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Answers to Questions for the Record
Subcommittee on Health
House Committee on Energy and Commerce
Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology

September 19, 2023

U.S. House Committee on Energy & Commerce, Subcommittee on Health
Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology
Tuesday, September 19, 2023
Questions for the Record

The Honorable Robert E. Latta

1) **I have heard significant concerns about a proposed rule CMS issued earlier this year that would require drug manufacturers to submit a significant amount of proprietary data to CMS that appears bureaucratic. In the proposed rule, CMS announced plans to require manufacturers to submit this data using authority Congress provided for CMS to "survey" manufacturers and verify the price data they submit. This survey authority was intended to ensure CMS could verify the drug pricing data manufacturers submit was accurate not to allow CMS to require manufacturers to justify their prices.**
    a. **How did CMS come about this decision?**

    Answer:
    Section 1927(b)(3)(B) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to survey manufacturers and wholesalers for information about the prices or charges for covered outpatient drugs to verify such prices and charges, in order to make payment. As part of the Drug Misclassification Notice of Proposed Rule Making, CMS is proposing to implement an annual Medicaid Drug Price Verification Survey through which certain manufacturers of high-cost drugs would be required to submit detailed pricing and other data to CMS. The survey's sole purpose would be to verify the accuracy of information on drug prices submitted to CMS.

The Honorable Earl L. "Buddy" Carter

1) **Diabetes Self-Management Training is a powerful tool in supporting individuals living with diabetes and their caregivers, while, in the long-term, reducing provider burden and improving the patients' health outcomes. CMS has wisely placed a good deal of emphasis on this program, including increasing the number and type of health care providers who can support patients with these services. However, many pharmacies have faced challenges receiving payment for providing these services – despite the fact that CMS and other National Accreditation Organizations certify pharmacies as DSMT-certified instructors.**

    a. **What steps is the agency taking/what steps will the agency take with payers to ensure that qualified health care providers who provide DSMT services are reimbursed fairly and quickly?**

Answer:
Medicare covers Diabetes Self-Management Training (DSMT) services when furnished by a Medicare-enrolled supplier or provider. DSMT services require a referral from the physician or qualified non-physician practitioner who is treating the patient's diabetic condition. DSMT can be provided by providers who meet quality standards of CMS-approved national accrediting organizations such as the American Diabetes Association and Association of Diabetes Care & Education Specialists (ADCES).

Medicare allows pharmacies, as an entity, to bill for DSMT services. Pharmacies must be enrolled as Medicare Part B suppliers to bill for the DSMT benefit. CMS does outreach and education to Medicare beneficiaries on the items and services covered and paid by Medicare. CMS has made educational materials available to providers about DSMT, including a DSMT Medicare Learning Network fact sheet (available at: https://www.cms.gov/files/document/mln909381-provider-information-medicare-diabetes-self-management-training.pdf) that describes DSMT and who may provide DSMT.

In the CY 2024 Physician Fee Schedule proposed rule, CMS included proposals to improve access to DSMT services. We propose to continue to allow institutional providers to bill for DSMT services furnished remotely until the end of CY 2024 (the same way that they could during the PHE) and revise our policy by eliminating the regulatory prohibition on providing full DSMT services via telehealth, particularly for injection training via telehealth for insulin-dependent patients when clinically appropriate. Additionally, we propose to clarify in regulations that a registered dietitian (RD) or nutrition professional must personally perform Medical Nutrition Therapy services, but the enrolled RD or nutrition professional, when acting as the DSMT certified provider, may bill for, or on behalf of, the entire DSMT entity, regardless of which professional personally delivers each aspect of the services.

2) **Although CMS is hosting "patient listening sessions" for the 10 drugs selected for price setting, only 20 individuals will be selected to speak during each session. Patients bring important information to bear as part of this process as CMS has admitted, including real life information on the "clinical benefit of the selected drugs as compared to therapeutic alternatives, how the selected drugs address unmet need, and how the selected drugs impact specific populations."**

    a. **Do you agree with CMS' decision to limit these sessions to only 20 patients? What is your view on how CMS has approached patient involvement as part of IRA implementation?**

    Answer:

Public feedback has been instrumental in implementing the Inflation Reduction Act so far, and CMS will continue this engagement moving forward. With respect to implementation of the Medicare Drug Price Negotiation Program (Negotiation Program), CMS has met with various interested parties representing the views of consumer and patient organizations, health care providers, health plans, pharmacy benefit managers, pharmaceutical and biotechnology manufacturers, pharmacies, researchers and academic experts, and wholesalers. In these meetings, CMS leadership and staff received feedback on implementation of the Negotiation Program ranging from policy concerns, questions requiring clarification, and recommendations on policy or operations. CMS received more than 7,500 comment letters in response to the initial guidance, representing a wide range of views, including patient organizations, and clarifications and changes were made to the Negotiation Program initial guidance based on these comment letters and meetings.

In the revised guidance, CMS outlined additional opportunities for engagement during the negotiation process. CMS established a web application through which any patients, health care providers, and other interested parties will be able to submit data by October 2, 2023, on each selected drug, such as data on therapeutic alternatives, and other relevant information. In addition, CMS is hosting meetings with manufacturers of selected drugs in Fall 2023 as well as CMS-hosted patient-focused listening sessions for the selected drugs. The patient-focused meetings are intended to bring together patients, beneficiaries, caregivers, and patient/public advocacy organizations as well as other interested parties to share their patient-focused feedback with CMS on the selected drugs and therapeutic alternatives and other relevant information, such as unmet medical need and impacts on a wide variety of diverse populations, as CMS develops initial offers to the manufacturers for each of the selected drugs. The sessions are being live streamed, so that patient groups and other stakeholders can listen in to the comments being made by the participants. We believe that these sessions will be important in helping to inform CMS as the negotiation process goes forward. CMS continues to seek out as much patient feedback as possible on this implementation process. CMS may also change the approach for future years of the Negotiation Program based on this experience.

3) **In GAO's report on rebates, the classes of drugs that were sampled showed the cheapest drug was rarely preferred, the most expensive drug was frequently preferred, and formularies often excluded the most affordable option for patients.**

   a. **What is CMS doing to stop this? Or is this something Congress needs to step in on?**

4) **Does CMS track or monitor health plans limiting network participation or plans steering patients to other pharmacies that they or a PBM may have a financial interest in?**

Answer 3-4:
Recognizing that Medicare can play a large role in promoting the use of more affordable drugs, HHS is committed to continuing to promote competition, support increased

utilization of generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries, within the authorities granted by statute. HHS is prohibited by Section 1860D-11(i) of the Social Security Act from interfering in negotiations between drug manufacturers, pharmacies, and prescription drug plan sponsors, and is generally prohibited from requiring a particular formulary or instituting a price structure for the reimbursement of covered Part D drugs. However, HHS conducts a robust review of all Part D plan formularies to ensure appropriate drug coverage for beneficiaries and compliance with Part D requirements. The formulary review that HHS conducts includes the requirement under section 1860D-11(e)(2)(D)(i) of the Act that CMS may only approve a Part D plan if it does not find that the design of the plan and its benefits (including any formulary and tier formulary structure) are likely to substantially discourage enrollment by certain beneficiaries, and it finds that beneficiaries receive clinically appropriate medications in compliance with the cost-sharing structure defined by statute. In addition, any analysis of the current rebate structure will not be reflective of future Part D benefit design, due to impending changes to the Part D program, as required under the Inflation Reduction Act.

5) **My bipartisan legislation, H.R. 2880, seeks to delink fees paid to PBMs from the cost of the drug to ensure we eliminate incentives for higher-price options. One such area where greater attention can be paid is the role of biosimilars, particularly now that the first wave of Part D biosimilars is on the market for chronic diseases through Humira competition. The HHS Secretary has previously directed CMS to investigate how biosimilar adoption could be approved to save patients and the system billions of dollars.**

   a. **Knowing HHS and CMS have taken this perspective, how can delinking improve adoption of these critical therapies and how will CMS approach it?**

6) **Knowing Medicare enrollees have limited access to these biosimilars due to misaligned formulary incentives, how would CMS utilize these provisions to advance benefits to patients?**

7) **What is CMS doing to ensure this marketplace can support biosimilar adoption, given difficult market conditions from PBMs, and reduce PBM incentives around high-cost drugs?**

Answers 5-7:
HHS is committed to encouraging the use of biosimilar biological products within the Secretary's scope of authority in order to reduce costs to both beneficiaries and the federal government. CMS reviews Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular population of beneficiaries. CMS reviews plan formularies for appropriate inclusion of all drug classes to ensure Part D sponsors' benefit structures meet statutory and regulatory requirements for the program.

HHS will continue using its authority where possible to seek to promote competition, support increased utilization of biosimilar and generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries.

Finally, while certain formulary changes are subject to CMS approval and 30 days' advance notice to affected beneficiaries, current regulations permit Part D sponsors to immediately remove from the formulary a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting these requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place and do not need to provide a transition supply of the substituted drug. Consistent with these requirements, the CY 2024 Medicare Advantage and Part D proposed rule included a proposal to permit Part D sponsors to immediately substitute: (1) a new interchangeable biological product for its corresponding reference product; (2) a new unbranded biological product for its corresponding brand name biological product; and (3) a new authorized generic for its corresponding brand name equivalent. CMS continues to consider comments received on this proposal.

The Honorable Mariannette Miller-Meeks

1) **At the September 19 Energy and Commerce Committee hearing, a number of our committee members expressed their interest in and support for H.R.4818 - The Treat and Reduce Obesity Act. I asked if you could detail any plans CMS has to update 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.**

   In your response to my question about CMS's ability to allow Part D plans to cover obesity medications, CMS reiterated that the statute prohibits coverage for obesity medications. I disagree and believe CMS' view is outdated and ignores the science of obesity as a disease, which the American Medical Association and other medical and scientific bodies have determined. Interpreting the prohibition on *weight-loss drugs* from over 20 years ago as the rationale for denying seniors access to a new class of *FDA-approved* safe and effective *anti-obesity medications* is unacceptable. Modern anti-obesity medications are not weight-loss drugs. They were approved based on 2007 FDA guidance that directs manufacturers of obesity medications to demonstrate improvement in clinical markers of obesity beyond weight and are referenced in clinical guidelines for the treatment of obesity as a critical component of the standard of care.

   Furthermore, CMS's own actions prove that they have the statutory authority to cover anti-obesity medication despite the exclusion of coverage of drugs for weight loss in the Medicare statute. The same Medicare statute included a prohibition on agents for weight gain, which CMS reinterpreted to permit Part D coverage of drugs used to treat AIDS wasting and cachexia. Clearly, CMS can and should reinterpret the statute to cover medications to treat the chronic disease of obesity.

a. Do you commit to analyzing the statute and your statutory authority to cover anti-obesity medications to ensure that Medicare beneficiaries with obesity have access to all effective treatments?

Answer:
We recognize the devastating impact obesity is having on the health outcomes of Americans broadly and, in particular, the disproportionate toll it has taken on communities of color. It is a priority of the Biden-Harris Administration to identify and address health inequities and improve patient outcomes across all of our programs. As detailed by the White House National Strategy of Hunger, Nutrition, and Health, the Administration set a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases— while reducing related health disparities. Integrating nutrition and health can optimize Americans' well-being and reduce healthcare costs.

Medicare covers specific services that aim to address obesity. For example, obesity screenings, intensive obesity behavioral therapy, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases. However, only a limited number of Medicare beneficiaries seek nutrition and obesity counseling services covered by Medicare. The President's FY 2024 Budget would increase access to nutrition counseling and obesity counseling in Medicare, to better prevent, manage, and treat diet-related diseases, by covering additional beneficiaries and making additional providers eligible to furnish these services.
We will continue to work toward providing equitable access to covered services and drugs to treat individuals with obesity and other diseases and conditions, consistent with statutory authority.

2) **There are approximately 6.5 million Americans currently living with Alzheimer's Disease, and nearly half of those Alzheimer's patients suffer from agitation. This number is expected to double by 2050. CMS must evolve the treatment paradigm in order to bring new, effective, and safe therapies for patients suffering from the symptoms of Alzheimer's Disease to reduce the burden on healthcare professionals and the system at large treating patients. As the FDA approves additional treatments to address symptoms of Alzheimer's Disease, such as agitation, we know patients, particularly those in settings of care like skilled nursing facilities or nursing homes often lack access due outdated regulations by CMS.**

a. **How can the agency ensure patients can receive timely access to these innovative new therapies?**

Answer:
The Centers for Medicare & Medicaid Services (CMS) and our partners have continuously worked to enhance the quality of life for people living with dementia, protect them from substandard care, promote goal-directed, person-centered care for every nursing home resident, and increase the use of non-pharmacologic approaches and person-centered dementia care practices. Through the efforts of the National Partnership

to Improve Dementia Care in Nursing Homes, which was launched in 2012, we've significantly reduced the use of antipsychotic medications when not clinically indicated. The National Partnership has a mission to deliver health care that is person-centered, comprehensive and interdisciplinary with a specific focus on protecting residents from being prescribed antipsychotic medications unless there is a valid, clinical indication and a systematic process to evaluate each individual's need. CMS promotes a multidimensional approach that includes; research, partnerships and state-based coalitions, revised surveyor guidance, training for providers and surveyors and public reporting.

The Honorable Dan Crenshaw

1) **With the new Part D rebate, we have to think about the impact it will have on varying products. What steps has CMS taken to ensure that these new cost-sharing burdens will not disrupt therapeutics with unique timeframes -- plasma-derived therapeutics in particular?**

2) **Has CMS considered providing a phased-in approach to the Medicare Part D catastrophic coverage rebate akin to what was provided for small biotech and other groups?**

Answers 1-2:
Beginning in 2025, the IRA eliminates the coverage gap benefit phase, introduces manufacturer discounts in the initial and catastrophic coverage phases, changes enrollee and plan liability in the initial coverage phase, and changes plan and government reinsurance liability in the catastrophic phase. Under the Medicare Part D Manufacturer Discount Program (Discount Program), participating manufacturers will be required to provide discounts on their applicable drugs both in the initial and catastrophic coverage phases of the Part D benefit. There is no manufacturer discount provided during the deductible phase. Because the administrative requirements of the Discount Program largely mirror those for the Coverage Gap Discount Program, CMS intends to implement the program in a similar manner, with some operational enhancements based on stakeholder feedback and extensive program experience.

Under the Discount Program, the IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022 during a multi-year phase-in period, which concludes by 2031. Under section 1860D-14C(g)(4) of the Act, there are two such phase-ins: one for certain applicable drugs of specified manufacturers dispensed to LIS beneficiaries and one for certain applicable drugs of specified small manufacturers dispensed to applicable beneficiaries. The IRA does not provide for a phase-in of manufacturer discounts in other cases. CMS intends to continue to implement the Discount Program consistent with statute.

3) **As CMS knows, the nation is experiencing a wide-spread shortage of neurologists and other specialists who treat Alzheimer's disease. Unfortunately, CMS has not provided any guidance thus far on how infusion centers, who will accept financial responsibility for taking title to approved medicines in this class, will be reimbursed when the responsibility to submit information to the nationwide portal lies with a third party- the treating physician.**

    a. **Can CMS please provide more clarity and guidance to ensure that infusion centers will be properly reimbursed for approved therapeutics in this class when they do not have direct responsibility for interacting with the nationwide portal?**

    Answer:
    Consistent with the National Coverage Determination, Medicare will cover and pay for drugs in the class of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease with traditional FDA approval when a physician and clinical team participates in the collection of evidence about how these drugs work in the real world, also known as a registry. To obtain coverage, the provider participates in a data submission effort, commonly referred to as a registry, to further evaluate whether the drug is reasonable and necessary in the Medicare population.

    The Medicare Administrative Contractors have issued instructions to providers on how to bill for these drugs. An example of these instructions can be found at: https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00278911

4) **During the national coverage analysis (NCA) process and even once the amyloid therapeutic national coverage determination (NCD) was finalized in April 2022, CMS repeatedly told patients, physicians, advocates, and Congress that the agency would reconsider the amyloid therapeutic NCD when new phase three data demonstrating clinical benefit became available. To date, we have seen compelling, phase 3 data for lecanemab, the first traditionally approved amyloid-targeting therapy in the class; and most recently for donanemab, which was presented at the Alzheimer's Association International Conference on July 17. Together, the results of these two phase three studies should be more than sufficient to meet the "high level of evidence" criteria set forth by CMS regarding reconsideration.**

    a. **When will CMS open the reconsideration process to ensure that patient have coverage – without barriers – for this class of treatments upon FDA approval?**

    Answer:
    We recognize that these medications are a unique, new class of drugs, and patients are currently accessing these drugs under the current coverage framework while we continue to gather evidence on how the treatments work in the Medicare population. CMS and the Food and Drug Administration (FDA) have different responsibilities and authorities

under their respective statutes. FDA makes approval decisions based on whether the drug is safe and effective for the indicated use. Under the current NCD, when FDA approves a drug in this class based on a direct measure of clinical benefit, CMS provides coverage of the drug for people with Medicare in CMS-approved studies, including studies that use a registry. For the CMS-facilitated registry that was approved on July 6, 2023, the data submission portal is an easy-to-use format. Clinicians furnishing this drug will have already gathered this information as part of routine clinical assessment and follow-up care for patients with mild cognitive impairment or mild Alzheimer's disease dementia who are being evaluated for or treated with these medications.

5) **In recent guidance CMS provided to treating physicians, CMS stated that physicians will "get the usual Medicare payment and cost-sharing to administer Leqembi…For dates of service beginning July 6, 2023, Medicare will pay for Leqembi when you submit a valid claim and information to help answer treatments questions in a qualifying study." As CMS knows, the approved medicines in this class are physician-administered drugs. Physicians who choose to administer these drugs in their offices to patients must therefore take financial responsibility for procuring these types of medications.**

    a. **Given the financial risk physicians assume when administering infused therapies, can CMS guarantee that physicians will be reimbursed if they make a good faith effort to submit a valid claim and enter information into the portal? For example, will a data entry error in the nationwide portal or missing information in the portal prevent a physician from receiving reimbursement?**

    Answer:
    Consistent with the NCD, Medicare will cover and pay for drugs in the class of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease with traditional FDA approval. Registries are common tools in clinical settings that have successfully gathered information on patient outcomes for decades. In facilitating the development of this registry, CMS is carefully balancing the need to collect information while keeping the registry as easy to use as possible. The required elements may already be available to the clinician from the patient's medical record. Data entry errors may be handled by CMS on a case-by-case basis.

6) **Similarly, Alzheimer's disease imaging, including positron emission tomography (PET) scans, is often conducted in independent imaging centers that bear financial responsibility for obtaining imaging agents. Access to amyloid PET scans will be critical to identifying the appropriate patients for approved medicines in the class.**

    a. **Can CMS please provide similar guidance to independent imaging centers, who will also be reliant on the treating physician's interactions with the nationwide**

portal in order to receive reimbursement for Alzheimer's disease imaging agents?

Answer:
In July 2023, CMS issued a proposal to remove the national coverage determination (NCD) at § 220.6.20, which provided Medicare coverage for one Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease scan per patient through coverage with evidence development (CED). If finalized, this proposal would end the NCD, which would remove the coverage limit of one scan per patient and would instead permit Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors (MACs) at a local level or on a claim-by-claim basis. CMS is committed to working within the confines of the law to provide beneficiaries with comprehensive access to the health services they need, and we look forward to working with you on this issue.

7) **There has been just one comprehensive study examining the outcomes of Coverage with Evidence Development (CED) in the United States, which linked CED studies with published trial and registry results. This study revealed significant variability in CED requirements and study durations, with limited utilization of results in making final coverage decisions. Out of the 26 CEDs, a surprising 3 of them had no data collection at all, and only 62% of studies that did collect data published their results. In just 3 instances, data collection requirements were formally completed.**

   a. **Will you commit to clarifying CED requirements and sticking to them, with the goal of making CED more attractive for innovators?**
   b. **How is CMS thinking about the application/ use of coverage with evidence development (CED) requirement for devices with robust pre-market clinical programs?**
   c. **Would CMS consider waiving this requirement for devices with strong pre-market clinical evidence?**

   Answer:
   CMS strives to improve patient care and innovation while maintaining robust safeguards for the Medicare population. As part of our further efforts to streamline the national coverage process, on June 22, 2023, CMS announced a proposed procedural notice outlining a new Medicare coverage pathway, the Transitional Coverage for Emerging Technologies (TCET) pathway for Breakthrough Devices. This pathway is intended to offer more timely and predictable access to new medical technologies for people with Medicare (88 FR 41633). In addition to the proposed TCET procedural notice, CMS issued an updated proposed Coverage with Evidence Development (CED) guidance document and a proposed Evidence Review guidance document. CMS also issued the first in a series of guidance documents that outline our current thinking on health outcomes within priority therapeutic areas. These documents offer insight into how CMS reviews clinical evidence and transparency regarding CED. We sought comments from

stakeholders on the proposed TCET procedural notice and the proposed guidance documents. The public comment periods for these documents closed in late-August. We are currently reviewing the comments and will respond to them when we finalize the documents.

The Honorable Anna Eshoo

1) **I have heard concerns from stakeholders about a draft proposed rule published by the Nuclear Regulatory Commission (NRC). The proposed rule acknowledges the misadministration of radiopharmaceuticals can result in radiation injury.**

   a. **What protections are in place for patients when misadministration of radiopharmaceuticals occur?**

   Answer:
   Hospitals participating in Medicare must meet health and safety requirements in the Medicare Conditions for Participation (CoPs). The Medicare CoPs for hospitals at 42 C.F.R. § 482.53 states that if a hospital "provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice." Additionally, CMS's guidance to state surveyors who review hospitals' compliance with the CoPs directs surveyors to review a hospital's written policies about the use of radioactive materials, which must be based on acceptable standards of practice as defined by Federal and State law and regulations as well as recommendations promoted by nationally recognized professional organizations. The guidance also notes that "nuclear medicine services must be integrated into [the hospital's] hospital-wide Quality Assessment and Performance Improvement (QAPI) program," which require the hospital to "monitor the quality and safety of nuclear medicine services" and "track medical errors and adverse events related to nuclear medicine services." In addition to these protections, Medicare beneficiaries are entitled to submit complaints about the quality of the care they receive from providers to state survey agencies and hospital accrediting organizations.

The Honorable Annie Kuster

1) **I know you agree that obesity is a severe chronic disease with multiple comorbidities that have significant health consequences for patients. FDA has approved treatments for obesity that have been shown to induce beneficial health outcomes distinct from weight loss, but access for Medicare beneficiaries is limited due to the current CMS legal interpretation of the statutory exclusion for weight loss agents, based on an antiquated analysis.**

   a. **Given the significant advancement in the clinical understanding of obesity as a chronic and treatable disease, could there be a distinction between "weight loss"**

drugs from drugs or biologicals that are approved by the FDA to treat the chronic disease of obesity?

Answer:
We recognize the devastating impact obesity is having on the health outcomes of Americans broadly and, in particular, the disproportionate toll it has taken on communities of color. It is a priority of the Biden-Harris Administration to identify and address health inequities and improve patient outcomes across all of our programs. As detailed by the White House National Strategy of Hunger, Nutrition, and Health, the Administration set a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases— while reducing related health disparities. Integrating nutrition and health can optimize Americans' well-being and reduce healthcare costs.

Medicare covers specific services that aim to address obesity. For example, obesity screenings, intensive obesity behavioral therapy, bariatric surgical procedures, and diabetes screenings and participation in a diabetes prevention program are covered under Medicare in certain cases. However, only a limited number of Medicare beneficiaries seek nutrition and obesity counseling services covered by Medicare. The President's FY 2024 Budget would increase access to nutrition counseling and obesity counseling in Medicare, to better prevent, manage, and treat diet-related diseases, by covering additional beneficiaries and making additional providers eligible to furnish these services. We will continue to work toward providing equitable access to covered services and drugs to treat individuals with obesity and other diseases and conditions, consistent with statutory authority.

The Honorable Nanette Barragan

1) **Alzheimer's disease patients and their families and caregivers face numerous challenges navigating this devastating disease. They deserve to have access to the best care possible, and all of the information necessary to make an informed decision about treatment options, including Leqembi. It is my understanding that Leqembi has an FDA "black box" warning about a potentially serious, genetically-based risk for certain patients, but Medicare does not provide coverage for genetic counselor services. This creates disparities in access to genetic counseling services, and can lead to inaccurate readings of genetic tests that can endanger patients and create additional costs for our healthcare system.**

    a. **Has CMS investigated if Medicare coverage of genetic counseling services would help patients and their providers understand and assess the benefits of taking prescriptions such as Leqembi, and protect patients from potentially harmful side effects?**

    Answer:
    Medicare covers certain types of FDA-approved diagnostic genetic tests for certain cancers and inherited diseases when medically necessary. In addition, physicians and non-physician practitioners who may independently bill Medicare for their services and who are counseling individuals would generally report office or other outpatient evaluation and management CPT codes for office visits that involve significant

counseling, including genetic counseling.

Additionally, screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit under the statute and are not covered.

The Honorable Angie Craig

1) **As of October 1st, the authorizations for critical navigator programs that enable our nation's most vulnerable Medicare beneficiaries to be connected to coverage have expired. These are programs that, over the past 15 years, have been extended 11 times with bipartisan support.**

   We had the opportunity to include a bill that would make these programs permanent in this hearing. But instead of encouraging an open dialogue on the issue, Republicans decided to exclude it from the noticed list of bills.

   I have some questions about what will happen now that we have let the authorizations for these authorizations lapse.

   a. **Dr. Hughes, can you comment on the impacts of Medicare's Part D low-income subsidy (LIS) program?**

   b. **How about Medicare Savings Programs (MSPs)?**

   c. **How many beneficiaries do you estimate have been connected to these programs through the federal government's outreach and enrollment efforts?**

   d. **What do you expect to see now that these program authorizations have expired?**

   Answer:
   We share your concern about the lapse in authorization for the critical grants funded under the Medicare Improvements for Patients and Providers Act (MIPPA) (42 U.S.C. 1395b-3 note).

   As you know, the MIPPA program helps Medicare beneficiaries with limited income and assets learn about programs that may save them money on their Medicare costs, including MSP and LIS. Through MIPPA, the Administration for Community Living (ACL) provides grants to states and tribes to support targeted outreach and education to eligible Medicare beneficiaries, especially those who are:

   - Low-income with limited resources
   - Residents of rural areas
   - Members of American Indian, Alaskan Native, and Native Hawaiian communities
   - People with disabilities under age 65
   - Speakers of English as a secondary language

ACL's MIPPA grants to grantees are made in three ACL programs: State Health Insurance Assistance Programs (SHIP), Area Agencies on Aging (AAA), and Aging and Disability Resource Centers/No Wrong Door Systems (ADRC/NWD). They also provide grants to tribes and tribal organizations.

In Grant Year 2022 (September 2022 – August 2023) the MIPPA state grantees:

- Educated 1.2 million beneficiaries through 19,000 outreach events,
- Conducted over 960,000 one-on-one contacts with Medicare beneficiaries, their families, and caregivers,
- Helped over 68,000 beneficiaries apply for the Medicare Savings Programs and Extra Help (LIS); and
- Educated over 122,000 beneficiaries on Medicare preventive services.

In the event of a lapse in authorization, ACL will wind down the program. Without action by Congress, millions will lose access to this important service. Assisting low-income beneficiaries to receive these extra benefits enables them to spend extra dollars at local pharmacies, grocery stores, for home maintenance, and other non-health related needs which has a multiplier effect on the economy and their communities. An estimated three million older adults and people with disabilities could benefit from LIS but are not currently enrolled. Maintaining funding for outreach to this population is particularly important given the expanded eligibility for full LIS that starts in 2024. If the MIPPA program funding is not extended the networks supported with this funding will be forced to reduce their outreach and education efforts which will negatively impact the communities that they serve.