September 18, 2020

Administrator Seema Verma Centers for Medicare & Medicaid Services Department of Health and Human Services 200 Independence Avenue S.W. Washington, District of Columbia 20201

RE: Multi-stakeholder Comments to the Centers for Medicare and Medicaid Services re: CY2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; etc. (CMS-1734-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. A consistently growing body of evidence demonstrates that connected health technologies improve patient care, reduce hospitalizations, help avoid complications, and improve patient engagement (particularly for the chronically ill). These tools, increasingly powered by artificial/augmented intelligence (AI), leverage patient-generated health data (PGHD) and range from wireless health products, mobile medical devices, telehealth and preventive services, clinical decision and chronic care management support, and cloud-based patient portals. It is essential that these tools be utilized to address the rising costs of healthcare to both the public and private sector, and with this objective in mind, we appreciate the opportunity to provide our comments on the Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule for calendar year (CY) 2021. The need for rapid modernization of Medicare incentives is even more imperative considering the ongoing 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 thereafter.

We offer the following input on the draft CY 2021 PFS rule:

- We support CMS' proposal to support for live voice/video telehealth services for the duration of the PHE, and encourage CMS to expand the list of Medicare telehealth services to permanently include services that were added during the PHE and maintain the subregulatory process for adding additional services to the list put in place during the PHE. Recognizing the statutory restrictions CMS faces in extending this support past the expiration of the PHE, we generally support CMS' proposed policy changes to expand Part B support for Medicare telehealth services, including the creation of a new Category 3 for services enabled during the PHE.
- We encourage CMS to permanently allow use of virtual check-ins and e-visits for new and established patients. We applaud CMS' efforts to minimize burdens on caregivers, and agree that patient consent for CBTS may be documented by auxiliary staff under general supervision.
- Based on CMS' proposed clarifications on remote physiologic monitoring (RPM) CPT Codes 99453, 99454, 99457, and 99458, we offer the following:
 - We call on CMS to align its interpretation of an "interactive communication" for purposes of CPT codes 99457 and 99458 to support a healthcare professional's time in a calendar month providing RPM. RPM services are not Medicare telehealth codes that must be synchronous, live communications; and they are not virtual check-ins. CMS' proposed interpretations and equivalencies with respect to "interactive communication" run counter to stakeholder experiences and expectations, as well as the nature of RPM technology, and are inconsistent with both CMS' approach to chronic care management services and with widespread practices and experiences in the field. Unless corrected, CMS' proposed approach would significantly undercut the ability to furnish RPM.
 - CMS should correct its proposed approach to billing CPT Codes 99091 and 99457 in the same month or being billed in conjunction, which is inconsistent with the CPT

- Codebook's clear statement that 99091 should not be billed in the same calendar month as the 99453, 99454, 99457, and 99458 codes.
- CMS should clarify that a provider may bill for RPM once per month per patient with no limitation on the number of providers. Patients suffering from multiple illnesses that require monitoring under different care plans should benefit from RPM services for each of those illnesses as medically appropriate.
- We support CMS' proposal to permit medical devices as defined in the Food, Drug and Cosmetics Act to be used for RPM, and further encourage clarification that patientspecific medical devices whose FDA product code has been formally placed under enforcement discretion should satisfy the requirements of RPM services. We also agree that medical devices used for RPM must "digitally (that is, automatically)" upload eligible PGHD.
- We support CMS' proposal to extend the PHE allowance for attaining patient consent at the time of furnishing RPM services, and further request that CMS allow RPM to be furnished to patients without an established relationship on a permanent basis.
- We encourage CMS to extend its PHE policy enabling RPM services to be reported to Medicare for periods of time that are fewer than 16 days, but no less than two days, if other requirements for billing are met. Numerous use cases across chronic and acute conditions illustrate that a requirement of 16 days is not always appropriate.
- We support CMS' proposal to allow auxiliary personnel to furnish CPT codes 99457 and
 99458 RPM services under general supervision of the billing physician or practitioner.
- We urge CMS to permit Independent Diagnostic Testing Facilities, as well as rural health clinics and federally qualified health centers, to bill for RPM.
- We encourage CMS' to enable greater workforce efficiencies and advancement of patient safety through permanently extending its PHE policies enabling virtual direct supervision.
- We agree with CMS' proposal to activate CPT Code 9225X for automated point-of-care retinal imaging, and encourage CMS valuate the code as recommended by the RUC. It is vital that the reimbursement of this code reflects an appropriate value to encourage continued AI innovation.
- CMS is long overdue to maximize virtual Medicare Diabetes Prevention Program (MDPP) services. We support CMS' modest proposals for support of virtual modalities, and further urge CMS to permanently expand the MDPP to support virtual providers and virtual encounters.
- We commend CMS for acknowledging that current coding (either through CPT codes or the HCPCS G codes) may not reflect additional models of critical care delivery, such as those that utilize a combination of remote monitoring and clinical staff at the location of the beneficiary, among other scenarios. For example, we encourage CMS to support collection and use of PGHD measuring pain and other key data parameters that are not readily measurable by a peripheral device but have significant value to clinicians. We support CMS' continued inquiry into the approval and creation of new codes to support digital health scenarios that will provide improved outcomes to beneficiaries at reduced costs.

We offer the following input on the draft CY 2021 QPP rule:

- We encourage CMS to continue to incentivize the flexible and scalable use of digital health technology throughout the Merit-based Incentive Payment System (MIPS). CMS should also avoid overburdensome MIPS Promoting Interoperability program compliance and reporting requirements in order to avoid technology-specific mandates and to alleviate provider burnout related to electronic health record use.
- CMS should explicitly endorse the use of connected 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.

We appreciate CMS' consideration of our input on the proposed PFS and QPP rule for CY2021, 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,

1564B Accuhealth **Advanced ICU Care** AliveCor **Amalgam Rx American Association for Respiratory Care American Telemedicine Association** Anelto **ASC Healthcare** BlueStar SeniorTech **Brilliant Care Canary Doctor LLC CarePICS** ChronWell CoachCare **Commonwealth Primary Care ACO Compliance Meds Technologies Connected Care, LLC Connected Health Initiative Constant Therapy Health Consumer Technology Association Coordination Centric DayaMed Diasyst Dogtown Media** eHealth Initiative GetWell Network Grektek

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