May 13, 2024

The Honorable Patty Murray Senate Appropriations Chairwoman U.S. Senate Washington, DC 20510

The Honorable Kay Granger House Appropriations Chairwoman U.S. House of Representatives Washington, DC 20515 The Honorable Susan Collins Senate Appropriations Vice Chair U.S. Senate Washington, DC 20510

The Honorable Rosa DeLauro House Appropriations Ranking Member U.S. House of Representatives Washington, DC 20515

Dear Senators Murray and Collins and Congresswomen Granger and DeLauro:

On behalf of the patients and patient advocates we represent, we are writing to request that you encourage the Centers for Medicare and Medicaid Services (CMS) to publish, via its annual rulemaking process, a formalized payment pathway for Artificial Intelligence (AI) and Machine Learning (ML) in FDA-regulated medical devices, otherwise known as Algorithm-Based Healthcare Services, in the agency's 2025 Hospital Outpatient Prospective Payment Systems rule.

As AI continues to impact various sectors of our lives, its promise to improve patient care is undeniable. In radiology, AI is being used effectively to help doctors and other healthcare professionals swiftly read and interpret images, aid in detecting illness and abnormalities, and analyze information to make a more informed diagnosis. From helping a physician detect polyps in a colonoscopy to prioritizing a scan showing a doctor that a patient needs an emergency intervention, AI in medical imaging benefits patients.

While some FDA cleared or approved AI applications are now part of the standard of care for many conditions, the CMS has only assigned payment for less than ten AI applications compared to the 600 plus AI-enabled medical devices that FDA has approved or cleared.

As physicians look to integrate FDA cleared or approved AI tools into care pathways, it is essential that these technological benefits reach all patients, regardless of their location or socioeconomic status. We cannot afford to exacerbate existing healthcare disparities by restricting access to cutting-edge AI-enabled medical devices only to those who can pay out-of-pocket. However, Medicare can help to address this issue and recognize the value AI brings to patient care by appropriately reimbursing physicians who use FDA cleared or approved AI tools.

We urge you and your colleagues to work with CMS to establish a formalized payment pathway for Al healthcare services. Thank you for your attention to this critical issue and we look forward to working with you to address these concerns and ensure a brighter, healthier future for all Americans.

Sincerely,

Avery's Hope Center for Medicine in the Public Interest Cervivor

Free2Care

Lupus and Allied Diseases Association

One Cancer Place

Patients Rising

Practicing Physicians of America

Retire Safe

Right Scan Right Time

Stronger Than Sarcoidosis

Support for People with Oral Head and Neck Cancer

Survivors for Solutions

SYNGAP1 Foundation

ZERO Prostate Cancer

CC: Members of the Senate Finance Committee, House Energy & Commerce Committee, House Ways & Means Committee, Senate Bipartisan AI Caucus, House Bipartisan AI Task Force