

Before the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare and Medicaid Services
Baltimore, MD 21244

In the Matter of	)	
	)	
2 CFR Part 425	)	CMS-1461-P
	)	
Medicare Program; Medicare Shared Savings	)	
Program; Accountable Care Organizations;	)	
Proposed Rule	)	

**COMMENTS OF THE
TELECOMMUNICATIONS INDUSTRY ASSOCIATION**

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COMMENTS OF THE TELECOMMUNICATIONS INDUSTRY ASSOCIATION

I. INTRODUCTION AND STATEMENT OF INTEREST

The Telecommunications Industry Association (TIA) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS) Notice of Proposed Rulemaking (NPRM) for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACO) participants, which was released for public input in December of 2014.¹ We applaud CMS for including discussion of needed changes to the MSSP that would help realize the potential of telehealth and remote monitoring, and believe that its inclusion in the NPRM reinforces CMS as a leader in shaping new ways to integrate and utilize innovative technologies that enable health information and communications technology (ICT) solutions to achieve improved care for Americans at lower costs.

¹ Department of Health and Human Services CMS, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 79 FR 72759 (Dec. 8, 2014).

II. THE BENEFITS OF TELEHEALTH AND REMOTE PATIENT MONITORING (RPM) TO ACCOUNTABLE CARE ORGANIZATIONS

TIA admires CMS' continued interest in exploring innovative technological healthcare delivery mechanisms. Information and communications technologies (ICT) enable more efficient delivery of healthcare services and are constantly evolving. A modern 21st century health care system should embrace the array of innovations available by advanced ICT such as remote patient monitoring technologies and asynchronous store-and-forward solutions which enable the delivery of health care beyond the four walls of the hospital room or the doctor's office.

To date, statutory and regulatory restrictions have limited the range of telehealth and remote patient monitoring technologies that may be offered to American patients and, in the view of TIA, have long been a hindrance to progress and adoption in this space. As notable examples, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services;² further, remote patient monitoring separately is unreasonably restrained by CMS' decision to bundle it with other codes, resulting in a lack of reimbursement for remote patient monitoring. The ICT manufacturer, vendor, and supplier community urges CMS (and other federal actors) to make use of every opportunity to work towards a connected healthcare system by removing such barriers to the utilization of advanced technologies.

TIA notes that remote patient monitoring of patient-generated health data (PGHD) is increasingly becoming an important aspect of any healthcare system. The known benefits of

² See 42 CFR § 410.78. We note that in 2014, TIA joined a broad cross-section of stakeholders in the healthcare space to urge HHS Secretary Burwell to waive 1834(m) restrictions on ACOs in the MSSP. See <http://bit.ly/1na1UrA>.

remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.³ A vivid example of the use of virtual chronic care management is by the Department of Veterans Affairs, which reported a substantial decrease in hospital and emergency room use.⁴ There is also a growing body of potential cost savings, noted most recently by a study predicting that remote monitoring will result in savings of \$36 billion globally by 2018, with North America accounting for 75% of those savings.⁵ Integrating the use of PGHD also engages some patients in their own care, which can lead to improved lifestyle choices and improve overall health.⁶

In its finalized Calendar Year 2015 Physician Fee Schedule,⁷ CMS has established provisions for a remote chronic care management current procedural terminology (CPT) code, moved to allow Medicare coverage for remote patient monitoring of chronic conditions, and has created seven covered procedure codes for telehealth which cover: psychotherapy services,

³ See Hindricks, et al., *The Lancet*, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4. See also U.S. Agency for Healthcare Research and Quality ("AHRQ") Service Delivery Innovation Profile, *Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>.

⁴ See Darkins, *Telehealth Services in the United States Department of Veterans Affairs (VA)*, available at <http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf>.

⁵ See Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), available at http://www.juniperresearch.com/reports/mobile_health_fitness.

⁶ See, e.g., Sanjena Sathian, "The New 21st Century House Call," *Boston Globe* (July 29, 2013), available at <http://www.bostonglobe.com/lifestyle/health-wellness/2013/07/28/century-house-call/tdupWvOQl6b3dKdKcEgdGM/story.html>.

⁷ See CMS, *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015*, 2014 FR 26183 (pub. Nov. 4, 2014), available at <https://www.federalregister.gov/articles/2014/11/13/2014-26183/payment-policies-under-the-physician-fee-schedule-revisions-etc-medicare-programs>.

prolonged service in the office, and annual wellness visits. These key steps are important to build upon as CMS looks to move forward in improving the MSSP. We also encourage you to take a technology-neutral approach towards a fully-connected health ICT ecosystem that embraces the diversity of solutions that allow for innovative improvements in care that technology can provide at each stage along the continuum of care. Further, we urge CMS to ensure flexibility in the how to address risk (including waivers and safe harbors), and for reliance on the adoption of common standards and certification requirements for interoperability.

Lastly, we urge for CMS to take clear steps, such as those recognized below, to fully embrace the benefits of telehealth and remote patient monitoring in the MSSP, consistent with not only the Federal Health IT Strategic Plan,⁸ but also the recent landmark announcement from the Department of Health and Human Services to tie 30 percent of fee-for-service Medicare payments to quality or values through ACOs (and other alternative payment models) by the end of 2016.⁹

⁸ See Office of the National Coordinator for Health Information Technology, Federal Health IT Strategic Plan 2015-2020 (rel. Dec. 8, 2014), *available at* <http://www.healthit.gov/sites/default/files/federal-healthIT-strategic-plan-2014.pdf>.

⁹ See HHS Press Release, *Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value* (January 26, 2015) *available at* <http://www.hhs.gov/news/press/2015pres/01/20150126a.htm>.

III. TIA STRONGLY URGES CMS TO WAIVE ARDUOUS 1834(M) RESTRICTIONS ON TELEHEALTH FOR ACCOUNTABLE CARE ORGANIZATIONS

A. CMS SHOULD WAIVE 1834(M) RESTRICTIONS ON TELEHEALTH IMMEDIATELY

TIA has long held that 1834(m) has resulted in onerous restrictions which limit patient access to new technologies, effectively discouraging providers from utilizing advanced ICT solutions in their practices, including within the MSSP. Notable restrictions on telehealth in 1834(m) include:

- No coverage for about 80% of Medicare beneficiaries who happen to live in the 1200 metropolitan counties not included in the definition of “rural;”
- No coverage for “store-and-forward” services (such as transmission of medical images) for the 43 million beneficiaries who live outside of Alaska and Hawaii;
- No coverage for services originating from a beneficiary’s home (even for the “homebound”), a hospice and other common non-medical locations from which a beneficiary seeks service;
- No coverage for otherwise covered Medicare services of physical therapy, occupational therapy, speech-language pathology, audiology and some other practitioners; and
- No coverage for most health procedure codes, precluding the best judgment of physicians and other practitioners about the medical needs and other circumstances of all Medicare beneficiaries.

TIA believes that providing ACOs with the ability to utilize advanced telehealth solutions is consistent with the goals of the MSSP – namely, improved quality of care and reduced costs. Further, such an approach would be consistent with the Affordable Care Act (ACA) which

requires MSSP-participating ACOs to “define processes...to coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”¹⁰

In the NPRM, CMS notes that if a Section 1899(f)-based waiver is used to grant relief of some telehealth restrictions, CMS will likely waive the originating site requirements in section 1834(m)(4)(C)(i)(I) through (III), and in section 1834(m)(4)(C)(ii)(I) through (VIII).¹¹ Further, CMS states that it may also limit waivers to Track 3 ACOs.¹²

As we note above, restrictions on telehealth in section 1834(m) – including those on originating sites – continue to prevent the realization of virtual care plans available today which would enrich the lives of millions of Americans. We continue to believe that, in order for CMS’ regulations and policies to reflect the dynamic and transformative nature of advanced and innovative ICT solutions available today, current restrictions in section 1834(m) should be waived for all MSSP participants. Such an approach would reflect the well-established and growing body of evidence supporting the benefits of telehealth, and would avoid unnecessary limitations on these benefits to millions of Americans.

Alternatively, should it choose to limit its waiver to certain restrictions contained in 1834(m) or to the type of ACO for which the waiver applies, we strongly urge CMS to continue to carefully collect and review evidence attained from existing and ongoing studies, as well evidence gained in the MSSP itself moving forward, towards incrementally expanding its waiver on these restrictions. Initially, this limited waiver should apply to Track 2 as well as Track 3 ACOs at minimum, as they collectively represent under 5% of all ACOs; further, Track 1 ACOs

¹⁰ 42 U.S.C. § 1395jjj(b)(2)(G).

¹¹ NPRM at 72821.

¹² NPRM at 72817.

should also have the ability to apply for a waiver of 1834(m) restrictions to the well-established benefits of advanced ICT solutions in the healthcare context. Finally, CMS should also memorialize its intention to, on an annual recurring basis, review data on the benefits of the waiver(s) in place and the ways in which they should be appropriately expanded as part of future MSSP rulemakings.

B. CMS SHOULD CONTINUE TO ENSURE THAT REMOTE PATIENT MONITORING IS NOT REGARDED AS TELEHEALTH

In the NPRM's discussion of a possible 1834(m) waiver for telehealth, CMS requests input on the definition of telehealth.¹³ While 1834(m)(4)(F)(i) provides a definition of "telehealth,"¹⁴ CMS describes in the NPRM how services that are commonly furnished remotely using telecommunications technology ("electronically, rather than by means of a verbal description") are paid under the same conditions as if the service were provided in-person (such as the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone). We support CMS' interpretation, and strongly urge for CMS to continue to maintain this vital interpretation that ensures the proper reimbursement for the monitoring of PGHD.

¹³ See NPRM at 234-235.

¹⁴ 1834(m)(4)(F)(i) defines telehealth as "professional consultations, office visits, and office psychiatry services," while the statute gives the Secretary authority to identify additional services as telehealth services for purposes of Medicare reimbursement.

IV. CMS SHOULD UTILIZE ITS WAIVER AUTHORITY TO ALLOW FOR UNBUNDLED PAYMENT FOR REMOTE PATIENT MONITORING

The Current Procedural Terminology (CPT®) code 99091 represents remote patient monitoring,¹⁵ and has been assigned 1.59 Relative Value Units (RVUs). Despite CMS' determination that the treatment of chronic care management under Evaluation and Management Code approach has been inadequate and should therefore be billed separately, 99091 remains a bundled code. Based on the demonstrated benefits of remote patient monitoring described above, we strongly urge for CMS to adequately reimburse remote patient monitoring for CCM by ACOs through the unbundling of 99091 by altering the designation of 99091 (currently "B") to allow for separate payment to ACOs who use remote patient monitoring for CCM. TIA believes that the Secretary holds the authority to make this change under 1899(f), and notes that such an exercise of authority would be consistent with other proposed waivers in the NPRM which rely on proven cost savings and decreases in hospital readmissions.

¹⁵ CPT Code 99091 is defined as "collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time."

V. CONCLUSION

TIA urges your consideration of the above views which support the wide use of telehealth and remote monitoring solutions to improve the United States' healthcare system, and we welcome the opportunity to work with you and your designees on such timely actions.

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