Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1770-P P.O. Box 8016 Baltimore, Maryland 21244-8016

RE: Multi-stakeholder Comments to the Centers for Medicare and Medicaid Services re: Medicare and Medicaid Programs: Calendar Year 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, Medicare Shared Savings Program Requirements, etc. (CMS-1770-P)

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the expanded use of connected health technologies in healthcare. Evidence demonstrates that digital health improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement (particularly for the chronically ill). These tools, increasingly powered by artificial intelligence (AI), leverage patient-generated health data (PGHD) and span, among others, wireless health products, mobile medical devices, telehealth and preventive services, clinical decision and chronic care management support, and cloud-based solutions.

Digital health technologies are essential in improving the cost-effectiveness of healthcare, both public and private, and increasing access to healthcare in multiple settings. With these objectives in mind we provide our comments on the Medicare Physician Fee Schedule (PFS) Proposed Rule for calendar year (CY) 2023. The need for further changes in the Medicare incentives for provision of digital health is even more imperative considering the continuing COVID-19 crisis in the United States. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient, during the public health emergency (PHE) and after.

We share CMS' priority for reducing the inequities in healthcare. Thanks to CMS' expanded support, reliance on digital health technologies increased in the COVID-19 PHE. Use of these tools continues to allow many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions while also providing routine care to Americans to safely observe public health protocols during the COVID-19 pandemic. CMS should leverage every opportunity for permanent policy changes that will incent responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

We offer the following comments on CMS' draft CY 2023 PFS for consideration:

- Remote Therapeutic Monitoring (RTM): We support CMS' efforts aimed at continuing to support and expand RTM services. The ability to monitor therapeutic data should enable a wide range of medical specialty use cases that rely on medical device data to monitor therapy adherence and therapy response. Medical specialties which can benefit from RTM treatment management services (TMS) include gastrointestinal diseases, endocrinology, cardiology, behavioral therapies, and pain management, among others, in addition to respiratory and musculoskeletal disorders. We recognize that there are lingering issues identified by CMS and stakeholders that need to be addressed and urge for the final rule to take steps to account for the concerns noted below to ensure that the full potential of RTM is met:
 - CMS' must remove parenthetical language under proposed HCPCS G-codes GRTM1, GRTM2, GRTM3, and GRTM4 which reads as follows: "(CPT codes 98975 and 98976 or 98977 must be billed prior to reporting GRTM1 and GRTM2)" and "(At least 16 days of data must be reported)." These requirements would significantly limit the ability for

providers to report such services. Forcing the supply codes to be first billed prior to the service would severely limit RTM-TMS to only exist for muscular-skeletal and respiratory use cases. The parenthetical language is problematic even for musculoskeletal and respiratory because providers have little to no control on whether a patient will achieve 16 days of medical device use as providers conduct treatment management services – under this proposal, if the patient fails to amass 16 days of device usage, the provider cannot bill the work codes. Such a policy change would also prevent providers from appropriately leveraging other Medicare payment systems to support their essential therapeutic care for beneficiaries. Furthermore, despite the addition of cognitive behavioral therapy (CBT) to the CPT code family for RTM/RTM-TMS, these parentheticals do not include CBT. Unless CMS removes the proposed parentheticals, its decision to make CPT codes 98980 and 98981 non-payable under Medicare is likely to have a chilling effect in their use across other markets, including state Medicaid programs and commercial payers.

- CMS should consider a monitoring frequency shorter than 16 days to accommodate use cases where a one-size-fits-all approach is inapplicable We note that the CPT Editorial Panel is currently proposing to create new CPT supply codes for reporting monitoring less than 16 days, as well as to change existing supply codes to cover reporting of 16 days or more.¹
- O We oppose CMS' proposed reduction of payments for RTM (via the proposed a non-Facility PE RVU of 0.24 for both HCPCS G-codes GRTM3 and GRTM4) that will significantly lessen the valuation provided for CPT codes 98980 and 98981, which does not reflect the services provided by a nonphysician provider under GRTM3 and GRTM4 which will not differ. This drastic payment reduction would make uptake of RTM difficult, for physical therapists and occupational therapists in particular. We urge CMS to maintain its existing valuation for RTM reflected in the valuation for RTM CPT codes 98980/98981, to ensure that a strong case exists for practitioners to leverage RTM tools.
- We appreciate that CMS acknowledges the changes to RTM by the CPT Editorial Panel to include CBT as a service under RTM-TMS and the adjoining new supply code 989X6. We look forward to the MAC process and their valuation of this important addition to the RTM family of codes.
- O PHE allowances that have reduced unnecessary barriers to the use of remote physiologic monitoring (RPM) and RTM should be extended as long as possible, such as attaining patient consent at the time of furnishing RPM and RTM services, allowing RPM and RTM to be furnished to patients without an established relationship on a permanent basis; and permitting less than 16 days of data, but no less than two days, during a month for patients with a COVID diagnosis or symptoms suspected of COVID.
- We request that Medicare invest in technical and organizational development to help state Medicaid programs understand these and other HCPCS Level II coding changes to ensure that changes are implemented immediately by state Medicaid programs.
- <u>Virtual Presence/Remote Supervision:</u> CMS must enable greater efficiencies in medical workforce and patient safety by permanently allowing the supervision of professionals through real-time audio/video technology across as many services as possible. We oppose CMS' proposal to discontinue virtual direct supervision at the end of the calendar year in which the PHE ends and urge for permanent support for expanded virtual presence/remote supervision, including for non-face-to-face care management services, remote therapeutic monitoring, and communication technology-based services.
- Medicare Telehealth Services: CMS should continue its expanded support for telehealth services for the duration of the PHE, and beyond the end of the PHE to the maximum extent possible. We support CMS' proposed expansion of the Medicare Telehealth Services list on a permanent basis, CMS' proposal to further expand the Medicare telehealth services list on temporary (Category 3)

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¹ https://www.ama-assn.org/system/files/cpt-panel-september-2022-agenda.pdf.

basis, and CMS' proposal that all PHE allowances for telehealth last for 151 days after the PHE ends.

CMS' support for audio-only telehealth services during the PHE has clearly enabled better care, many of which are beneficiaries in the same underserved communities that CMS is prioritizing support for (and particularly for those who lack access to adequate connectivity to support a live video visit). Reverting audio-only telehealth to pre-PHE bundled treatment would be a disservice to the most underserved Medicare beneficiaries, and we urge CMS to do all that it can, including working with Congress, to enable permanent support for audio-only telehealth.

While we appreciate CMS' efforts to support mental health services via telehealth, we continue to oppose requiring that the billing practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the six-month period before the date of the telehealth service. Such a restriction is antithetical to use of remote care modalities and is inconsistent with CMS' general approach to telehealth services. We support CMS' proposed 151-day period postponement of this requirement once the PHE ends, and we urge for collaboration with Congress to amend the law to remove the requirement entirely.

- Care Management Codes for Chronic Pain Management (CPM) and General Behavioral

 Health Integration (GBHI): We support CMS' proposed support for CPM and GBHI. We urge

 CMS to clarify how RTM tools and services can be used in conjunction with CPM and GBHI, and to
 ensure that a diversity of caregivers be enabled to do so.
- Artificial Intelligence (AI): We appreciate CMS' collaboration over the last few years about medical AI definitions, present and future AI solutions, the ways that AI is changing the practice of medicine, and the future of AI medical coding. Many of us continue to provide views and data on these questions, and we commit to continued partnership with CMS to responsibly leverage AI to realize the benefits of AI tools in Medicare equitably. CMS is strongly encouraged to utilize the CPT Editorial Panel's Appendix S² as a baseline for taxonomy of medical AI moving forward in order to harmonize CMS' the framework of medical AI. We also urge CMS to pose key questions it has raised on AI in healthcare, including in its CY2022 proposed Physician Fee Schedule, in a standalone Request for Information that is not tied to an annual payment rule.

Further, we offer the following input on the draft CY 2023 QPP rule:

- Merit-based Incentive Payment System: We encourage CMS to continue to incent the flexible use of digital health technology throughout the Merit-based Incentive Payment System (MIPS). At the same time, CMS should avoid overburdensome MIPS Promoting Interoperability program compliance and reporting requirements to alleviate provider burnout and avoid technology-specific mandates that reduce eligible practitioners' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries.
- Alternative Payment Models: We share CMS' goal of developing a vibrant, diverse, and inclusive Alternative Payment Model (APM) ecosystem that will drive value for all beneficiaries. Digital health innovations must play a central role in successful APMs. CMS should clearly endorse the use of digital health technologies' role in the success of Alternative Payment Models. We urge CMS to utilize every opportunity available to move away from legacy measurement programs and towards a truly connected continuum of care through its implementation of the QPP.

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² https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

We appreciate CMS' consideration of our input on the proposed PFS and QPP rule for CY2023, and for its proposals to leverage the extraordinary potential of digital health technologies. We encourage CMS' thoughtful consideration of our input and stand ready to assist further in any way that we can.

Sincerely,

Omron Healthcare Inc.

Alliance Tele-Med, LLC MSNVA

America's Physician Groups Multiple Sclerosis Association of America

American Association for Respiratory

Care (AARC)

Nixon Gwilt Law

American Clinical Neurophysiology

Nova Insights

Society

American Health Information

Management Association (AHIMA)

Asthma and Allergy Foundation of

Optimize Systems Inc.

Patient Premier, inc

Pear Therapeutics

America Pillsy Inc.

BrightCloud International PreventScripts

CarePICS, LLC Propeller Health
ChronWell, Inc. Qualcomm Incorporated

CircleLink Health
Coala Life Inc.

Reemo Health
ResMed Inc.

Connected Health Initiative Rimidi

Diasyst Diagnostic

Diasyst Roche Diagnostics Corporation
Digital Therapeutics Alliance RxLive, Inc.

EmPowerYu Stel Life, Inc.
Healthcare Leadership Council Strive MedTech

HealthDatix, Inc.

TelemedicineHealth, Inc.

Hygieia The Clinic by The Cleveland Clinic

Kaia Health The Omega Concern, LLC

KCI Technology Solutions Theranica USA, Inc.

LIFE365 HEALTH TracPatch Health, Inc.

Limber Health Upside Health, Inc.

Limbix Health Inc.

URAC

MedSign International UVA Health

Melius Health Care, Inc. Validic

Mend VIP Verustat

MiCare Path Videra Health

Motionmobs