September 10, 2018

Attention: CMS-1693-P
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: *Multi-stakeholder Comments to the Centers for Medicare and Medicaid Services on* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program *(CMS-1693-P)*

We represent a wide – and growing – coalition of stakeholders that span the healthcare and technology sectors who support connected health technologies. A consistently growing body of evidence demonstrates that connected health technologies such as "telehealth," "mHealth," "store and forward," "remote patient monitoring," and other modalities improve patient care, reduce hospitalizations, help avoid complications, improve patient engagement (particularly for the chronically ill), and increase efficiencies. These tools which leverage patient-generated health data (PGHD) range from wireless health products, mobile medical devices, telehealth and preventive services, clinical decision support, chronic care management, and cloud-based patient portals. It is essential these tools be utilized to address the rising costs of healthcare to both the public and private sector, and we appreciate the opportunity to provide our consensus input on CMS' draft Physician Fee Schedule (PFS) and Quality Payment Program (QPP) for calendar year 2019.[1]

We commend the Centers for Medicare and Medicaid Services (CMS) for its efforts to advance the uptake of connected health innovations across its programs. For example:

- In the calendar year 2018 Physician Fee Schedule (PFS), CMS distinguished between "remote monitoring" services and "telehealth," and permitted separate payment for remote physiological data monitoring by activating and unbundling Current Procedural Terminology® (CPT) Code 99091 ("physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver"). The code allows reimbursement to physicians and qualified healthcare professionals who rely upon remotely gathered physiologic data to monitor patients.
- CMS further adopted QPP Merit-based Incentive Payment System (MIPS) Improvement activities to incent providers to leverage PGHD for patient care and assessment collected outside of the four walls of the doctor's office (e.g., IA_BE_14, "Engage Patients and Families to Guide Improvement in the System of Care"). CMS is encouraged to build upon these important steps to further leverage evidence-based connected health innovations to improve care and reduce costs.

[1] Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program*, 83 FR 35704 (July 27, 2018) ("Draft CY2019 PFS/QPP").

CMS has proposed to activate and pay for further remote monitoring codes that originated from the collaborative work of the American Medical Association's Digital Medicine Payment Advisory Group in its draft 2019 PFS, as well as to take steps to promote flexible use of remote monitoring innovations in the Quality Payment Program. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every American patient. We offer the following consensus viewpoints on CMS' proposals in the draft CY2019 PFS/QPP:

- We appreciate and support CMS' recognizing "communication technology-based services" that do not meet the Medicare telehealth services definition in Section 1834(m) of the Social Security Act. We have long advocated to CMS that it should waive 1834(m)'s overburdensome and unnecessary restrictions, including its geographic and originating site constraints, in all ways possible as widely as possible. While 1834(m) must still apply to the narrow set of defined services that fall under its definition moving forward, **any sweeping of new modalities in as Medicare telehealth services by CMS would harm the development of connected health technology innovations as well as their being made available to countless American Medicare beneficiaries.**
- We appreciate and support CMS' proposal provide payment for brief communication technology-based services (Healthcare Common Procedure Coding System [HCPCS] GVCI1), and offer the following recommendations:
    - We do not believe audio-only telephone interactions are solely sufficient for GVCI1 to provide value to beneficiaries. An audio-only telephone interaction simply cannot provide the range and depth of data that innovative asynchronous PGHD automated systems can. **We strongly urge CMS to clarify that GVCI1 supports virtual check-ins in a modality-neutral manner so that providers will have the option to offer virtual check-ins via not only "audio-only telephone interactions" but the range of connected health tools that will enable efficacious collection of PGHD in follow-up to an E/M service.**
    - GVCI1 should not exclusively require direct engagement by a qualified health care professional (QHCP) during the virtual check-in, as such a requirement would discount automated and AI-driven tools used for virtual check-ins. Further, as clinical staff, in addition to physicians and QHCPs, are essential in the evaluation of PGHD in a provider's work flow where clinical staff can include physicians in decisions where escalation is necessary (as opposed to evaluating all check-ins), **we urge that CMS clarify that GVCI1 is available to clinical staff in addition to physicians and QHCPs**.
    - **We urge CMS to remove its proposed requirements its restriction on billing GVCI1 when the virtual check-in originates from a related evaluation and management (E/M) service provided within the previous 7 days or leads to an E/M service or procedure within the next 24 hours or soonest available appointment.** If CMS does not remove this restriction, it is likely to exclude numerous essential use cases from billing GVCI1 where check-ins may easily be medically necessary within 7 days of the related E/M service or procedure (e.g., surgeries), as well as where the result in an in-person visit within 24 hours of the check-in may provide very valuable and timely medical advice to a patient.
    - **We encourage CMS adjust its proposed requirement for 5-10 minutes of medical discussion** to take a modality-neutral approach to virtual check-ins, recognizing that evaluation of PGHD can take much less than 5-10 minutes at a time, particularly when automated tools can, at intervals, identify over time whether a future in-person visit is required across a time period.

- **We strongly urge that CMS waive the copay requirement for GVCI1**.Our experiences have shown copays to be a barrier to uptake by beneficiaries, which would hinder the success of the GVCI1 code CMS is proposing.

- We appreciate and support CMS' proposal provide payment for remote evaluation of recorded patient information (HCPCS GRAS1). Consistent with our views on billing constraints described above for GVCI1, **we urge CMS to remove its proposed billing restriction for GRAS1 when it does not originate from a related E/M service provided within the previous 7 days nor lead to an E/M service or procedure within the next 24 hours or soonest available appointment.** We believe that this constraint on the code would exclude numerous outcome-improving and cost-saving essential use cases from billing GRAS1. Further, as they have been shown to be barriers to beneficiary uptake, **we strongly urge that CMS waive the copay requirement for GRAS1**.

- We support CMS proposes payment for interprofessional consultations performed via communications technology such as telephone or internet (CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449). **We believe that each CPT code should be available not only to physicians, but also to QHCP care management team members across rehabilitation and palliative settings**.

- We support CMS proposals to, per the Bipartisan Budget Act of 2018 (BBA), to (1) allow an individual determined to have end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth; and (2) remove the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished.

- We strongly supports CMS' proposals to activate each of the three CPT codes developed to address chronic care remote physiologic monitoring (990X0 [Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment]; 990X1 [Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days]; and 994X9 [Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month]). Specifically:

    - **We strongly urge that CMS waive the copay requirement for 990X0, 990X1, and 994X9,** which threaten to impede the uptake of remote monitoring innovations by beneficiaries and would hamper the goals of CMS' activation of these CPT codes.

    - We support CMS' proposed activation of and payment for 990X0, which covers key technical components of the use of remote physiologic monitoring of parameters in treatment of chronic conditions identified by the DMPAG. **We further request that CMS provide the following clarifications that (1) patient set-up and education on the use of equipment is permitted via communications technology (e.g., video call, live online chat, etc.); (2) 990X0 may be billed again if it becomes medically and reasonably necessary and to monitor one or more further parameters at a later time; and (3) one parameter is required to be monitored**.

    - We support CMS' proposed activation of and payment for 990X1, which also covers crucial technical aspects of remote physiologic monitoring of parameters in treatment of chronic conditions. Noting our strong support, we urge that:

        - **CMS reconsider its proposed approach that would exclude the monthly cellular and licensing service fee supply as a form of indirect practice expense**. CMS bases its proposal on a belief that such licensing fees should be

understood as "forms of indirect costs similar to office rent or administrative expenses." Without dedicated wireless connectivity for the patient's specific device, the vast majority of the remote monitoring technology needed to achieve remote physiologic monitoring of parameters in treatment of chronic conditions would be excluded, contrary to the stated intentions of CMS. The monthly cellular and licensing fee is a direct cost that is attributable to a specific patient for a specific service, as the device that each patient uses to facilitate remote monitoring must have the capability to transmit healthcare data either via a cellular network or other wireless network.

        - CMS should **clarify that "programmed alert(s) transmission" includes transmissions at intervals other than daily**. Such a clarification would provide valuable certainty to stakeholders that scalable remote monitoring intervals deemed medically appropriate are reimbursable in addition to those that are daily.

    - We support CMS' proposal with regard to 994X9, covering the professional component of remote physiologic monitoring of parameters in treatment of chronic conditions. We specifically note our support for the inclusion of clinical staff, along with physicians and QHCPs, as those who can provide 994X9 services. We request, however, that **CMS confirm that 994X9 is not restricted to the monitoring of two or more chronic conditions. Further, CMS is urged not to require the physician and clinical staff to be physically located in the same office in order facilitate greater flexibility for program participants**, which can be accomplished through CMS exercising its discretion to permit billing of clinical staff time as time "incident to" the billing practitioner, where the billing practitioner exercises "general," rather than "direct," supervision.

- With the passage of MACRA, Congress has clearly directed CMS to evolve the Medicare program to maximize care quality over quantity, arguably requiring the system to embrace enhancements like connected health technology. Through this rulemaking, CMS has an unprecedented opportunity to improve the American healthcare system by leveraging a wide array of connected health technologies – those available today, as well as future innovations. We urge CMS to utilize every opportunity available to move towards a truly connected continuum of care through its implementation of the QPP. Specifically:

    - We support CMS taking all practicable steps to advance the use of PGHD collected via remote monitoring into the American healthcare system widely including using application program interfaces (APIs), including those offered through 2015 Edition CEHRT. We are committed to working with CMS and all other stakeholders to introduce new technology-driven efficiencies into care that will save costs and improve care.

    - We support the overall approach by CMS to the Improvement Activities (IAs) that have taken a more goal-oriented and technology-neutral approach to compliance providing needed flexibility to MIPS practitioners to select the most effective approaches for their patients, and which will very often include connected health technology innovations. Changes in MIPS are inherently linked to other important rules CMS is responsible for, including the Physician Fee Schedule which has recently begun to incent the use of asynchronous tools that will bring PGHD into care. CMS' steps to revise MIPS generally should be made in alignment with key pro-remote monitoring changes to these important programs and others.

    - Connected health technologies, either in the form of an electronic health record (EHR) or as a supplemental module of an EHR, dynamically support the feedback related to participation in the QPP and quality improvement in general, and we believe that the

CMS' evaluation must reflect the fact that remote monitoring and telehealth – across patient conditions – offer such key "health IT functionalities," including the automatic collection and transmission of important biometrics for timely caregiver review and analysis, which contribute to the improvement of beneficiary health outcomes by reducing healthcare disparities in support of the feedback loop related to Quality Payment Program participation. Diverse APIs are emerging to assist in bringing PGHD into the continuum of care through the efforts of innovative technology developers, which should be enabled through appropriate steps by HHS to ensure interoperability. **Further**, **we urge CMS to consider shifting away from rigidly requiring the use of certified EHR technology (CEHRT) to an outcomes-based approach that would permit the responsible use of non-CEHRT by MIPS caregivers.**

- **We urge CMS to make compliance burdens for Promoting Interoperability (PI) participants as low as possible to maximize participation, and supports proposed changes to the PI scoring regime and measures proposed with increased flexibility and lower compliance burdens in mind** (e.g., scoring measures at the objective level; and moving away from numerator/denominator scoring, and instead utilize a yes/no attestation; and aligning the hospital and physician PI programs by extending the 50-point score standard – recently finalized for hospitals in the IPPS – to physicians).

- We support Congress's goal of realizing innovative APMs and continues to work with stakeholders to find eligible alternatives to MIPS. At a minimum, we strongly believe that APMs must affect the utilization of connected health technology in a significantly expanded way. APMs, with their financial and operational incentives, should demonstrate the best uses of remote monitoring or telehealth tools. To date, CMS has not discussed telehealth and remote monitoring's key role in the success of APMs. **We believe that this oversight may force eligible clinicians, as well as other key stakeholders and organizations, to make the unfortunate conclusion that telehealth and remote monitoring do not have a role in APMs**. We call on CMS to provide this crucial commentary and insight in the final CY2019 QPP rule. Such a step would also be consistent with CMS endorsement of telehealth and remote monitoring in MIPS.

- Regarding program integrity risks, we note our support for measures to avoid waste, fraud and abuse. The use of asynchronous technology as a modality does not inherently mean that it will translate to greater waste, fraud and abuse; to the contrary, program integrity is more easily ensured through real-time data analytics that greater use of connected health technologies provide. We therefore urge **CMS to embrace asynchronous and automated connected health modalities to utilize the ability of these technologies to improve the ability to avoid programmatic waste.** Additional measures should be implemented for specific modalities based on demonstrated heightened risks to program integrity, specific to that modality.

We appreciate CMS' seeking input on its draft CY2019 PFS and QPP, and for its proposals to leverage the incredible potential of remote patient monitoring technologies. We encourage CMS' thoughtful consideration of the above input and stand ready to assist further in any way that we can.

Sincerely,

AliveCor

American Association for Respiratory Care (AARC)

American Heart Association

Baxter Corporation

Connected Health Initiative

Dogtown Media

For All Abilities

HealthTechApps

Medical Society of Northern Virginia

National Association of ACOs

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