American Diabetes Association.
Connected for Life

United States House of Representatives Request for Information: *Medicare Access and CHIP Reauthorization Act (MACRA)*

Response from the American Diabetes Association

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Submitted electronically to macra.rfi@mail.house.gov

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Introduction and Background

The American Diabetes Association (ADA) appreciates the opportunity to provide input to Congress on its the request for information (RFI) regarding the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and associated payment mechanisms. Congress is requesting feedback on potential actions it can take to stabilize the Medicare payment system, without making dramatic spending increases, while also ensuring that successful value-based care incentives are in place. Congress seeks information in the following areas:

- The effectiveness of MACRA;
- Regulatory, statutory, and implementation barriers that need to be addressed for MACRA to fulfill its purpose of increasing value in the U.S. health care system;
- How to increase provider participation in value-based payment models; and
- Recommendations to improve Merit-Based Incentive Payment System (MIPS) Advanced Alternative Payment Models.

About ADA

The ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 133 million individuals living with diabetes and prediabetes, and has more than 500,000 general members, 15,000 health professional members, and more than one million volunteers. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes[1] and publishes the most influential professional journals concerning diabetes research and treatment.[2]

More people in the U.S. have diabetes today than ever have before – and prevalence rates continue to rise. In the last 20 years, the number of American adults diagnosed with diabetes has more than doubled.[3] Nearly 50 percent of the U.S. population, or more than 133 million Americans, live with diabetes and

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2022, Diabetes Care 45: Supp. 1 (January 2022).
[2] The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes
[3] U.S. Centers for Disease Control and Prevention, "Diabetes Quick Facts," September 30, 2022, https://www.cdc.gov/diabetes/basics/quick-facts.html.

prediabetes today.[4] Rates of underlying chronic disease, many of which stem from and are related to diabetes, mirror this trend – six in 10 U.S. adults now have at least one chronic disease, and four in 10 have two or more.[5] Chronic diseases are the leading cause of death and disability in America today, and result in $4.6 trillion in health care expenses annually.[6]

The burden of these rising diabetes rates falls disproportionately on low-income communities, historically underserved Americans, and people of color. Diabetes prevalence today among minority groups is nearly twice as high as it is for white Americans.[7] Much of this is because the social, economic, and environmental factors that put people at a higher risk for developing diabetes are especially pervasive in America's communities of color. Zip code, educational opportunity, and socioeconomic status often dictate how far someone lives from the nearest grocery store, whether they have access to healthy foods, and whether they have quality health care nearby, putting needed resources out of reach for many of those among us who need them most.

While the COVID-19 pandemic shined a needed spotlight on these issues, it is imperative that we strive to make the United States an equitable place for all – irrespective of race, income, zip code, age, education, gender, or health status – both through the end of this pandemic and beyond. To address this system-wide problem, we must look toward system-wide solutions. To generate this type of structural change, we need to look further upstream and address the cause of these problems rather than just the symptoms.

For those reasons, the ADA launched its Health Equity Now campaign in 2020 and published the Health Equity Bill of Rights, a set of principles guiding the ADA's ongoing efforts to confront, through policy and programmatic action, the systemic barriers to health and health care that persist in our country today.[8]

Through this work, we aim to ensure that no person with diabetes or prediabetes, regardless of where they are from, or what they look like, lacks the resources they need to stay safe and healthy – a bare necessity that has remained out of reach for far too many for far too long.

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[4] Centers for Disease Control and Prevention. National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/data/statistics-report/index.html.
[5] U.S. Centers for Disease Control and Prevention, "Chronic Diseases in America," https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm.
[6] Hugh Waters and Marlon Graf, *The Cost of Chronic Disease in the U.S.*, The Milken Institute, August 2018, https://milkeninstitute.org/sites/default/files/reports-pdf/ChronicDiseases-HighRes-FINAL_2.pdf.
[7] American Diabetes Association, "Statistics About Diabetes."
[8] American Diabetes Association, "#HealthEquityNow," https://www.diabetes.org/healthequitynow ; American Diabetes Association, "Health Equity Bill of Rights," https://www.diabetes.org/sites/default/files/2020-08/Health%20Equity%20Bill_2nd_v2.pdf.

The right to avoid preventable amputations is a centerpiece of the ADA's Health Equity Now campaign.[9] In September 2022, the ADA launched the Amputation Prevention Alliance (Alliance), its latest initiative to tackle health inequities in our community. The Alliance seeks to reduce the tens of thousands of unnecessary, diabetes-related amputations that take place every year and make amputations a last-resort option for Americans. Unfortunately, amputations are on the rise in the United States. In 2018, a total of 8.25 million hospital discharges were reported with diabetes, which included 154,000 for a lower-extremity amputation – a 75% increase in just a decade;[10] and even worse, rates of amputations are significantly higher among minority communities.[11] Black Americans are four times more likely to have an amputation than a non-Hispanic white American. LatinX communities are 50 percent more likely to have an amputation and Indigenous communities face amputations rates that are two times higher than those among non-Hispanic white Americans.[12]

An amputation significantly reduces a person's quality of life, and an individual who has had an amputation has a worse chance of five-year survival than someone with coronary artery disease, breast cancer, and colorectal cancer.[13]

Every American with diabetes should have access to the care they need to prevent diabetes-related amputations, as well as high quality care should they develop a diabetic foot ulcer, peripheral artery disease (PAD), neuropathy, or critical limb ischemia (CLI). Our mission is to disrupt the curve of amputations among low-income and minority individuals with diabetes. This begins with policy change at multiple levels, including finding new ways to ensure broad access to high quality health insurance coverage, inclusion of quality measures within the Medicare program, and how MACRA intersects with both of those issues, among others.

Please consider our high-level recommendations below.

Consider aligning meaningful quality measures

The Centers for Medicare & Medicaid Services (CMS) included an RFI on the development of quality measures within the Merit-based Incentive Payment System (MIPS) that address amputation avoidance, in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Proposed Rule (CMS-1770-P). The ADA's

[9] American Diabetes Association, "American Diabetes Association Unveils Amputation Prevention Alliance to Address the Diabetes-Related Amputation Pandemic ", September 22, 2022, https://diabetes.org/newsroom/press-releases/2022/ADA-unveils-amputation-prevention-alliance-to-address-diabetes-related-amputation-pandemic.
[10] https://www.cdc.gov/diabetes/data/statistics-report/coexisting-conditions-complications.html
[11] Centers for Disease Control and Prevention, National Diabetes Statistics Report, 2020. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
[12] Holman, Kerianne; Henke, Peter; Dimick, Justin; Birkmeyer, John: "Racial Disparities in the Use of Revascularization Before Leg Amputation in Medicare Patients," Journal of Vascular Medicine; August 2011: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152619/
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092527/

comment letter on the subject[14] highlights how the current 2022 MIPS includes only two foot-care related measures:

1. **Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation (National Quality Forum (NQF) number: 0417):** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.

2. **Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (NQF number: 416):** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.

However, as we discuss in our response, these measures alone do not encompass all aspects of the amputation prevention continuum. Distinct quality measures need to track diabetic foot ulcer prevalence, prevention, evaluation and potential specialty referral, and follow-up. Diabetes is the most expensive chronic disease in the United States, and 61% of diabetes costs come from Americans 65 years or older, the Medicare population.[15] Yet, currently, there are no quality measures that evaluate quality of life for people with diabetes or people living with diabetes-related amputations.

Diabetes care and amputation prevention involve a team-based approach, and patients often see any number of providers, including general practitioners, podiatrists, physician assistants, community health workers, endocrinologists, interventional cardiologists, and vascular surgeons. The overarching goal of quality measures should ensure that amputations occur only as a last resort.

We encourage Congress to work with the ADA and other stakeholders to understand the unique challenges for people living with diabetes and with diabetes-related amputations. Quality measures alone may not evaluate if there are improvements in patient health outcomes.

Lack of consistent data alignment across payers often dissuades value-based care participation

Alternative Payment Models (APMs) vary in payment structure, incentives, and financial risks. Value-based care rewards quality, but demonstrating improved health outcomes rely on data, technology infrastructure, workforce and workflow improvements, and processes for accurate reporting. Despite value-based care efforts, even providers participating in APMs must report different measures to

[14] https://www.regulations.gov/comment/CMS-2022-0113-23580
[15] American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018; 41:917–928.

various systems, creating additional burdens for an already over-burdened population of providers.

For example, providers must report and provide different outcomes to private payers for Medicare fee-for-service beneficiaries in states with managed care organizations. However, physician practices and providers often do not receive claims data in a timely fashion, or in a digestible manner, yet are expected to operate in both an alternative payment and a fee-for-service world. Requiring providers to report different quality measures to multiple sources, burdens an already taxed workforce even more. It is especially difficult for smaller provider practices, rural providers, and safety-net providers to participate in APMs, as they may not have the additional administrative staff or the technological infrastructure built into their operations to stay in regulatory compliance, which may change annually. Further, any incentive payments that physicians may receive, may still not cover general costs, particularly as practices face inflation, making this an unlikely opportunity for investment. Many practices continue in a loop where any savings generated goes to focus on caring for illness in their patient population. In turn, many providers are unable to invest savings into system-wide wellness, preventive practices, and upstream value-based strategies.

The ADA urges Congress to work with CMS on its Meaningful Measures Initiative,[16] which aims to streamline quality measurement across payers, as well as with the Office of the National Coordinator for Health Information Technology (ONC) to promote interoperability.

Alternative Payment Models currently focus on select groups of beneficiaries

To date, most CMS Innovation models, and Accountable Care Organizations have focused on Medicare beneficiaries. Congress must consider innovative ways to improve the care for all patients, especially Medicaid and dual-eligible beneficiaries. Medicaid payment varies by state, and often has lower payment rates than Medicare. A recent *Health Affairs* article demonstrates how dual-eligible beneficiaries often serve as a proxy for patients most at risk of poor health outcomes, yet providers are often paid less to treat such patients.[17]

Again, this ties back to barriers to provider participation in value-based care. This divide of basic reimbursement often discourages providers from accepting patients who do not have private health insurance. Yet Medicaid and Dual-eligible patients often have higher risk factors, and thus need proper screening

[16] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy
[17] Payment Policy And the Challenges of Medicare And Medicaid Integration For Dual-Eligible Beneficiaries, " Health Affairs Health Policy Brief, October 20, 2022. DOI: https://www.healthaffairs.org/do/10.1377/hpb20220923.93608/full/.

for Health-Related Social Needs (HRSNs) as well as proper care management, follow up, and resources. Congress should support a healthcare team-based approach to address HRSNs. For example, a healthcare team can support patients with food insecurity or transportation issues, which can ultimately improve patient health outcomes for diabetes, amputation prevention, and other chronic diseases.

Center health equity in Medicare and Medicaid policies to reduce barriers to enrollment, coverage, and access

Despite wanting to "do no harm," policies and reimbursement rates often prevent providers from delivering the best care to their patients. Repeatedly, the ADA hears about access to patient care due to punitive reimbursement and coverage policies, or prior authorization barriers. Anecdotally, we have heard some providers say that a diabetes-related amputation is the most "cost-effective" measure for reimbursement, yet the patient, their family, and friends experience the significant toll of mental, physical, and emotional stress.

Amputation prevention begins with screening interventions. Minimally invasive procedures are now available for at-risk patients that can help improve blood flow and ultimately save limbs and lives. Additionally, most amputations are preceded by a Diabetic Foot Ulcer (DFU), which with the application of new evidence-based therapeutics can in many cases be healed. But the reality is that these procedures are not covered widely enough by government insurance programs, severely restricting their potential benefit.

We urge Congress to also consider our comments[18] to the United States Office of Management and Budget (OMB), Request for Information: *Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government* (Document No. OMB-2021-0005), which covers the following issues:

Prescription drug prices and devices reform

- Need for rebate reform
- Ensuring patients benefit from 340B discounts
- Curtailing drug prices

We applaud the administration's work on the Inflation Reduction Act of 2022, especially the insulin co-pay cap provisions in the Medicare program, and the recent Executive Order for lowering prescription drug costs for Americans.[19]

[18] https://www.regulations.gov/comment/OMB-2021-0005-0381
[19] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/

Proper and financially stable reimbursement rates and flexible waivers for Medicaid and Medicare

Included in ADA's comments to OMB and our comments[20] to CMS' CY 2022 PFS Proposed Rule, ADA advocates for the following flexibilities:

- Appropriate physician reimbursement rates
- Appropriate reimbursement rates for revascularization procedures, particularly for those occurring in labs
- Coverage of earlier interventions and screenings for PAD and CLI
- Ensure people with diabetes can access appropriate, routine podiatric services

Partner with CMS and key stakeholders after payment regulations are finalized and RFI comments on CMS quality measures are reviewed

We additionally look forward to working with Congress and CMS once the comment period closes on November 4, 2022, for CMS' RFI entitled: "*Make Your Voice Heard: Promoting Efficiency and Equity Within CMS Programs,"*[21] as many of the questions in that RFI focus on potential opportunities for policy improvement, provider experiences, provider and patient burdens, and strategies to address health inequities. We encourage Congress to work with CMS on what it gleans from the responses to that RFI, as it may provide additional insights into this important work.

Further, once the CY 2023 PFS proposed rule is finalized, the ADA is committed to serving as a resource to Congress and with other stakeholders on the issues described above. We are interested in providing proper feedback on issues related to MACRA once we understand the regulatory requirements and changes to the Medicare Shared Savings Program, telehealth services, the Quality Payment Program, basic physician reimbursement rates, and other factors.

Conclusion

The American Diabetes Association appreciates the opportunity to provide information on ways to improve MACRA, and we look forward to having further conversations to look for ways to improve health outcomes, particularly for those with diabetes. Should you have any questions or seek additional information regarding these comments, please reach out to Laura Friedman, Vice President, Regulatory Affairs at: lfriedman@diabetes.org.

[20] https://www.regulations.gov/comment/CMS-2021-0119-34638
[21] https://cmsgov.secure.force.com/forms/resource/1662492311000/OBRHI_GIAG