September 3, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, District of Columbia 20201

Administrator Brooks-LaSure:

RE: *Multi-stakeholder Comments to the Centers for Medicare and Medicaid Services re:* CY2022 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Updates to the Quality Payment Program; etc. (CMS-1751-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 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 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 addressing the rising costs of healthcare, both public and private, and with this objective in mind we provide our comments on the Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule for calendar year (CY) 2022. The need for rapid modernization of Medicare incentives 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 allowed and 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 incentivize responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

<u>We offer the following comments on CMS' draft CY 2022 PFS for consideration:</u>

- **Medicare Telehealth Services:** CMS should continue 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' proposal to retain all services added to the Medicare telehealth services list on temporary (Category 3) basis until the end of CY 2023.

  We applaud CMS' proposal to support mental health services via audio-only telehealth, but strongly oppose requiring that the billing physician or 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 as such a restriction is antithetical to use of remote care modalities, is medically necessary or beneficial, and is inconsistent with CMS' general approach to telehealth services. During the initial PHE period, CMS used its mandate to include numerous flexibilities as they relate to statutory requirements to continue to provide access to all beneficiaries. Given

the addition of a record number of eligible beneficiaries, telehealth may be the only way beneficiaries can gain access especially those in rural or underserved communities. Further, many may have never accessed care through the Medicare program and waiving this requirement during the PHE aligns with the Administration's intent of extending the PHE.

- **Virtual Check-Ins:** CMS should permanently adopt coding and payment for HCPCS code G2252 as a direct crosswalk to CPT code 99442, reflecting the resources associated with a longer service delivered via synchronous communication technology, including audio-only communication.
- **Remote Supervision:** 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. The use of remote supervision technologies has demonstrated immense value during the COVID-19 pandemic. There is no reason it cannot continue to aid beneficiaries thereafter.
- **Remote Therapeutic Monitoring:** We support CMS' proposal to activate and pay for new CPT codes 989X1, 989X2, 989X3, 989X4, and 989X5 for remote therapeutic monitoring (RTM). CMS' proposal to price new RTM codes at the values recommended by the RVS Update Committee (RUC) is well-reasoned. The ability to monitor non-physiologic data will enable a wide range of medical specialty use cases that rely on medical device data to monitor therapy adherence and therapy response in connection with gastrointestinal diseases, endocrinology, cardiology, behavioral therapies, pain management, and medication adherence, in addition to respiratory and musculoskeletal disorders. We appreciate CMS' discussion of various technical issues related to how these codes have been presented, and offer the following:
    - RTM 989X4 and 989X5 for "treatment management services" should be designated as Evaluation and Management (E/M) codes included in the family of Care Management Services, similar to Remote Physiologic Monitoring Treatment Management Services. As E/M codes, 989X4 and 989X5 should be billable for physicians and qualified healthcare professionals who may bill E/M including physician assistants, nurse practitioners, certified nurse specialists, and certified nurse midwives. This designation is essential to ensuring that auxiliary personnel and clinical staff are able to assist in the provision of RTM services "incident to" and under the general supervision of a billing provider.
    - CMS should create temporary HCPCS G-Codes that mirror 989X4 and 989X5 for treatment management services (consistent with CMS' creation of the G2061, G2062, and G2063 codes for e-visits, mirroring the CPT Codes for e-visits by physicians/QHCPs), allowing non-physician providers who cannot bill E/M to bill these codes directly. In doing so, CMS will allow a greater array of providers (those who cannot bill E/M directly) to offer RTM services, as intended.
    - In keeping with the relationship envisioned by CMS between RTM and RPM, CMS should develop new G codes mirroring CPT codes 99457 and 99458 for RPM, allowing providers such as therapists to offer RPM treatment management services. Such an approach would be consistent with CMS' established solution to support a broader range of practitioners providing online digital evaluation and management services as described *supra*. Similarly, CMS should create a temporary HCPCS G-Code for supply of RTM device that parallels the condition-agnostic "supply of device" for RPM to support other acute and chronic conditions for which monitoring of therapeutic metrics and therapy adherence is useful.
    - CMS should clarify that, as with RPM and RPM/treatment management services (TMS), the new code family of RTM and RTM/TMS is subject to the same clarifications governing RPM codes particular to areas including consent; asynchronous/real-time audio conversation as part of "interactive communications," and the availability for RTM to be used for acute and chronic diseases. PHE allowances, such as attaining patient

consent at the time of furnishing RPM services, allow RPM to be furnished to patients without an established relationship on a permanent basis; and periods of time shorter than 16 days of data, but no less than two days for patients with a COVID diagnosis or symptoms suspected of COVID, should be extended as long as possible.
    - We agree with CMS that RTM services require medical devices as defined by the Food, Drug and Cosmetics Act, and further encourage clarification that medical devices whose FDA product code has been formally placed under enforcement discretion should satisfy the requirements of RPM services.
    - "Software as a Medical Device (SaMD)" used in medical practice such as RTM should not be categorized as an Indirect Practice Expense (PE). CMS' final rule must reflect that SaMD is not off-the-shelf computer software. Like medical equipment and medical supplies, SaMD is a device as defined by FDA regardless of whether it is loaded onto and used on general purpose platforms or as dedicated ancillary medical devices. Therefore, just like medical equipment, SaMD is a Direct PE and software updates and security patches to SaMD are analogous to medical supplies (which are also Direct PEs).
- **Artificial Intelligence (AI):** We are encouraged by CMS starting the conversation about medical AI definitions, present day and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding. Many of us are providing views and data in response to questions on AI posed by CMS, and we commit to continued collaboration with CMS to leverage AI to realize the benefits of AI tools in Medicare equitably. CMS proposes complex and detailed questions that will require input from highly technical stakeholders not typically involved in annual PFS rulemakings and should pose these questions in a standalone Request for Information that is not tied to creating binding Medicare regulation at a time where a foundational understanding by stakeholders and CMS is not yet fully developed.

  We note our appreciation for CMS' support of AI in addressing diabetic retinopathy, and support CMS' proposal to crosswalk CPT code 92229 to CPT code 92325 as an interim measure to more adequately account for the purchase and use of software algorithms in CPT code 92229's PE methodology. Ultimately, it is vital that the reimbursement of this code reflects an appropriate value (as originally recommended by the RUC) to encourage continued AI innovation.
- **Medicare Diabetes Prevention Program:** CMS is long overdue to offer virtual Medicare Diabetes Prevention Program (MDPP) services yet continues to refuse to propose meaningful changes that would do so. CMS must permanently expand the MDPP to support virtual providers and virtual encounters.

<u>Further, we offer the following input on the draft CY 2022 QPP rule:</u>

- **Merit-based Incentive Payment System:** We encourage CMS to continue to incentivize 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 related to electronic health record use 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.

We appreciate CMS' consideration of our input on the proposed PFS and QPP rule for CY2022, 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,

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American Association for Respiratory Care
American Board of Quality Assurance and Utilization Review Physicians
American Society of Nephrology
Association for Behavioral Health & Wellness
Biocom California
Brightree LLC
CarePICS
Catalia Health
CircleLink Health
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Consumer Technology Association
Diasyst
Digital Therapeutics Alliance
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MiCare Path
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PCHAlliance
Pear Therapeutics, Inc.
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Propeller Health
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