August 28, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3421–NC
Mail Stop C4–26–05
7500 Security Boulevard,
Baltimore, Maryland 21244

RE: Multistakeholder Consensus Comments on CMS' Medicare Transitional Coverage for Emerging Technologies Proposal (CMS–3421–NC; 88 Fed Reg 41633)

The undersigned represent a diverse coalition of stakeholders that span the healthcare and technology sectors that support the responsible use of digital and connected health technologies in healthcare. We appreciate the opportunity to provide consensus input to the Centers for Medicare and Medicaid Services (CMS) on its proposed transitional coverage for emerging technologies (TCET) coverage pathway.[1]

Data and clinical evidence from a variety of use cases continues to demonstrate how the digital and connected health technologies improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, all while reducing costs. Digital health tools offer the potential to fundamentally improve and transform American healthcare, particularly for the Medicare population. Unfortunately, despite the proven benefits of digital health technology to the American healthcare system, a range of statutory and agency-level restrictions inhibit their use. Today, attaining even nominal device coverage takes, on average, nearly 6 years,[2] As a result, digital health innovations are quite underutilized today in Medicare, which ultimately harms patients.

While we support the FDA's Breakthrough Devices Program and the TCET concept, there are steps CMS should take to improve its proposal in order to provide fair and responsible access to the TCET pathway. CMS should, for example, make the TCET pathway more accessible by expanding eligibility to more than seven new devices per year. Further, both devices and diagnostics should be considered equitably for inclusion in TCET, as emerging digital healthcare technologies are under development in both areas, and both are subject to the same criteria and evaluation in the FDA's Breakthrough Device Program.

More broadly, we urge CMS to recognize that most cutting-edge medical technologies today include digital and connected characteristics. In particular, Software as a Medical Device (SaMD) includes Clinical Decision Support, Artificial Intelligence, and mobile medical applications that meet the legal definition of a medical device under the Food, Drug, and Cosmetic Act. However, SaMD generally does not fall within an existing benefit category and accordingly will be excluded from the TCET pathway as proposed, precluding countless Medicare beneficiaries from realizing the improved outcomes and reduced costs they bring.

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[1] 88 Fed Reg 41633.

[2] *JAMA Health Forum*. 2023;4(8):e232260. doi:10.1001/jamahealthforum.2023.2260.

From a coverage standpoint, we agree with CMS' own assessment in its proposed rule that illustrates the disjointed and complex pathways to device coverage in today's regulatory environment. We are supportive of CMS' goal to realize innovation and value in Medicare, which can be accomplished through regulatory changes encouraging the responsible deployment and utilization of digital health technology. In this respect, the proposed TCET pathway should be viewed as an important but incremental step to much-needed modernizations for Medicare coverage, including the harmonization of descriptive terms and the synchronization of associated clinical evidentiary standards for FDA approval, CPT coding, and CMS coverage focused on the clinical meaningfulness of the output from the digital device.

Accordingly, past its TCET pathway, CMS must take much broader steps at the policy level to enable responsible support for digital health products. Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute. For instance CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as software as a medical device (SaMD), are included in existing benefit categories and if so, which category.

We stand ready to work with CMS, FDA, Congress, and others to responsibly advance coverage of digital health technologies that are demonstrated to save lives and reduce costs.

Sincerely,

Accuhealth

Alliance Tele-Med, LLC

AMC Health

American Academy of Neurology

American Telemedicine Association

ATA Action

Biocom California

Cala Life, Inc

CoachCare

College of Healthcare Information Management Executives (CHIME)

Connected Health Initiative

DAYAMED

Digital Therapeutics Alliance

eMedical Sentry

EmPowerYu

Frank Healthcare Advisors, LLC

HealthFlow.io

Hygieia

Medical Society of Northern Virginia

Melius hs LLC

Mend

Nova Insights

Otsuka America Pharmaceutical Inc.

Patient Premier, Inc.

PureTalk.AI

Remote Care Partners

ResMed Corp.

Rimidi

The Omega Concern

Theranica

TJones Consulting LLC

URAC

Validic, Inc.