAO report and give that to the FTC as they do their investigative probe into pharmacy benefit managers, I think it'd be our opening for them as well, sir. Dr. Hughes, I'm going to talk about something that's not on the slate of bills today. But you know, I introduced bipartisan legislation, it is called the seniors access to critical medications act. And unfortunately, post public health emergency CMS has ruled that physicians cannot deliver their patients medicine via mail. Nor can a family member pick up a sick cancer patients medicine, for example. And they say that they can't do that because it would violate the Medicare Stark self referral law. And this does not make a lick of sense, especially as Medicare transitions from a fee for service to value based model. And as we talk about Medicare Modernization, we should especially be thinking about seniors who are too sick, or don't have access to transportation, to come pick their medication up. I mean, we need to have mail order, or we need to be able to have a family member come pick that up for them, because the bottom line is it's going to worsen their outcome. So my question to you, Dr. Hughes is will CMS work with us to ensure Medicare patients have timely and appropriate access to their medications?

Speaker 2 53:09

Thank you for raising this. I certainly will take this back to my colleagues and Medicare. And we certainly would love to work with you on this issue.

Speaker 14 53:16

Thank you, ma'am. But I am going to talk about a bill that I know the subcommittee's considering as part of this legislation, and it's the coverage parity for Medicare patients act. And as I said in our hearing in July, Americans should not have to rely solely on a health bureaucracy and politicians to determine the value of innovation and whether or not to cover a medical product. Yet in Medicare, that's exactly what happens. And we often hear that Medicare has to cover something before private insurers to as Mr. Carter, I've been a pharmacist for 36

years, and I see how this coverage, how that's related to waiting 15 years or more for Medicare to pick up the slack. But it shouldn't have to be this way health insurance carriers and commercial markets should have incentives to cut the cover their products in either number one, reduces overall cost or make them more competitive by proving access to patients. Or number two, if a product meets this criteria for commercial payers, it makes sense that the same benefit should apply to Medicare. This bill would establish a demonstration program for Medicare administrative contractors to test a new pathway for medical necessity, necessity determinations under Medicare, it would maintain for Medicare coverage, the requirements that are not on be safe and effective and not experimental or investigational. But for the appropriateness criteria, my bill would add a new pathway providing that appropriateness can also be satisfied if an item or service receives significant coverage in the commercial insurance market. So the principle here is pretty simple. If an item is safe and effective, and and widely covered by the private market seniors should be should, as a general matter have access to those innovations and our family members shouldn't be treated any differently when they're put on Medicaid than when they have private insurance or Medicare when they're put on private insurance. And Dr. Hughes understand CMS has proposed a policy like this in the past to try to create coverage parity for Medicare patients. So would you commit to work with me on this, man,

Speaker 2 55:30

thank you for this important question. For us, our statutory standard also contemplates reasonable and necessary for Medicare beneficiaries. And there are important differences between our population and the commercial population, as you know, but that being said, as we we share your commitment to enhancing access and we would love to work with you on your proposal.

Speaker 14 55:54

Fantastic. I have one other question for you, Dr. Hughes. On the issue of Medicare Modernization. As you may be aware, Medicare has an inconsistent policy on how it reimburses compound medications, for example, if a patient's hospitalized and need something that's compounded from bulk ingredients Medicare Part A covers these products however, Medicare Part D plans are not allowed to reimburse for prescriptions that are compounded from bulk drug ingredients. beneficiaries have to pay out of pocket for these prescriptions in this financial barrier these patients. So would you be willing to work with me to allow Medicare Part D is compounding from bulk drug substances reimbursement policy for seniors.

Unknown Speaker 56:37

And thank you for that we will work with you on this proposal.

Unknown Speaker 56:40

Thank you, ma'am. And with that, I yield back.

Speaker 3 56:42

Thank you. The gentlelady yields back, Dr. Joyce is recognized for five minutes.

Speaker 15 56:47

Thank you for yielding Mr. Chairman for convening this important hearing. included for consideration today are three common sense bills that I have either LED or CO led aimed at increasing access to care or decreasing costs for our nation's seniors. Specifically, I would like to highlight hr 2408, the access to innovation Treatment Act, HR 4371, the choices for increased mobility ACC and HR 5372. The expanding seniors access to lower cost medicines act, and thank the committee for including these pieces of legislation today. Dr. Hughes, thank you for being here. I like you. I'm a board certified internist. I understand the impact of what costly medicines, patients have to make decisions each and every day. And this year, we are seeing the first ever biosimilars for the popular drug Umera. We see that come online, which could present substantial cost savings for our seniors. However, I've heard from companies who make these biosimilars that they have not seen a large amount of usage and volume in Medicare Part D for these products. Dr. Used, do you believe that allowing for real time formulary adjustments in Part D plans that CMS oversees as provided in my legislation, HR 5372 can drive higher utilization of these more affordable biosimilars. So that the patients and that the government ultimately benefits from the savings that are offered by these lower cost products.

Speaker 2 58:28

Thank you. Thank you for the question. Certainly CMS agrees that we have to enhance access to biosimilars for the reasons that you outlined, particularly to reduce drug spending for the government and for beneficiaries. I would note the CMS Innovation Center and one of their earlier oncology model, one of the encouraging findings that they found was the shift to greater use of biosimilars by providers and their patients. And so I certainly would love to continue to work with you on this proposal. As you move it forward.

Speaker 15 59:01

Thank you, I would you commit to working with us to address the necessary formula adjustments so that these cost saving Biosimilars are available as a to your point in mind, saving both the government and saving patients dollars.

Unknown Speaker 59:15

We would work with you on this.

Speaker 15 59:16

Thank you very much for that on another topic regarding breakthrough medical devices. In order for Medicare beneficiaries to have better access to innovative medical technologies. CMS must provide coverage pathways for these technologies in the much awaited propose notice on T set diagnostic tests unfortunately, were not included. Diagnostic tests are a critical part of healthcare, and yet they had been excluded. Dr. us how can we work with you to ensure that the FDA approved innovative diagnostic technologies can obtain expedited Medicare coverage while the manufacturer develops evidence?

Speaker 2 59:57

Thank you for that question. As you know, there are Literally 1000s of these tests and they, many of them hold great potential for earlier diagnosis and, and help with treatment for a number of conditions. Through our local Medicare administrative contractors to the max a number of them help with review and local coverage decisions on these diagnostic tests. They have specialist pathologists, geneticists, others on staff that really are able to provide that high level expertise that are needed to review these tests.

Speaker 15 1:00:32

As CMS continues, its bipartisan supported focus on creating a coverage pathway for breakthrough products to Medicare beneficiaries. I worry that the agency is ignoring the significant pediatric population that are covered by Medicaid, nearly 35 million children under the age of 19 have health coverage under Medicaid. Today, unfortunately, there is no pathway for FDA approved devices with a breakthrough designation to get to pediatric patients in a reasonable period of time. I'm sure you can see how this could create an uneven playing field when kids with commercial insurance could get better and faster and more. More care more available care to the latest technology before kids who unfortunately are on Medicaid, what

steps can CMS take ownership of this challenge and help lead state Medicaid programs to providing the necessary coverage to break through devices that are targeted at kids?

Speaker 2 1:01:33

Thank you for that. As you know, the reasonable and necessary standard does direct us to make these decisions for Medicare beneficiaries. But to your point, we are starting to work across the other centers. At CMS particularly, of course, there are colleagues in Medicaid to think about how we could what are the additional steps that we can do to affect the quality and the care and the access for pediatric populations. And I think our work on the universal foundation of measures is one good example of how we are trying to prioritize the needs of our pediatric beneficiaries of Medicaid.

Speaker 15 1:02:10

Mr. Chairman, my time has expired. thank the witnesses for being with us today. And I yield

Speaker 3 1:02:15

Thank the gentleman yields back. Dr. Miller Meeks is recognized for five minutes.

Speaker 16 1:02:20

Thank you, Mr. Chair. My bill. The treat and reduce obesity act is designed to effectively treat and reduce obesity and older Americans by enhancing Medicare beneficiaries access to providers who are trained to administer intensive behavioral therapy under Part B, and by allowing Medicare Part D to cover FDA approved anti obesity medications. Doctors use CMS is viewed as a leader in treatment coverage policy and programs for chronic disease management. It is undeniable that obesity is a serious chronic disease that affects 42% of Americans, and approximately the same level and older Americans enrolled in Medicare. We know that on account of its antiquated structure and Richard rigid coverage limitations traditional Medicare does not provide for flexible or customizable obesity treatment coverage policies in both Part B and Part D. the Medicare Modernization Act excluded coverage of anti obesity medications in Part D, which made sense at the time given the paucity of available treatment options. As a result of the remarkable scientific research and innovation. Since the MMA obesity has become recognized as a serious chronic disease with highly effective medications to treat it. Moreover, the rapid growth in obesity and related health and economic consequences was corroborated by the University of Southern California's Shaffers center dynamic analysis which

suggested Medicare could save as much as 175 billion over 10 years if patients had access to new obesity treatments. Can you please detail any plans CMS has to update these coverage policies for obesity treatments, and how your agency thinks about the trade offs between increased utilization and obesity coverage on the front end with the prospective program and broader health system savings that may accrue over time.

Speaker 2 1:04:07

Thank you. Thank you for that important question. And CMS certainly shares your view that obesity remains a serious and significant public health problem, particularly for our Medicare beneficiary particularly for underserved beneficiaries. As you note we are prohibited by statute from covering drugs for weight loss under Part D. We would be willing to work with you on your proposal as it moves forward.

Speaker 16 1:04:34

Thank you very much for your comments, and I will enjoy working with you on this issue. I'm also proud to see the share the savings with seniors Act included in this hearing. This bill is full rebate pass through for medicines used to treat chronic conditions such as diabetes, asthma, chronic obstructive pulmonary disease, congestive heart failure, and medicines used to prevent stroke. This ensures that patients who are most likely to face high output pocket costs directly benefit from the savings that plans and PBMs negotiate on their behalf. A recent GAO report authored by today's witness Mr. Dixon, found that beneficiaries pay more than their plan sponsor for nearly 80% of most rebated drugs. The report states that Part D plans received 48 point 6 billion in rebates from drug manufacturers and 2021. But went on to say that rebates do not lower individual beneficiary payments for drugs as these are based on the gross cost of the drug before accounting for rebates doctors use? Well, I understand that HHS did not concur with the GAO specific recommendation in the report. I hope you'll agree with members of this committee that the status quo benefits industry actors at the expense of patients, especially low income patients with chronic conditions. As with your agency's recent actions to address some of these rebate policy excesses through your recent dir policy. Will you commit to working with me and others on addressing this PBM malfeasance in Part D to lower patients out of pocket cost?

Speaker 2 1:06:05

Thank you. Thank you for the question. We certainly value transparency, want to make sure that our beneficiaries can afford medications we would work with you on this proposal. Thank you.

Unknown Speaker 1:06:18

Parents you park is important. I now yield back.

Speaker 3 1:06:21

Thank you. The gentlelady yields back Seeing no other member of the subcommittee present for asking questions. The chair will now go to our way ones. And so the first will be Miss metsu from California recognized for five minutes.

Speaker 17 1:06:33

Thank you very much, Mr. Chairman. And I want to thank you, Mr. Chairman and Ranking Member as you for having this hearing today. And I want to thank the witnesses for being here. today. I'm excited to see my bill the access to prescription digital therapeutics act. Notice in today's hearing, this bill is critical to ensuring Medicare and Medicaid beneficiaries receive equitable access to innovative mental health treatments. I hope my colleagues would join me in pushing for this critical bipartisan bill and a markup soon. Prescription digital therapies, also known as PTS are software based treatments designed to directly treat a disease. Pts are tested and approved by the FDA. Much like traditional prescription drugs. They are prescribed by healthcare providers to treat a wide range of mental health issues, including PTSD, insomnia, anxiety and depression. patients deserve a timely access to the treatment that works best for them. It access to PTTs is hindered with a lack of Medicare coverage. That's why I'm co leading the access and prescription drug therapeutics act that would expand Medicare and Medicaid coverage to include PTTs. Dr. Hughes, how might digital therapeutics help bridge the gap for mental health services among Medicare beneficiaries, especially among underserved populations?

Speaker 2 1:07:59

Thank you. Thank you for the question. As you may know, behavioral health is one of our key priorities at CMS and providing access in underserved populations. Especially within that we recognize the potential for PTTs to address some of the accessing care needs of our beneficiaries. We're mindful that FDA has approved at least a couple of applications. We have asked questions in a recent payment proposed payment rule, we're reviewing those comments, and we hope to have more information shortly. For you and other others interested parties on this issue. Yeah,

Speaker 17 1:08:32

I realized that what does CMS see as next steps for incorporating digital therapeutics as it is an existing benefit?

Speaker 2 1:08:43

Yes, and that is part of what we ask questions in our proposed rule. We also are looking in terms of thinking about the benefit categories. There is also coding and payment issues. I'm not from the center of Medicare, but certainly be happy to take these questions back and provide more details, more detailed information, if that would be helpful.

Speaker 17 1:09:03

Okay. Yes, sir. Thank you very much. I want to briefly turn to rare diseases. Dr. Hughes, your testimony focused on CMS has worked to streamline coverage for innovative treatments and technologies. However, in the case of rare diseases, existing treatments may have promise if repurpose for additional indications beyond their approved views. Yet off label treatments remain out of reach for Medicare patients. Congress acted to address this issue for cancer patients who faced the same issue. Dr. Hughes, how did the change allow Medicare coverage for off label cancer drugs if included in certain Compendia impact cancer care?

Speaker 2 1:09:46

Thank you for that question. As you know, we don't interfere or direct the decision making by doctors. It's between doctors and their patients. We know that Congress develop the companion proposal that's used in many settings. The to the extent that it's improved quality or access. I haven't seen the evidence on that. But I would love to get back to you with the information that that we that we have likely within my within this in our Medicare.

Speaker 17 1:10:17

Okay. Well, thank you very much. I'd like to work with you and this committee to explore a similar solution for rare disease also. So that's the end of my questions. I yield back, Mr. Chairman.

Speaker 3 1:10:26

Thank you. The gentlelady yields back. The Chair recognizes Mr. Balderson, for five minutes for questions.

Speaker 18 1:10:31

Thank you, Mr. Chairman. And it's an honor to be waved on to the team today. So thank you for allowing me to ask my questions that includes two pieces of legislation. Both of my bills, including this hearing today, expand seniors access to care outside of a hospital or doctor's office through the provision of innovative technology like remote patient monitoring services. Excuse me. Expanding access to digital health can reduce provider workload while improving patient outcomes by catching problems early to help reduce avoidable hospitalizations, and communities like mine. These services are particularly beneficial. In rural Appalachia. Ohio, in many rural communities like it, providers are in shortage and patients often struggle with access to care. The first rule I would discuss as HR 5394, the expanding remote monitoring Access Act that I reintroduced with Congresswoman Katey Porter as well as Dr. Dunn, who is on this committee. During the COVID. Public Health Emergency, CMS lowered the monitoring requirements for billable remote monitoring services from 16 days to two days per month. This waiver demonstrated the clinical value of expanded monitoring. Our bill follows the Model Congress started for our telehealth flexibilities and extends for two years coverage of remote monitoring at the two days per month threshold, while Congress and CMS works to develop a proper long term billing threshold. Dr. Hughes, my questions are directed at you today as as I've been here, you've received all of them. I have three questions today. And the first is any of you've been asked this several times, are you willing to commit to working with me on expanding access to remote remote monitoring, including, including by discussing the proper day threshold for billing?

Unknown Speaker 1:12:16

Yes, we work with you on this proposal.

Speaker 18 1:12:18

Thank you very much. My second bill hr 5388. The supporting innovation for seniors Act will expand expand flexibility for Medicare Advantage plans to cover innovative products that traditional Medicare does not offer. CMS offers value based insurance design models that let ma plans test innovations to either lower overall cost of care or improve the quality of care for patients. One current model allows plans to cover an FDA approved medical device or technology either for the first time, or for a new indication that is different from the Medicare Coverage Determination. When ma plan is using this offer to coverage of continuous glucose monitoring devices for patients with diabetes and remote monitoring devices for patients with

heart failure, my bill would permanently expand these flexibilities to allow all ma plans to offer these to qualify patients. The government should not be implementing the ability of Ma plans to lower costs have increased satisfaction for patients. That is why I want to open this flexibility up to all seniors. Dr. Hughes, Can you provide any further detail on the outcomes of this versus the BID model so far?

Speaker 2 1:13:32

I thank you for this question. And through the CMS Innovation Center The VBid models there. I know that they are have started collecting more data on how the supplemental benefits are being used. starting this summer, actually, we should have more information early next year, as I understand it.

Speaker 18 1:13:49

Thank you very much. And just follow my office please. Thank you. Many devices and technologies that provide remote monitoring services, use artificial intelligence to analyze incoming patient data and alert providers to any concerns. Dr. Hughes, can you speak to how CMS is considering future coverage of artificial intelligence, particularly in FDA approved devices and software?

Speaker 2 1:14:15

Thank you. I mean, across a number of different centers, we're starting to explore the the promise and the potential for AI and technologies and thinking through what are the coverage implications for such technologies. And I think we've as I understand as I've started to ask questions about it and certainly as a several of our proposed rules, so I would be happy to get back to you with more information and, and work with you on any proposals that you may have.

Unknown Speaker 1:14:45

Okay, thank you very much. Appreciate you both being here. Thank you.

Speaker 3 1:14:50

gentleman yields back and the chair recognizes Mr. O'Boyle, notI for five minutes.

Speaker 19 1:14:54

Thank you very much. Thank you, Mr. Chairman. Thank you to both of our witnesses. As on this really important topic, Dr. Hughes, I'd like to start with a question for you. I am a big fan of the T set program, I think it's has the potential to bring some really innovative treatments to, to, to Medicare, and I'm glad that CMS is implementing it. But it certainly has been criticized for its lack of breath. Because with only the capacity to process five applicants applications a year, you know, it really is not considered a viable pathway by a lot of different medical providers just because the competition for those slots is so intense. We've got a bill that we're considering the package today, HR 6091, which would provide some relief for that, but only in the case of medical devices, not treatments or medications. So can you give us some, some comfort that tea sets a viable program? And that, that maybe there is a viable pathway for these innovative treatments in the future?

Speaker 2 1:15:59

Thank you for that important question. Certainly, we share your interests that we have to facilitate timely access to these devices, I would know the tea set pathways in addition to the other three coverage processes, processes, and the vast majority of decisions for breakthrough devices are made at the local level on a claim by claim basis or through a local coverage determination. And so those will stay in place with respect to the tea set pathway. As we work with FDA and look to see what is in the pike, once you would allow a number of devices that would not be appropriate, whether it's for pediatric populations, or they don't have a benefit category, or the cosmetics or then the number does decrease significantly. And we think that we expect maybe about eight nominations, this is voluntary self nominations by manufacturers. And with our current resources, we think that we could accommodate five reviews, of course, that is we have about four to five NCDs open at any one point in time, generally. And so this adding additional five, that is a significant expansion for us,

Speaker 19 1:17:11

I think that we would be interested in working with you to make sure that we have a viable pathway for the approval of these technologically advanced treatments, particularly in expanding the universe of services and products that we're offering those treatments. And for example, diagnostics is one that I think is underutilized right now. And I think that, you know, overall, the goal here is to not only improve the quality of health care for our beneficiaries, but also to lower the cost and these approvals that are being that use the tea set pathway have the potential to do that in ways that few other few other treatment plans do. So we'd be interested in working with you on that.

Unknown Speaker 1:17:51

Thank you, we would work with you, Mr. Dixon, I

Speaker 19 1:17:53

really enjoyed your testimony. And I found some of it extremely eye opening, I know particularly when you're talking about the impact that rebates have on the operation of the free market. And when it comes to the provisions of pharmaceuticals, it's very clear that these rebates quite often are untransparent. And quite often they result in counterintuitive market behaviors that come at the disadvantage of the people ultimately paying the bills, which are the taxpayers and the patients. In particular, I was struck by the point that you made that you've identified cases where we're so some some companies use the rebate scheme to provide preferential treatment to brand name drugs, which actually resulted in a savings for them, but a higher cost to the people that ultimately paid the co pays for those drugs, which obviously is not something that we want to to encourage. And I know this is probably outside your purview at the GAO but obviously you're an expert. Can you tell me what what should we in Congress be doing about that? Because it seems to be a really tenacious and pervasive problem.

Speaker 5 1:19:07

Yeah, no, thank you for the question. And you know, you you've identified kind of where we found for these very highly rebated drugs that might be paying 3040 50% of the list price rebated, but not which which would lower the overall price for that drug, but not help the beneficiary when they're bank paying that drug. Their costs are to pharmacy. You know, that's why we recommend as the first step to at least have continued monitoring, certainly as the as new drugs come online as their significant changes in the authority that CMS has under the inflation Reduction Act, important to have that information that can help Congress help CMS to make sure that these aren't unduly affecting certain types of beneficiaries that are not getting access to lower cost alternatives.

Speaker 19 1:19:59

Well, I'm sure I'm not unique here on the Dyess when I say, I'm extremely skeptical that more monitoring is going to solve the problem. I mean, we have been monitoring, we're aware that this problem exists when we've have when we have plans that are making more money on the rebates for a drug than it cost them to buy the drug, and that results in higher costs for the people who are taking the drug. There's something wrong with the system. And I think that we in

Congress have a role in making sure that that does not continue. But I thank you both for your testimony. Mr. Chairman, I yield back.

Speaker 3 1:20:30

Thank you. Thank you for your questions. The gentleman yields back that concludes member questions. And we have a list and some members mentioned unanimous consent I believe they're all encompassed on our list that are provided to the ranking member and ask unanimous consent to insert in the record the documents including on the staff hearing documents list what I just gave you and as everything mentioned that others brought up today from your side and both sides without objection that will be in order. So thanks everyone, I remind the members they have 10 days to submit questions for the record and ask the witnesses to respond to the questions promptly we appreciate that members should submit their questions by the close of business on october third and without objection the subcommittee is adjourned.

Unknown Speaker 1:21:33

Okay

Unknown Speaker 1:21:38

Thanks How are you good doing better doing great good good

Unknown Speaker 1:22:00

name

Unknown Speaker 1:22:07

is thanks for

Unknown Speaker 1:22:21

stopping by

Unknown Speaker 1:22:31

pocketing

Unknown Speaker 1:22:40

thanks for I know there's a lot to thank you for

Unknown Speaker 1:23:07

we appreciate that was great