September 16, 2019

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 on* Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures (84 FR 34478)

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 the Center for Medicare and Medicaid's (CMS) proposal to implement the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model), two new mandatory Medicare payment models under section 1115A of the Social Security Act.[1]

We commend the CMS for its efforts across key programs to advance the uptake of connected health innovations. For example, in the CY2019 Physician Fee Schedule (PFS), CMS activated and paid for new CPT codes representing the technical and professional components of remote physiologic monitoring (99453, 99454, and 99457). CMS has also taken steps to promote flexible use of connected health technology innovations in the Quality Payment Program's Merit-based Incentive Payment System (MIPS) through, for example, adopting a MIPS Improvement Activity that incents providers to leverage any connected health tool that utilizes an active feedback loop for patient care and patient assessments outside of the four walls of the doctor's office. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every American patient.

Building on the above, we offer the following specific input on CMS' proposed approach to implementing the RO and ETC Models:

- CMS' omission of any discussion of connected health technology in the proposed rule text represents an oversight and a disservice to Medicare beneficiaries. Connected health technologies are poised to make immense contributions to the success of both models. For example, interoperable connected health technologies can (and should) provide great value in the care of patients with chronic kidney disease through dialysis to kidney transplant, providing a much-

[1] Centers for Medicare and Medicaid Services, *Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures*, 84 FR 34478 (July 18, 2019).

needed flow of patient data to assist with benchmarks or outcomes. As a further example, telehealth visits can permit much more efficient care management by a nephrologist of patients in stages 4 and 5 of chronic kidney disease to delay the start of dialysis or get a kidney transplant before the native kidneys completely fail, particularly when the patient is in a location far away from the location of the nephrologist's practice. Yet, without any discussion or endorsement of such connected health technologies by CMS, caregivers and other key stakeholders are left to "round down" and conclude that they do not have a role in the RO and ETC Models.

We strongly urge CMS to ensure that its final rule contains robust discussion and endorsement of the use of connected health tools in the success of the RO and ETC models, and to include guidance on how Model participants should utilize connected health technologies. This crucial commentary and guidance in the final version of its rule will contribute to the success of the RO and ETC Models, and will support of the public interest, through the improvement of patient outcomes, enhanced engagement in care by patients, and reduced programmatic costs. Making this improvement to its rules for the RO and ETC Models would also bring them into alignment with CMS' endorsement of connected health technologies in other key payment programs, including the PFS, QPP, HHPPS, and Medicare Advantage.

- We have long been concerned with the statutory burdens that limit the range of remote access technologies that may be offered and have long hindered progress in the connected health space. A notable example, Section 1834(m) of the Social Security Act, has resulted in arduous restrictions on telehealth services with no discernable connection to serving a public good.[2] We urge CMS to utilize every opportunity to remove barriers to the use of advanced technologies within a connected healthcare system, even if just for "telehealth" (which is synchronous voice and video only under Medicare rules). CMMI already has the authority in 42 U.S.C. § 1315a(d)(1) to waive 1834(m)'s burdensome restrictions on telehealth in order to adequately explore, track, and release data in a timely fashion.

  In addition to 1834(m)'s restrictions, co-pays represent another key reason for telehealth's embarrassingly low utilization in Medicare. We therefore oppose CMS' conclusion that it is not necessary in the testing of the ETC Model to waive the co-insurance requirement for the KDE benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites. We strongly encourage CMS to waive such KDE benefit requirements.

- Regarding program integrity, we generally support measures to avoid waste, fraud and abuse in the RO and ETC Models. The use of various connected health innovation modalities, including RPM technology, does not inherently mean that remote monitoring will translate to greater waste, fraud and abuse; to the contrary, program integrity is more easily ensured through data analytics that connected health technologies provide. We therefore urge CMS to acknowledge (1) the ability of connected health technologies to improve programmatic waste; and (2) to leverage existing and developing program integrity tools and metrics in the RO and ETC Models in a modality-neutral manner, with additional measures being implemented for specific modalities based on demonstrated heightened risks to program integrity specific to modalities.

[2] *See* 42 CFR § 410.78.

We appreciate CMS' seeking input on its proposed rule. We encourage CMS' thoughtful consideration of the above input and stand ready to assist further in any way that we can.

Sincerely,

College of Healthcare Information Management Executives (CHIME)

Connected Health Initiative

Diasyst

Digital 360 Health

InTouch Health

Life365

LifeWire

Medical Alley Association

Personal Connected Health Alliance (PCHAlliance)

Pt Pal

Telehealth Suites

UnaliWear