



Continua
HEALTH ALLIANCE

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1345-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

**RE: CMS-1345-P; Comments to Medicare Shared Savings Program:
Accountable Care Organizations Proposed Rule**

Dear Administrator Berwick:

The more than 230 members of the Continua Health Alliance (Continua) thank the Centers for Medicare & Medicaid Services (CMS) for accepting comments related to the Notice of Proposed Rulemaking for the Accountable Care Organization (ACO) program.¹ Continua is a non-profit, open industry coalition of healthcare, technology, and medical device companies joining together in collaboration to improve the quality of healthcare through the use of personal telehealth, remote patient monitoring (RPM), and other health information technologies. Continua is dedicated to establishing interoperable personal connected health solutions with the knowledge that extending those solutions into the home saves money, fosters independence, empowers individuals, and provides the opportunity for personalized health and wellness. More information about Continua and its members can be found at www.continuaalliance.org.

We are pleased that CMS recognizes the value of telehealth, RPM and health IT in the Proposed Rule and believe that these services will assist in encouraging and rewarding patient engagement and patient-centeredness. “Telehealth” is defined in statute, and it includes professional consultations, office visits, and additional services.² Telehealth enables new and flexible approaches for health services that directly support Shared Savings Program goals. Live, multi-disciplinary care delivery and care team

¹ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528 (Apr. 7, 2011).

² 42 U.S.C. § 1395m(m)(4)(F).

collaboration support efficient, more effective care. ‘Care-at-a-distance’ clinical services increase patient access to care, patient engagement and pro-active management of acute and chronic conditions. Collaboration among care teams across the continuum of care supports better more effective care coordination and a patient-centered medical home approach.

Though not defined in statutes or regulations, ‘RPM’ is recognized widely to mean wired, wireless and mobile health (mHealth) enabled medical devices, sensors, and applications that monitor patients’ conditions from home or someplace other than health care providers’ offices. Telehealth and RPM products also can transmit physiological or biometric data to family members, physicians, health care providers, and Personal Health Record (PHR) or Electronic Health Record (EHR) systems, enabling patients to be full partners in their care. We are encouraged that CMS recognized RPM devices in the final rule on EHR ‘Meaningful Use Stage I’ as the kinds of devices that help populate EHRs with patient-generated data and, if certified, can be ‘EHR Modules.’³ In implementing the ACO rule, CMS has an opportunity to build upon the recognition of RPM devices as an element of ‘Meaningful Use.’ However, the proposed rule falls short of ensuring the use of telehealth and RPM within the ACO context as intended by the Patient Protection and Affordable Care Act, Pub. L. 111-148 (ACA).

We are concerned that the Proposed Rule does not include sufficient waivers to permit ACO participants to make use of telehealth, RPM, or health IT tools as integral elements of the care plan and to encourage Medicare beneficiaries to use such technologies. Additionally, as written, the Proposed Rule does not implement Congress’s intent in Sec. 3022 of the ACA, which requires ACOs to ‘promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.’ Below we explain our concerns in detail.

³ 75 Fed. Reg. 44590, 44595 (Jul. 28, 2010).

The Proposed Rule does not include sufficient waivers to permit ACO participants to make use of telehealth tools.

ACO participants cannot receive payment for use of telehealth services as the Proposed Rule is written because the statutory definition of “originating site” does not include locations from which critical health status data most often would be transmitted. That is to say, the originating site from which Medicare beneficiaries usually would transmit health status data would be places where they live their lives when they are not in a physician’s office or other health care setting. In the proposed rule, CMS calls for ACOs to promote patient centeredness, coordination of care, and patient engagement. Yet telehealth statutes and regulations, as written, preclude the use of critical telehealth tools that could help achieve what Congress specifically called for in the legislation. In order to meet the intent of Sec. 3022, waivers of these requirements are necessary so that all ACO participants – not just a few participants in very limited circumstances – can avail themselves of innovative telehealth tools, including RPM and health IT.

Continua strongly encourages CMS to waive the statutory and regulatory provisions and definitions that limit the locations that may be “originating sites” from which eligible Medicare beneficiaries may transmit health status data via telehealth. Currently, the definition of an “originating site” does not include a patient’s home or other places outside of a health care facility from which health status data may be transmitted to a physician or an EHR system. The definition also limits the “originating site” mostly to rural areas of the country with health professional shortages.⁴ Continua also encourages CMS to waive the regulatory limitations on the use of and payment for “asynchronous store and forward” technologies (those technologies that permit health status data to be collected and transmitted, stored, and reviewed by a patient and health care provider at a later time). Currently, Medicare reimbursement is available only when such data is transmitted from one of the limited “originating sites” and only for telemedicine demonstration projects in Alaska and Hawaii.⁵ Telehealth services are

⁴ See 42 U.S.C. § 1395m(m)(4)(C); 42 C.F.R. § 410.78.

⁵ See 42 C.F.R. § 410.78.

dependent on “interactive telecommunications” systems, meaning multimedia communications equipment that include, at a minimum, audio and video permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner (telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system).⁶ Inevitably, with such limited criteria for reimbursement of telehealth services, large segments of the U.S. population are being deprived the best available management of healthcare.

Without a waiver of the definition of “originating site” and a waiver of the requirement that use of “asynchronous store and forward” technologies can be reimbursed only in very limited circumstances, very few – if any – ACOs could make substantial use of either RPM or telehealth to help promote coordination of care. Even though the preamble to the Proposed rule identifies “remote monitoring” and telehealth as two of the strategies an ACO may use to comply with the requirement that it have a processes in place to promote coordination of care, the failure to waive the limits of the use of telehealth makes the use of RPM and telehealth for these purposes virtually meaningless for the vast majority of Medicare patients.

The Proposed Rule falls short of implementing Congress’ clear statutory intent to support and promote telehealth and RPM.

The Affordable Care Act includes provisions to improve beneficiary outcomes and increase the value of care. Section 1899(a)(1)(A) of the Act provides that groups of providers and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO. Section 1899(b)(2)(A) through (H) of the Act establishes the requirements that such eligible groups must meet in order to participate in the program.

One such requirement included by Congress is that an ACO must define processes to “promote evidence-based medicine and patient engagement, report on quality and cost

⁶ *Id.*

measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”⁷ However, as written, the Proposed Rule does not permit ACOs to manage beneficiary care and reduce costs by harnessing the power of telehealth and RPM. The Proposed Rule itself requires an ACO to have “a mechanism in place for the coordination of care (for example, via use of enabling technologies...).” Yet without the applicable waivers, ACOs cannot adhere to the rule, and CMS cannot implement Congress’ clear intent to support and promote telehealth and RPM. While Continua appreciates that CMS recognizes the value of these technologies, we are concerned that ACOs cannot fully adopt their use as the rule has been proposed.

Unfortunately, CMS missed another opportunity to implement Congress’ intent when it declined to include telehealth and RPM use in its Proposed Quality Performance Measures. In its explanation of how it selected the measures, CMS said, “We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.”⁸ Although CMS included in its Proposed Quality Performance Measures five other Care Coordination/Information Systems measures, it did not include telehealth and RPM. Incorporating telehealth and RPM into the performance measures would incentivize ACOs and promote the use of telehealth, RPM and other health IT as Congress intended.

The members of Continua encourage CMS to require ACOs to demonstrate that telehealth and RPM are integrated into their delivery systems for appropriate patients. If these measures are not included, the ACOs should explain why the providers have chosen not to integrate these services into the care plan for Medicare patients. In this manner, and with the addition of the waivers necessary to make full use of these services, CMS can ensure the congressional requirement to include telehealth, RPM and health IT is actually implemented.

⁷ Pub. L. 111-148, § 3022, codified at 42 U.S.C. § 1395jjj(b)(2)(G).

⁸ 76 Fed. Reg. 19569.

Continua appreciates the opportunity to comment on the Proposed Rule and encourages CMS to harness innovative technologies to improve the quality of patient care and decrease costs. We urge you to consider our recommendations to waive the limiting definition of “originating site” and to include telehealth and RPM use in the Proposed Quality Performance Measures. Thank you for your consideration of Continua’s recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Chuck Parker". The signature is fluid and cursive, with the first name "Chuck" being more prominent than the last name "Parker".

Chuck Parker

Executive Director

Continua Health Alliance

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