June 27, 2016

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5517-P  
P.O. Box 8013  
Baltimore, Maryland 21244-8013

RE: Multistakeholder Consensus Comments regarding Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

The undersigned organizations write to provide comments to the Center for Medicare and Medicaid Services (CMS) in response to its proposed rule establishing the Merit-based Incentive Payment System (MIPS) for MIPS-eligible clinicians or groups under the Physician Fee Schedule (PFS) as well as incentives for participation in certain alternative payment models (APMs) and criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making recommendations on physician-focused payment models.¹

We represent a wide – and growing – coalition of stakeholders that span the healthcare and technology sectors who hold that a consistently growing body of evidence has demonstrated that the wide array of connect health technologies available today – whether called “telehealth,” “mHealth,” “store and forward,” “remote patient monitoring,” or other similar terms – improve patient care, reduce hospitalizations, help avoid complications, and improve patient engagement, particularly for the chronically ill.² These tools, ranging from wireless health products, mobile medical device data systems, converged medical devices, and cloud-based patient portals (to name a few) are revolutionizing the medical care industry by allowing the incorporation of patient-generated health data (PGHD) into the continuum of care. To illustrate the effectiveness of these diverse solutions, we have appended to this comment a non-exclusive list of studies we strongly urge CMS to review.

¹ Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, 81 Fed. Reg. 28161 (May 9, 2016).

Despite the proven benefits of connected health technology to the American healthcare system, these solutions are largely ignored by the current Medicare system. For example, according to the Centers for Medicare & Medicaid Services (CMS), traditional fee-for-service Medicare “telehealth” reimbursement totaled a mere $13.9 million in calendar year 2014. Remote monitoring technologies, which are mostly dependent on technologies disallowed as telehealth services, are unreasonably restrained by CMS’ decision to bundle monitoring with other codes, resulting in a lack of reimbursement for remote monitoring solutions.

CMS has relatively recently started to take steps to better utilize connected health technology in several components of Medicare, such as for the Medicare Shared Savings Program. However, the protracted pace at which the system is being altered to incorporate connected technologies leaves the Medicare system and the millions of Americans it serves with outdated, inefficient, and ineffective methods and treatments.

With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress has clearly directed CMS to evolve broadly the Medicare program to maximize care quality over quantity, arguably requiring the system to embrace enhancements like connected health technology. Through this rulemaking, CMS has an unprecedented opportunity to improve the American healthcare system by leveraging a wide array of connected health technologies – those available today as well as future innovations.

We urge CMS to utilize every opportunity available to progress towards a truly connected continuum of care through its implementation of MACRA. Further, we, urge CMS to consider and adopt the following:

- As a threshold issue, CMS cannot continue to rely on Medicare’s over 15-year-old definitional restraints to “telehealth” in 42 CFR 410.78 to serve as a definition of telehealth. To shift truly to a value-driven approach, the Medicare system must leverage the wide array of advanced connected health technology solutions available today, as well as future innovations we cannot predict. CMS should evolve its telehealth definition to one that takes a technologically-neutral approach to the use of connected health, and provides the flexibility for eligible practitioners to appropriately utilize the range of these solutions, lowering costs to Medicare while vastly improving patient care. Because providers are encouraged to report telehealth delivered care in MIPS, it is essential that the definition of telehealth be a technology neutral definition that may adapt with the clinical evidence base.

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4 For example, 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.
• Congress specifically states that the Clinical Practice Improvement Activity (CPIA) “shall include activities such as…remote monitoring or telehealth” under the Care Coordination performance subcategory, signaling these technologies’ importance in widely supporting providers through the transition from volume- to value-based reimbursement. The CPIA Inventory should provide a robust menu of activities that, through appropriate use of remote monitoring and telehealth (and consumer-oriented digital and interoperable information technology), eligible practitioners may use for care improvement. It is crucial that the Inventory, from which all MIPS-eligible clinicians or groups must select activities, reflects both Congressional intent and the demonstrated benefits of connected technologies to the Medicare program.

• The Advancing Care Information (ACI) program should utilize an outcome-based approach that incent practitioners to flexibly incorporate digital and interoperable PGHD into their activities. Incorporating PGHD into the ACI program is consistent with the direction of HHS health technology policy, such as the ongoing ONC effort to develop a PGHD framework.

• For APMs, CMS should waive the entirety of 1834(m)’s restrictions that have caused the Medicare system to utilize a backwards-looking approach to connected health technology. From the perspective of wanting to attract participants in the APM program, being able to offer less restricted telehealth can be a reward and a competitive advantage. Further, this approach would allow these APMs to take the lead in demonstrating the value of connected health technologies in innovating care delivery and improving access and efficient delivery of care, in both rural and urban settings. APMs should also have the flexibility to provide other telehealth services, including remote monitoring for beneficiaries with specific at-risk chronic conditions.
The undersigned urge your consideration of the consensus of the broad community of stakeholders which support the wide use of remote monitoring and telehealth solutions to improve the U.S. healthcare system, by promoting value, increasing quality, and reducing costs. We welcome the opportunity to work with you and your designees on to reach this goal.

Respectfully submitted,

ACT | The App Association
AirStrip
American Academy of Neurology
American Academy of Sleep Medicine
American Association for Respiratory Care
American Heart Association
American Telemedicine Association
Avizia
Baxter Corporation
Biocom
California Life Sciences Association
CareSync
Cerner
CHRISTUS Health
College of Healthcare Information Management Executives
Connected Health Initiative
CTIA
Dogtown Media
Hahnemann University Hospital
Hill-Rom
HIMSS
LifeWIRE
Locus Health
National Association of Community Health Centers
NTCA–The Rural Broadband Association
Panasonic Corporation of North America
Personal Connected Health Alliance
Qualcomm Incorporated and Qualcomm Life
Rimidi
Stroll Health
Symple Health
University of Mississippi Medical Center – Center for Telehealth
Key Clinical Studies Demonstrating the Benefits of Connected Health Technologies

**CHRONIC CONDITION MANAGEMENT**

**Audit of the Veterans Health Administration Home Telehealth Program: Over 15,000 patients**

On March 09, 2015 the VA Office of Inspector General released an Audit which showed that the Home Telehealth Program increase patient access and reduced costs by reducing the number of admissions. For example, before the program there were 2,365 admissions over six months by the over 15,000 patients who participated in the Home Telehealth Program. After the program there were 1,773 admissions for the following six months. This equates to about 8 fewer hospital admissions for every 100 patients in this program.


**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.

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”


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.”

[Attev 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]

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.”


Reduced Hospitalizations of Nursing Facility Residents
A study that introduced telemedicine in a Massachusetts for-profit nursing home chain, during the period October 2009 – September 2011, demonstrates the cost-effectiveness of utilizing telemedicine to reduce potential re-hospitalizations for nursing facility patients. The study’s findings show that savings to Medicare from using telemedicine to reduce re-hospitalizations for nursing facility patients exceed the investment in the telemedicine equipment.
• The findings of the study suggest that the nursing facilities that were more engaged in off-hours telemedicine coverage could generate cost savings for Medicare that exceeded the facility’s investment in the telemedicine service.
• The average savings to Medicare for a nursing facility that participated and was engaged with telemedicine, was $151,000 per nursing facility per year, relative to the less-engaged facilities.
• During the two-year period, the rate of hospitalizations per 1,000 resident days declined across the pre- and post-intervention periods for both the treatment and the control groups.
• The difference in the hospitalizations in the treatment group was 4.4 percentage points lower.


Integrated Telehealth And Care Management Program For Medicare Beneficiaries With Chronic Disease Linked To Savings

A study from the Health Affairs found significant savings among patients who used the Health Buddy telehealth program, which integrates a telehealth tool with care management for chronically ill Medicare beneficiaries. Specifically, patients who utilized the Health Buddy Program saw spending reductions of approximately 7.7–13.3 percent ($312–$542) per person per quarter.

September 2011: http://content.healthaffairs.org/content/30/9/1689.abstra

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.”


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
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]

Program Evaluation of Remote Heart Failure Monitoring: Healthcare Utilization Analysis in a Rural Regional Medical Center

“HF patients enrolled in this program showed substantial and statistically significant reductions in healthcare utilization during the 6 months following enrollment, and these reductions were significantly greater compared with those who declined to participate but not when compared with a matched cohort... The findings from this project indicate that a remote HF monitoring program can be successfully implemented in a rural, underserved area. Reductions in healthcare utilization were observed among program participants, but reductions were also observed among a matched cohort, illustrating the need for rigorous assessment of the effects of HF remote monitoring programs in healthcare systems.”

William T. Riley, PhD, corresponding author Pamela Keberlein, RN, MSN, Gigi Sorenson, RN, MSN, Sailor Mohler, BS, Blake Tye, MPIA, A. Susana Ramirez, PhD, and Mark Carroll, MD, Telemed J E Health. 2015 March 1; 21(3): 157–162. doi: 10.1089/tmj.2014.0093.
[http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365431/]

DIABETES MANAGEMENT

Early Results Support Efficacy and Clinical efficiency of Diabetes Management Decision support software for Blood Glucose Control: Two cohorts of 43 comparative cases

Preliminary results from an ongoing study by Rimidi indicate that the decision support software, Diabetes+Me, helps to ensure a safe but meaningful reduction in A1c and therefore reduction in event rate as well as overall healthcare costs. Diabetes+Me has not only lead to improved benefits to patients, but has also allowed Desert Oasis healthcare, the facility who is conducting the study, to expand the scalability of its already successful diabetes management program without having to make the expensive investment of hiring additional healthcare providers.

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.”


RESPIRATORY AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE MANAGEMENT

Content-Driven Telehealth System Coupled with Care Management: Study Size Medicare patients enrolled in CMS’ Health Buddy Program demonstration from 2006-2010
The Health Buddy Program is a content-driven telehealth system combined with care management designed to enhance patient education, self-management, and timely access to care. “The Health Buddy Program was associated with 23% lower quarterly all-cause hospital admissions and 40% lower quarterly respiratory-related hospital admissions compared to baseline for intervention beneficiaries vs. controls. In subgroup analyses, patients who engaged in the intervention during the study period (n=247) demonstrated significantly lower quarterly hospital admissions for chronic obstructive pulmonary disease exacerbations. CONCLUSIONS: A content-driven telehealth system combined with care management has the potential to improve health outcomes in Medicare beneficiaries with chronic obstructive pulmonary disease.”


Home Telehealth for Patients with Severe COPD: 60 patients
Telehealth is an important part of the need for innovative models of care for patients with severe COPD and frequent acute exacerbations. In a cluster assignment, controlled trial study design, 60 patients were recruited: 30 in home telehealth (TH) and 30 in conventional care (CC). Results: “After 7-months of monitoring and follow-up, there was significant reduction in ER visits (20 in HT vs 57 in CC), hospitalizations (12 vs 33), length of hospital stay in (105 vs 276 days), and even need for non-invasive mechanical ventilation (0 vs 8, all p < 0.05)


Tele-assistance (TA) in chronic respiratory failure patients: 240 patients (101 with COPD)
Chronic respiratory patients requiring oxygen or home mechanical ventilation experience frequent exacerbations and hospitalizations with related costs. Patients were randomized into two groups: an intervention group (1-year TA) and control group (conventional care). “Compared with controls, the TA group experienced significantly fewer hospitalizations (-36%), fewer GP calls (-65%) and acute exacerbations (-71%). After deduction of TA costs, the average overall cost for each patient was 33% less than for usual care.”

**Home telemonitoring program: 369 patients with at least one COPD exacerbation per year prior to enrollment**

The study was designed to evaluate the effects of home telemonitoring on healthcare utilization in patients with COPD. “Of these, 71.5% had a reduction in number of ED visits and exacerbations requiring hospitalization after enrollment in the program. The average number of hospital admissions, ED visits, and total exacerbations were all reduced (0.41 ± 1.68, 0.15 ± 1.65, and 0.56 ± 2.3, respectively; all with p < 0.01).”


**Telehealth Program for CPAP Adherence: 122 patients**

This study evaluated the effectiveness of coaching labor requirements of a web-based automated telehealth (TH) messaging program compared with standard of care (SOC) in newly diagnosed patients with obstructive sleep apnea. “There was a significant reduction in the number of minutes coaching [by respiratory therapists] required per patient in the TH vs SOC group (23.9 ± 26 vs. 58.3 ± 25, 59% reduction; p < 0.0001).”


**Telemedicine Versus Face-to-Face Evaluations by Respiratory Therapists**

The study aimed to determine how well respiratory assessments for ventilated neonates and children correlated when performed simultaneously by 2 RTs face-to-face and via telemedicine.

“Telemedicine evaluations highly correlated with face-to-face for 10 of 14 aspects of standard bedside respiratory assessment.”


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**MEDICATION ADHERENCE FOR CHRONIC CONDITIONS**

**Case Study: Medication Adherence and mHealth: The George Washington University and Wireless Research Pill Phone Study**

The research study was designed to determine if the Pill Phone mobile application can improve medication adherence in underserved hypertensive populations. “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.”
BLOOD PRESSURE MANAGEMENT

Using simple telehealth in primary care to reduce blood pressure: a service evaluation (n=364) with 124 intervention patients. “Conclusions: Simple telehealth is acceptable and effective in reducing patients’ BP. In future, poorly controlled patients could be targeted to maximize BP reductions or broader use could improve diagnostic accuracy and accessibility for patients who struggle to regularly attend their GP surgery.”

http://bmjopen.bmj.com/content/2/6/e001391