



TELECOMMUNICATIONS
INDUSTRY ASSOCIATION

1320 N. Courthouse Rd., Suite 200
Arlington, VA 22201 USA
www.tiaonline.org

Tel: +1.703.907.7700
Fax: +1.703.907.7727

By Electronic Delivery via HealthPlanInnovationRFI@cms.hhs.gov

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Attn: Beth Schalm
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: *Center for Medicare & Medicaid Innovation Request for Information on Health Plan Innovation Initiatives at CMS*

I. Introduction and Statement of Interest

The Telecommunications Industry Association (TIA) hereby submits input to the Department of Health and Human Service's Centers for Medicare & Medicaid Services (CMS) request for information on possible initiatives to test innovations in Center for Medicare and Medicaid Innovation (CMMI) Health Plan Innovation Model Concepts (RFI).¹

TIA² is a trade association representing nearly 400 global manufacturers, vendors, and suppliers of information and communications technology (ICT), and engages in policy efforts specific to health ICT to promote a modern healthcare system that leverages innovative technologies to transform the way care is delivered and implemented. Many of TIA's member companies develop, manufacture, and supply health information technologies and medical devices, producing the tools that allow patients and healthcare providers to connect virtually anytime, anywhere.

TIA's comments below are limited to discussion of "Remote Access Technologies" under Section III, *Medicare Advantage and Medicare Advantage Prescription Drug (MA and MA-PD) Plans*, of the RFI (questions 21-23) and Section IV, *Medicaid Managed Care*, of the RFI (question 28).

¹ <http://innovation.cms.gov/files/x/hpi-rfi.pdf>

² <http://www.tiaonline.org/>

II. TIA Supports CMMI's Examining the Benefits of Advanced ICT Solutions in Healthcare Services

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 to asynchronous store-and-forward solutions which empower the delivery of health care beyond the four walls of the hospital room or the doctor's office.

As the RFI points out, statutory restrictions "limit the range of remote access technologies that may be offered" and, in the view of TIA, have long been a hindrance to progress in this space. Growing bodies of clinical evidence suggest that interoperable remote monitoring improves care, reduces hospitalizations, helps avoid complications, and improves satisfaction, particularly for the chronically ill.³ However, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. As a notable example, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services.⁴ The ICT manufacturer, vendor, and supplier community urges that CMS (and other federal actors) utilize every opportunity to work towards a connected healthcare system by removing barriers to the utilization of advanced technologies. Earlier 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 Accountable Care Organizations in the Medicare Shared Savings Program.⁵

Remote patient monitoring of patient-generated health data (PGHD) is increasingly being proven as an important aspect of any healthcare system. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.⁶ A vivid example of the use of virtual chronic care management is by the Department of Veterans Affairs who reported a substantial decrease in hospital and emergency room use.⁷ There is also a growing body of potential cost savings, noted most recently by a study predicting that remote

³ See, e.g., 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 42 CFR § 410.78.

⁵ See <http://bit.ly/1na1UrA>.

⁶ 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>.

⁷ 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>.

monitoring will result in savings of \$36 billion globally by 2018, with North America accounting for 75% of those savings.⁸ Integrating the use of PGHD also engages some patients in their own care, which can lead to improved lifestyle choices and improve overall health.⁹ The efforts of CMS through its Center for Medicare & Medicaid Innovation (CMMI) grants will be key in exploring and providing further support for these technologies in the future of the American healthcare system, such as the CMMI Independence at Home pilot program,¹⁰ which is using remote monitoring and mobile diagnostic technologies. We also urge CMS to review an appended list of studies demonstrating the benefits of remote access technologies.

Furthermore, in its finalized Calendar Year 2015 Physician Fee Schedule,¹¹ CMS has established provisions for a remote chronic care management 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, prolonged service in the office, and annual wellness visits. These steps taken by CMS are important to build upon as CMMI looks to find further test innovative model concepts.

Based on TIA's views, we urge for CMS to consider the following factors as it develops a model test that allows plans to include a broader range of remote access technologies in the basic benefit package, beyond the telehealth technologies that are covered in Original Medicare:

- **Services to be Covered (e.g. CPT codes):** For the purposes of developing a CMMI model test, we urge for examining remote patient monitoring for congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), and diabetes, along with flexibility for further expansion for eligible chronic conditions identified by the Secretary based on an annual review of the evidence. Ultimately, CMS should strive for the development of models that serve as micro chasms, lending to the full coverage of telehealth and remote patient monitoring.
- **Utilize Existing Quality Outcomes and Metrics and Build Upon the Growing Body of Research Demonstrating the Benefits of Remote Access Technologies:** extensive clinical studies exist for CMS to consult, including in the areas of: chronic condition management; heart failure management; diabetes management and medication adherence for chronic conditions which meet stringent review standards and have

⁸ 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.

⁹ 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/tdupWvOQI6b3dKdKcEgdGM/story.html>.

¹⁰ See <http://innovation.cms.gov/initiatives/independence-at-home/>.

¹¹ 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>.

demonstrated the benefits of non-synchronous telehealth and remote patient monitoring. In the attached appendix, TIA provides a list of numerous clinical studies that can inform CMS' consideration moving forward with its exploration of the benefits of remote access technologies. TIA urges for CMS to ensure that CMMI grants build upon the growing body of evidence demonstrating the benefits of remote patient monitoring technologies.

- **Technology- and Platform-Neutrality:** as CMS considers developing a model test, we urge CMS to use every opportunity to utilize these advanced technologies and work towards a more connected health care system, prioritizing technology- and platform-neutrality in CMMI program examinations. In other words, CMMI programs should set objectives, but avoid dictating how those objectives are met. Whether technologies that utilize or offer real-time interactive audio, or video telecommunications, asynchronous store-and-forward technologies, or remote monitoring services, the focus should be on the patient objectives and outcomes as opposed to the modality. Not only does this promote innovation, but it prevents favoritism of one solution or company over others, and in this way enhances competition. In other words, CMMI programs should utilize the diverse range of ICT innovations in exploring the use of remote access technologies in the basic benefit package, from remote monitoring to asynchronous store-and-forward solutions. While asynchronous store-and-forward solutions do have demonstrated value, more advanced synchronous monitoring technologies that break down the four walls of the hospital room hold great promise for reducing costs while improving patient care.¹²

¹² For example, the American Telemedicine Association offers numerous case studies that demonstrate the value of telemedicine. See <http://www.americantelemed.org/learn/telemedicine-case-studies>.

III. Conclusion

TIA advocates for the general extension of care beyond the hospital walls as a key step towards modernizing the delivery of health care, and we encourage CMS to allow and incentivize the use of remote access technologies at every opportunity.

TELECOMMUNICATIONS INDUSTRY ASSOCIATION

By: /s/ Danielle Coffey

Brian Scarpelli
Director, Government Affairs

David Gray
Associate, Government Affairs

TELECOMMUNICATIONS INDUSTRY ASSOCIATION

1320 North Courthouse Rd
Ste 200
Arlington, VA 22201
(703) 907-7000

APPENDIX: Existing Clinical Studies Demonstrating the Benefits of Remote Access Technologies

CHRONIC CONDITION MANAGEMENT

Veterans Administration: Study Size: Over 17,000 patients.

“Routine analysis of data obtained for quality and performance purposes from a cohort of 17,025 CCHT patients shows the benefits of a 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% after enrolment into the program. The cost of CCHT is \$1,600 per patient per annum, substantially less than other NIC programs and nursing home care. VHA's experience is that an enterprise-wide home telehealth implementation is an appropriate and cost-effective way of managing chronic care patients in both urban and rural settings.” “Care Coordination/Home Telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic condition” [Darkins A, Ryan P, Kobb R, Foster L, Edmonson E, Wakefield B, Lancaster AEs, Telemed J E Health. 2008 Dec;14(10):1118-26. doi: 10.1089/tmj.2008.0021.] <http://online.liebertpub.com/doi/pdf/10.1089/tmj.2008.0021>

Note: this specific area has been supplemented with further data from Darkins, available at:

<http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf>

Primary Care E-Visit v. Physician Office Visit: Study Size 8,000 Office and E-Visits

From The Washington Post, 1/21/2013: “A new study suggests that “e-visits” to health-care providers for sinus infections and urinary tract infections (UTIs) may be cheaper than in-person office visits and similarly effective.” [Ateev Mehrotra, MD; Suzanne Paone, DHA; G. Daniel Martich, MD; Steven M. Albert, PhD; Grant J. Shevchik, MD, JAMA Intern Med. 2013;173(1):72-74. doi: 10.1001/2013.jamainternmed.305] <http://archinte.jamanetwork.com/article.aspx?articleid=1392490>

Randomized Control Trial of Telehealth and Telecare: Study Size 6,191 patients, 238 GP practices

“The early indications show that if used correctly telehealth can deliver a 15% reduction in A&E visits, a 20% reduction in emergency admissions, a 14% reduction in elective admissions, a 14% reduction in bed days and an 8% reduction in tariff costs. More strikingly they also demonstrate a 45% reduction in mortality rates.” [Source: “Whole System Demonstrator Programme, Headline Findings – December 2011”, Department of Health, United Kingdom] http://www.telecare.org.uk/sites/default/files/file-directory/secure_annual_reports/Publications/Effect%20of%20Telehealth%20on%20use%20of%20secondary%20care%20and%20mortality%20findings%20from%20the%20WSD%20cluster%20randomised%20trial.pdf

HEART FAILURE MANAGEMENT

Remote Patient Monitoring of Heart Failure Patients, Meta analysis: Study Size 4,264 patients

“Remote monitoring programmes reduced rates of admission to hospital for chronic heart failure by 21% (95% confidence interval 11% to 31%) and all cause mortality by 20% (8% to 31%); of the six trials evaluating health related quality of life three reported significant benefits with remote monitoring.” [Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis, Robyn Clark, Sally Inglis, Finlay McAlister, John Cleland, Simon Stewart, MJ (British Medical Journal), doi:10.1136/bmj.39156.536968.55 (published 10 April 2007)]

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1865411/>

Remote Patient Monitoring of Heart Failure Patients, Meta analysis: Study Size 6,258/2,354 Patients

“RPM confers a significant protective clinical effect in patients with chronic HF compared with usual care.” [J Am Coll Cardio: 2009;54:1683-94]

<http://content.onlinejacc.org/article.aspx?articleid=1140154>

Telehome Monitoring Program: 1,000 Patients Enrolled

“Research at the Heart Institute has shown telehome monitoring at the Heart Institute has cut hospital readmission for heart failure by 54 percent with savings up to \$20,000 for each patient safely diverted from an emergency department visit, readmission and hospital stay.” [University of Ottawa Heart Institute, February 24, 2011, Press Release]

[http://www.heartandlung.org/article/S0147-9563\(07\)00084-2/fulltext](http://www.heartandlung.org/article/S0147-9563(07)00084-2/fulltext)

Remote Patient Monitoring at St. Vincent's Hospital:

“Impact: In less than two years, preliminary results show that the care management program implemented by St. Vincent Health and facilitated by the Guide platform reduced hospital readmissions to 5 percent for patients participating in the program – a 75 percent reduction compared to the control group (20 percent), and to the national average (20 percent).”[St. Vincent’s Hospital Reduces Readmissions by 75 percent with a Remote Patient Monitoring-Enabled Program, Case Study by Care Innovations, an Intel GE Company]

http://www.careinnovations.com/data/sites/1/downloads/Guide_product/guide_stvinc ent_profile.pdf

DIABETES MANAGEMENT:

Mobile Phone Personalized Behavior Coaching for Diabetes: Study Size 163 patients over 26 Practices

“Conclusions – The combination of behavioral mobile coaching with blood glucose data, lifestyle behaviors, and patient self-management individually analyzed and presented with evidence-based guidelines to providers substantially reduced glycated hemoglobin level over 1 year.” [Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control, Charlene Quinn, Michelle Shardell, Michael Terrin, Eric Barr, Soshana Ballew, Ann Gruber-Baldini, Diabetes Care. Published Online July 25, 2011]

<http://care.diabetesjournals.org/content/34/9/1934.long>

Mobile Phone Diabetes Management: Study Size 30 patients from 3 group practices

“Conclusions: Adults with type 2 diabetes using WellDoc’s software achieved statistically significant improvements in A1c. HCP and patient satisfaction with the system was clinically and statistically significant.” [WellDoc™ Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction, Charlene Quinn, Suzanne Sysko Clough, James Minor, Dan Lender, Maria Okafor, Ann Gruber-Baldini, Diabetes Technology & Therapeutics, Vol 10, Number 3, 2008, pps 160-168]

<http://online.liebertpub.com/doi/pdf/10.1089/dia.2008.0283>

MEDICATION ADHERENCE FOR CHRONIC CONDITIONS: 50 patients

“There was a trend toward increased prescription refill rates with the use of the Pill Phone application and a decrease after the application was discontinued” [Case study titled: “Medication Adherence and mHealth: The George Washington University and Wireless Reach Pill Phone Study”, Study designed, conducted and analyzed by George Washington University Medical Center; Qualcomm Wireless Reach Initiative was the primary funder of this study]

<http://www.qualcomm.com/media/documents/files/wireless-reach-case-study-united-states-pill-phone-english-.pdf>