

United States Senate

WASHINGTON, DC 20510

June 10, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Promoting Innovation and Access to Algorithm-Based Health Care Services

Dear Administrator Brooks-LaSure,

We write about the need to promote innovation of and protect Medicare beneficiaries' access to algorithm-based health care services (ABHS) with uniform payment standards. We urge the Centers for Medicare & Medicaid Services (CMS) to consider policies and processes that will create predictability for ABHS in the upcoming Hospital Outpatient Prospective Payment System (HOPPS) rulemaking cycle.

ABHS are medical devices cleared by the Food and Drug Administration (FDA) that rely on artificial intelligence (AI), machine learning (ML), or other similar software to produce quantitative and/or qualitative clinical information to aid in the diagnosis or treatment of a patient's condition that cannot be otherwise obtained by their health care provider. ABHS can improve care delivery by providing clinicians with new or additional information about a patient's specific clinical presentation. For example, ABHS can identify and quantify cancer, assess signs of liver disease, and measure the caliber of coronary arteries via medical technology not otherwise available to health care providers. The devices will improve patient outcomes,¹ and some ABHS are now part of the standard of care for certain conditions.²

Despite the established value ABHS provides, we understand that CMS has not formalized a reimbursement pathway for ABHS. As a result, manufacturers face an uncertain regulatory landscape and providers must balance the benefit of ABHS against unpredictable payment policies. Together, these issues present challenges to deploying innovative, clinically significant services, especially in rural and underserved communities. We understand that CMS currently provides separate payment for a limited number of ABHS and does so on a case-by-case basis. This is in sharp contrast to the nearly 700 FDA approved or cleared AI/ML medical devices. With an increase in innovation in the AI space, CMS should adopt a uniform payment policy to increase efficiency. Without a consistent and stable payment pathway in the Medicare program,

¹ See, e.g., Julia Karady, et. al., *Cost-effectiveness Analysis of Anatomic vs Functional Index Testing in Patients With Low-Risk Stable Chest Pain*, JAMA Network Open (Dec. 14, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774097>; Miguel Areia, et. al., *Cost-effectiveness of artificial intelligence for screening colonoscopy: a modelling study*, 4 The Lancet Digital Health 436 (2022).

² See Martha Gulati, et. al., *2021 Guidelines for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines*, 144 Circulation 368 (2021).

there is an inherent barrier to adopt ABHS, which prevents beneficiaries from accessing these innovative services.

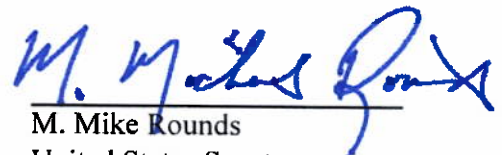
To ensure future innovation and to protect access to ABHS for Medicare beneficiaries, we urge CMS to develop a formalized payment pathway for ABHS. We urge CMS to codify in regulation its existing Software-as-a-Service (SaaS) payment policy that the agency articulated in the calendar year 2023 Medicare HOPPS Final Rule³ to provide stability and certainty moving forward. Furthermore, CMS should consider modifying both the New Technology Ambulatory Payment Classification (APC) application requirements and corresponding annual payment policies to ensure they are tailored to the unique aspects of ABHS. We understand that the current New Technology APC application does not appropriately reflect how ABHS may be deployed in hospital outpatient settings, limiting the availability of this pathway for some ABHS. For those ABHS that receive a New Technology APC assignment, there must be sufficient stability such that these services are not inappropriately reassigned to a different New Technology APC. These two impactful steps will lay the groundwork for increased ABHS innovation while protecting access to care for Medicare beneficiaries.

Thank you for your attention to this matter. We look forward to working with you to ensure all Medicare beneficiaries receive access to new and innovative technologies that can improve their health.

Sincerely,



Martin Heinrich
United States Senator



M. Mike Rounds
United States Senator



Marsha Blackburn
United States Senator



Todd Young
United States Senator

³ *Calendar Year 2024 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule*, 87 Fed. Reg. 71748 (Nov. 23, 2022).