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August 31, 2015

Attn: Twi Jackson
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P, P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: *Proposed Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for CY 2016, CMS-1633-P*

The undersigned organizations write to provide you with consensus views from across a wide array of stakeholders on the Center for Medicare and Medicaid Services (CMS) proposed revisions to the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2016.¹ We appreciate the opportunity to provide input on additional requirements for hospitals to bill and receive OPPS payment for Current Procedural Terminology® (CPT) code 99490, and provide comment on CMS' proposal that limits hospital reimbursement for CPT code 99490 for CCM

¹ See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System, 80 Fed. Reg. 39200 (Jul. 8, 2015).

services only when CCM is furnished to patients who are admitted to the hospital or registered as an outpatient of the hospital within the last 12 months and for whom the hospital furnished therapeutic services.²

Under the proposed rule, “a hospital would be able to bill CPT code 99490 for CCM services only when furnished to a patient who has been either admitted to the hospital as an inpatient or has been a registered outpatient of the hospital within the last 12 months and for whom the hospital furnished therapeutic services.”³

We propose a minor revision to these criteria. To ensure that certain beneficiaries are not unintentionally excluded from receiving CCM from their primary care practitioner, we respectfully request that CMS expand its proposed criteria to permit a hospital to bill for CPT 99490 if the physician or non-physician practitioner providing general supervision previously furnished CCM services for the beneficiary, regardless of whether that service was billed under the physician’s or practitioner’s National Provider Identification number or by a rural health clinic (RHC) or federally qualified health center (FQHC). Stated simply, if a practitioner accepts employment with a hospital and his or her practice is then converted to a hospital outpatient department some of the physicians’ patients who are Medicare beneficiaries receiving CCM services may be deemed as not having received any hospital inpatient or outpatient therapeutic services in the twelve months prior to the physician’s practice transition.

We also respectfully suggest that should CMS make any revisions to the CCM scope of service elements and billing requirements for group practices and solo practitioners, CMS should make corresponding changes to the elements and requirements for hospitals.

We urge CMS’ to use every administrative and policy tool to ensure coverage of provider use health information technology that improves care and care delivery. 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, from remote patient monitoring (RPM) 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.

CMS reimbursement policies do not permit reimbursement for the monitoring of patient-generated health data (PGHD). While Medicare coverage for telehealth is lacking⁴ due in part on CMS’ interpretation of its statutory authority and the restrictive governing payment for telehealth (Section 1834(m) of the Social Security Act⁵), CMS can take steps to improve coverage for RPM

² *Id.* at 39288-39290.

³ 80 Fed. Reg. 39,289 (July 8, 2015).

⁴ For example, according to the Centers for Medicare & Medicaid Services (CMS), Medicare telemedicine reimbursement totaled a mere \$13.9 million in Calendar Year 2014. See <http://ctel.org/2015/05/cms-medicare-reimburses-nearly-14-million-for-telemedicine-in-2014/>.

⁵ See 42 CFR §410.78.

(which is not telehealth services under Medicare’s definition of “interactive telecommunications systems”).⁶

Based on the above, we have found consensus around the following general priorities that we recommend to CMS:

- CMS should effect the establishment of an RPM benefit for beneficiaries with chronic conditions. CMS could, using its existing authority, provide adequate reimbursement for collection and interpretation of physiologic data stored/transmitted by patient/caregiver by “unbundling” the relevant code CPT 99091.⁷ Such a practice would align with CMS’ established approach to chronic care management in CPT 99490, where, because the challenges of preventing and managing chronic disease caused “the focus of primary care [to evolve] from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management,” CMS found that the reimbursement for chronic care management that had historically been included in evaluation and management (E/M) codes was insufficient; as a result, CMS concluded that chronic care management should be separately reimbursed, and noted its anticipation that increased reimbursement for chronic care management (CCM) will be more than offset by the corresponding reduction in more costly services.
- CMS should ensure that improvements to chronic care management are applied widely to any Alternative Payment Model plan under consideration or implementation by the Center for Medicare & Medicaid Innovation (CMMI). We urge CMS to ensure that it works to apply improvements to patients with chronic conditions across CMMI (Independence At Home, bundled payment plans, etc.).
- We are concerned with the lack of focus on tracking use and benefits of telehealth and remote patient monitoring in CMS’ CMMI innovation grants despite provisions in its authorizing legislation that list payment models that could be tested, including telehealth technology and remote patient monitoring.

A well-established, and ever-growing, body of clinical evidence suggests that interoperable remote monitoring improves care, reduces hospitalizations, helps avoid complications, and improves satisfaction, particularly for the chronically ill.⁸ Use and provision

⁶ In addition to the restrictions on telehealth services in 1834(m) of the Social Security Act, we note that “interactive telecommunications systems” are not defined in any relevant part of the Social Security Act. Rather, CMS chose to define “interactive telecommunications systems” in its 2001 Physician Fee Schedule final rulemaking to include at a minimum, audio and video equipment that hat permits real time consultation between the patient and physician, or practitioner at the distance site. *See* 66 Fed. Reg. 55, 281 (Nov. 11, 2000).

⁷ Medicare considers CPT Code 99091 (“Physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver”) as “bundled” into payment for other basic services (*e.g.*, an office visit provided the same day or other services incident to the service provided) and therefore does not currently make separate payment for 99091.

⁸ *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>.

of RPM is restrained in Medicare by CMS' decision to provide no reimbursement for it. We urge CMS (and other federal payors) to utilize every opportunity to incorporate RPM and other proven eCare technology based health care delivery to work towards a connected healthcare system.

Despite these over-burdensome restrictions, remote patient monitoring of PGHD is increasingly being proven as an important aspect of any healthcare system. The known benefits of remote patient monitoring services, as stated above, include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.⁹ 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.¹⁰ Telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are all up-and-coming technologies that are revolutionizing remote patient monitoring and the medical care industry, representing an immense opportunity. 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.¹¹ RPM has the potential to positively engage patients when addressing chronic and persistent disease states to improve management of chronic conditions.¹² The Hackensack Alliance in New Jersey reduced readmission rates from 28% to 5% for congestive heart failure patients.¹³ Christus Health reduced the average cost for congestive heart failure readmissions from \$12,937 compared to \$1,231 per re-admission after implementing a remote patient monitoring system.¹⁴ Further, we have appended to this letter a non-exclusive list of studies demonstrating the value of telehealth and RPM to patients with chronic conditions.

In its CY 2015 Physician Fee Schedule,¹⁵ CMS established provisions for a chronic care management procedural terminology (CPT) code and permitted CCM delivery through remote

⁹ 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>.

¹⁰ 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>.

¹¹ 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.

¹² Agboola, Stephen, et al. "Home blood pressure monitoring program improves management of hypertension." *Circulation: Cardiovascular Quality and Outcomes* 5.3 Supplement (2012): A118.

¹³ [Use Case Study: Hackensack Alliance ACO - Remote Patient Monitoring for Chronic Disease. HIMSS, 2014](#)

¹⁴ [Use Case Study: Christus Health –Remote Patient Monitoring and Chronic Disease. HIMSS 2014](#)

¹⁵ 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>.

patient monitoring technologies. Further, CMS has proposed to further expand Medicare to support new telehealth services in CY 2016.¹⁶ We urge CMS to build upon these steps to put in place coverage for RPM for beneficiaries with chronic conditions and support reimbursement for hospital outpatient delivered CCM. We note several key points for consideration in finalizing CCM standards for the Medicare OPPS:

- We encourage you to take a technology-neutral approach for health information technology used to provide CCM.
- We strongly urge CMS to avoid placing over burdensome requirements on 99490. Specifically, we recommend that CMS eliminate the requirement for a certified EHRs since current certified EHRs do not include standards and capabilities supporting chronic care management that are core services for CCM.

We commend CMS for undertaking edits to modernize the American healthcare system for those beneficiaries most in need, and urge consideration of the above consensus views.

Respectfully submitted,

American Association for Respiratory Care (AARC)
American Telemedicine Association (ATA)
Baxter Corporation
Intel
Personal Connected Health Alliance (PCHA)
Qualcomm
Telecommunications Industry Association (TIA)
Underwriters Laboratories
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¹⁶ See *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016*, 80 Fed. Reg. 41685 (Jul. 15, 2015).

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

CHRONIC CONDITION MANAGEMENT

Adam Darkins: Telehealth and the VA FY2013 Report

In FY2013, **608,900 (11%)** of veterans received some element of their health care via telehealth. This amounted to **1,793,496** telehealth episodes of care. **45%** of these patients lived in rural areas.

Home Telehealth Services: Helps patients with chronic conditions

- Provided care for 144,520 veterans
- 59% reduction in bed days of care
- 35% reduction in hospital readmissions
- Saves \$1,999 per annum per patient
- 84% patient satisfaction

Store-and-Forward Telehealth: Remote scanning, then send to specialist

- Served 311,396 veterans
- 95% patient satisfaction
- Saves \$38.41 per consultation

Clinical Video Telehealth: Real-time video consultation that covers over 44 specialties

- 94% patient satisfaction
- Saves \$34.45 per consultation

TeleMental Health

- Over 278,000 encounters to 91,000 patients
- 1.1 million patient encounters since FY2003
- Reduced bed days of care by 38%
- Nearly 7,500 patients with chronic mental health conditions are now living independently thanks to TeleMental Health

The number of veterans receiving care through telehealth is climbing by **22%** each year.

<http://ehrintelligence.com/2014/06/23/va-reduces-admissions-by-35-due-to-telemedicine-services/>

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

<http://www.va.gov/health/NewsFeatures/2014/June/Connecting-Veterans-with-Telehealth.asp>

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 MANAGAGEMENT

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 convers 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_stvincent_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>