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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: Comments of the Connected Health Initiative 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)
  - I. Introduction and Statement of Interest

The Connected Health Initiative (CHI) writes 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.<sup>1</sup>

The CHI, convened by ACT | The App Association, is the leading effort by connected health ecosystem stakeholders to clarify outdated health regulations, incent the use of remote patient monitoring (RPM), and ensure the environment is one in which patients and consumers can see improvement in their health.<sup>2</sup> This coalition of leading mobile health companies and key stakeholders urges Congress, the Office of the National Coordinator for Health Information Technologies (ONC), the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

<sup>&</sup>lt;sup>1</sup> 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).

<sup>&</sup>lt;sup>2</sup> <u>http://connectedhi.com</u>.

II. Connected Health's Integral Role in the Future of Medicare

A consistently growing body of evidence demonstrates that the wide array of connected health technologies available today – whether called "telehealth," "mHealth," "store and forward," "remote patient monitoring," or other similar terms – improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement, particularly for the chronically ill.<sup>3</sup> These tools, ranging from wireless health products, mobile medical device data systems, telehealth screening and preventive services, 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.

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 CMS, traditional fee-for-service Medicare "telehealth" reimbursement totaled a mere \$13.9 million in calendar year 2014.<sup>4</sup> 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.<sup>5</sup>

CMS has relatively recently begun 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 very 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.

<sup>&</sup>lt;sup>3</sup> 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 III Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs (last updated Feb. 6, 2013), available at <u>http://www.innovations.ahrg.gov/content.aspx?id=3006</u>.

<sup>&</sup>lt;sup>4</sup> <u>http://ctel.org/2015/05/cms-medicarereimburses-nearly-14-million-for-telemedicine-in-2014/</u>.

<sup>&</sup>lt;sup>5</sup> 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.

We urge CMS to utilize every opportunity available to progress towards a truly connected continuum of care through its implementation of MACRA. Further, CHI provides specific input below on key opportunities for CMS under this rulemaking. Specifically:

- As a threshold issue, CMS cannot continue to rely on Medicare's over 15-year-old definitional restraints on "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 may and 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.
- 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 or 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 incents practitioners to incorporate PGHD flexibly into their activities. Incorporating digital interoperable 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.
- III. CMS Should Update its Telehealth Definition of "Interactive Telecommunications Service"

The CHI is encouraged by proposals from CMS that embrace connected health technologies. For example, CMS proposes to include telehealth services in the definition of patient-facing encounters.<sup>6</sup> CMS also states that Medicare-eligible telehealth services can "substitute for an inperson encounter and meet other site requirements under the PFS as defined at 42 CFR 410.78."<sup>7</sup> Uncertainty remains, however, about whether CMS will continue to limit unreasonably these "telehealth" services to 42 CFR 410.78's current restraints. Specifically, because 1834(m) requires that telehealth utilize an "interactive telecommunications system," we urge CMS to update properly its now 16-year-old definition of an "interactive telecommunications system" to reflect the wide range of connected health technology available today. Furthermore, as discussed throughout this submission, CMS should exercise its established authority to waive arduous restrictions imposed by 1834(m) on "telehealth."

The term "interactive telecommunications system" is not defined in Section 1834(m) or any other relevant statute text. The limited definition of this term originates in the 2001 Medicare Physician Fee Schedule Final Rule, where CMS promulgated 42 CFR 410.78 in establishing the billing rules for telehealth services. CMS offered the following explanation of the relevant regulatory provision in the regulatory preamble (emphasis added):<sup>8</sup>

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. *We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication* between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous store and forward technologies as the transmission of the patient's medical information from an originating site to the physician or practitioner at the

<sup>&</sup>lt;sup>6</sup> See 81 FR 28175.

<sup>7</sup> Id.

<sup>&</sup>lt;sup>8</sup> Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule, 66 Fed. Reg. 55,281 (Nov. 1, 2001).

distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan.

CMS' legacy definition of the statutory term "interactive telecommunications system" to require the use of "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication"<sup>9</sup> is now unmistakably out-of-date given the diverse and innovative developments in connected health technology since 2001. Notably, there is no statutory restriction prohibiting CMS from replacing its outdated reference to "audio and video equipment permitting two-way, real-time interactive communication" with something more modern to capture the reality of medical technology including remote monitoring. This definition should be technologically-neutral and provide maximum flexibility so that eligible practitioners can appropriately utilize a range of connected health solutions, lowering costs to Medicare while vastly improving patient care.<sup>10</sup> CMS can do this by replacing "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication" within this definition with "devices and/or software permitting transmission of data."

IV. CMS Should Embrace Connected Health Technology in the MIPS Clinical Practice Improvement Activities, Consistent with Congress' Intent

Initially, we note our support for CMS' overall approach to the CPIA, which has taken a more goaloriented and technology-neutral approach to compliance. This shift is important because it will provide needed flexibility to MIPS practitioners to select the most effective approaches for their patients. MACRA lists six CPIA subcategories that contribute to the MIPS composite score:<sup>11</sup>

- (1) Expanded practice access;
- (2) Population management;

<sup>&</sup>lt;sup>9</sup> 42 CFR 410.78(a)(3). We further note that Section 190 in Chapter 12 of the Medicare Claims Processing Manual notes that "[a]n interactive telecommunications system is required as a condition of payment; however, [the law] does allow the use of asynchronous "store and forward" technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii."

<sup>&</sup>lt;sup>10</sup> Such an approach would be consistent with U.S. government policies supporting outcome-driven and technology-neutral approaches in agency decisions. *See, e.g.*, Office of Management and Budget (OMB) Circular A-4, Regulatory Analysis, available at <a href="https://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf">https://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf</a> ("Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way."); see also OMB Memorandum on Technology Neutrality, available at <a href="https://www.whitehouse.gov/sites/default/files/omb/assets/egov\_docs/memotociostechnologyneutrality.pdf">https://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf</a> ("...as program, IT, acquisition, and other officials work together to develop requirements and plan acquisitions, they should follow technology neutral principles and practices.").

<sup>&</sup>lt;sup>11</sup> MACRA Section 101(c)(2)(B)(iii)(II).

- (3) Care coordination, "including use of remote monitoring or telehealth;"
- (4) Beneficiary engagement;
- (5) Patient safety and practice assessment; and
- (6) Participation in an APM.

CMS has further proposed to add three new additional subcategories: Achieving Health Equity; Integrating Behavioral and Mental Health; and Emergency Preparedness and Response; and has suggested comment on two further future subcategories: Promoting Health Equity and Continuity, and Social and Community Involvement.<sup>12</sup>

By specifically including "shall include activities such as...remote monitoring or telehealth" under the Care Coordination performance subcategory, Congress signaled 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 or telehealth (and consumer-oriented information technology), eligible practitioners may use for clinical care improvement. It is crucial that the CPIA Inventory, from which all MIPS-eligible clinicians or groups must select activities, reflect both Congressional intent and the benefits of connected technologies to the Medicare program. CMS should look for ways to provide MIPS clinicians with the flexibility in as many ways as practicable to utilize these innovations. For example, we believe that CMS should specify that CPIA Inventory activities may be satisfied through use of any medical device that is listed (Class I), cleared (Class II), or approved (Class III) by the FDA; or under the agency's enforcement discretion (meaning FDA does not intend to enforce requirements under the FD&C Act).<sup>13</sup>

Further, while we appreciate CMS undertaking an environmental scan to ensure the initial CPIA Inventory is inclusive of activities in line with the statutory intent,<sup>14</sup> this evaluation must reflect that remote monitoring or telehealth are key activities that contribute to the improvement of beneficiary health outcomes by reducing healthcare disparities, regardless of whether the patient resides in a rural or urban location. CMS should specify how the use of connected health technologies will help eligible MIPS clinicians across each CPIA subcategory.

However, as proposed, the Inventory does not reflect the unambiguous Congressional intent noted above, nor does it adequately reflect the benefits of connected health technology to the CPIA program generally. For example, the Inventory contains more than 90 activities with descriptions, yet only includes two references to using remote monitoring or telehealth. Further, despite the clear language of MACRA Section 101(c)(2)(B)(iii)(II), the Inventory of activities for Care Coordination

<sup>&</sup>lt;sup>12</sup> 81 FR 28212-28213.

<sup>&</sup>lt;sup>13</sup> See Mobile Medical Applications, 2015 Guidance for Industry and Food and Drug Administration Staff Document, *available at* <u>http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf</u>.

<sup>&</sup>lt;sup>14</sup> 81 FR 28213-28214.

contains minimal references to remote monitoring or telehealth. In addition, the CPIA Inventory contains text that would restrict the use of such technologies to those in "rural or remote" locations, presenting the potential that onerous 1834(m) geographic restrictions might continue in the CPIA program.

We therefore request a rationale from CMS for the inadequate inclusion of remote monitoring or telehealth in the CPIA Inventory and believe that CMS must revisit the CPIA to clearly communicate to those consulting the final rule and the Inventory the prominent role remote monitoring or telehealth plays in satisfying subcategories across the CPIA (or, at minimum, in all Care Coordination). We believe that CMS can accomplish this in a way that preserves clinician flexibility through changes to text within the "Activities" column to Table H. To assist CMS, we have appended proposed updates to many of the Inventory's activities with changes reviewable in redline.

Further, in response to certain detailed questions and issues raised by CMS under the CPIA:

- In response to CMS' request for comment on how to weigh PCMHs in the MIPS program,<sup>15</sup> we believe that PCMHs and similar Medicare demonstration models should continue to achieve the highest score for the program. In particular, CMS should factor criteria such as the effective use of electronic tools (for example, remote physiologic monitoring, electronic data acquisition and reminders, patient education modules, and informed decision making tools), which should correlate with each subcategory within the CPIA Inventory.
- CMS requests input on the appropriate activities for non-patient-facing MIPS-eligible clinicians or groups.<sup>16</sup> We believe that these activities should be similar to the CMS list of permissible telehealth services for distant site practitioners who may furnish and receive payment for covered telehealth services<sup>17</sup> (subject to state law). In addition, consistent with our views above on the MIPS program generally, we strongly urge CMS to waive the arduous restrictions in 1834(m) for telehealth services for distant site practitioners.
- CMS requests comment on the appropriate CPIA activities for small practices and practices located in rural areas, or practices in geographic Healthcare Professional Shortage Areas (HPSAs).<sup>18</sup> We urge CMS to ensure that this list is akin to the CMS list of permissible telehealth services for distant site practitioners who may furnish and receive payment for covered telehealth services (subject to state law).
- CMS proposes to, in order to better understand the current processes and limitations, conduct a study on CPIAs and measurement to examine clinical quality workflows and data

<sup>&</sup>lt;sup>15</sup> 81 FR 28210.

<sup>&</sup>lt;sup>16</sup> 81 FR 28212.

<sup>&</sup>lt;sup>17</sup> See CMS, Telehealth Services C 2016 Fact Sheet, *available at* <u>https://www.cms.gov/Outreach-and-Education/Medicare-</u> Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcsfctsht.pdf.

<sup>&</sup>lt;sup>18</sup> 81 FR 28212.

capture using a simpler approach to quality measures.<sup>19</sup> We support CMS' exploration of ways for clinicians to improve data and workflows in both urban and rural settings. We strongly urge CMS to ensure that this study within the CPIA explore the full continuum of care discussed above, which must include the integration of PGHD collected from outside of the clinician's facility. Further, these studies should be coordinated with ONC's development of a policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery through 2024.<sup>20</sup> We support this effort within ONC as remote monitoring of PGHD continues to represent the most promising avenue for improving care quality while lowering costs.

- We support CMS' proposal to develop a call for measures and activities processes for future years of MIPS, where MIPS-eligible clinicians or groups and other relevant stakeholders may recommend activities for potential inclusion in the CPIA Inventory.<sup>21</sup> As part of the process, MIPS-eligible clinicians or groups should be able to nominate additional activities that CMS could consider adding to the CPIA Inventory, particularly in the areas of remote monitoring, telehealth, and connected digital healthcare. We believe that this has been more than adequately demonstrated through the work of sister U.S. government agencies (Agency for Healthcare Research and Quality, ONC, Department of Veterans Affairs, etc.) as well as through a strong evidence base (e.g., our effectiveness study appendix).
- V. The Advancing Care Information (ACI) Program Should Facilitate Practitioners to Flexibly Attain Relevant and Interoperable Data

The MACRA Advancing Care Information (ACI) program provides CMS with an important opportunity to improve vastly on the Meaningful Use program, the ACI program's predecessor. We believe that the ACI program should utilize an outcome-based approach that incents practitioners to incorporate PGHD flexibly into their activities. We also note that while patient access to data is important, clinicians also need interoperable data from a variety of sources to integrate seamlessly into their work flow. Third party applications will play a major role in satisfying this need to ensure data "quality" so that physicians get the most relevant data in a useable format, when and where they need it.

In its final rules for Meaningful Use Stage 3 (MU3) of the EHR program, CMS already took steps to support the interoperable exchange of health information by including API utilization within its view, download, and transmit (VDT) criteria, as well as related measures regarding secure messaging and PGHD. CMS has included this Objective into its proposed ACI program.<sup>22</sup> The CHI

<sup>&</sup>lt;sup>19</sup> 81 FR 28214.

<sup>&</sup>lt;sup>20</sup> <u>http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2023-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html</u>.

<sup>&</sup>lt;sup>21</sup> 81 FR 28215.

<sup>&</sup>lt;sup>22</sup> 81 FR 28227.

supports PGHD's inclusion in the ACI program's certification criteria. We further note that incorporating PGHD in the ACI program is consistent with the direction of HHS health technology policy, such as the ongoing ONC effort to develop a PGHD framework.<sup>23</sup>

However, we urge CMS (as well as ONC) to ensure that providers utilizing connected health solutions are not incented to limit the innovative features of their products and services due to overly-prescriptive ACI program requirements. ACI program measures should therefore provide flexibility for physicians and other clinicians to select the most effective approaches for their patients through outcome-based measures that are agnostic to the processes used to meet those goals.

VI. Restrictions on Remote Monitoring and Telehealth Should be Waived for Alternative Payment Models

We also support Congress's goal of realizing innovative APMs, and continue to work across the stakeholder community towards eligible alternatives to MIPS. At a minimum, we strongly believe that APMs must affect the utilization of connected health technology in a significantly expanded way, consistent with the discussion above. APMs, with their financial and operational incentives, should lead in demonstrating the best uses of remote monitoring or telehealth tools. For this reason, we find the current restrictions of 1834(m) particularly inappropriate for such Medicare services, and strongly support allowing APMs relief from the onerous Medicare telehealth restrictions in 1834(m).

Already, in a limited set of circumstances, CMS has taken steps to provide relief from 1834(m)'s originating site requirements in section 1834(m)(4)(C) to APMs, demonstration projects, and Innovation Center models. For example, CMS provided this limited relief to Next Generation Accountable Care Organizations (ACOs).<sup>24</sup> In addition, in the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, CMS waived the rural geographic requirement and allowed telehealth services to be covered in patients' homes or their place of residence.<sup>25</sup>

While these small steps are encouraging, this rulemaking presents CMS with a golden opportunity to extend waivers to APMs from all 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, such a waiver would allow these APMs to take the lead in demonstrating the value of connected health technologies in innovating care

<sup>&</sup>lt;sup>23</sup> https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data-pghd.

<sup>&</sup>lt;sup>24</sup> <u>https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/.</u>

<sup>&</sup>lt;sup>25</sup> Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 FR 73273 (Nov. 24, 2015).

delivery and improving access and efficient delivery of care, in both rural and urban settings. APM quality and performance measures and other participation requirements will provide protection against fraud and Medicare's traditional fee-for-service utilization controls.

Further, an APM should have the flexibility to utilize connected health technology for beneficiaries with specific at-risk chronic conditions. In addition to the statutory benefits enjoyed by qualifying alternative payment model participants, including the initial five percent incentive payment under the PFS, CMS should waive specific payment and program requirements for these participants. Specifically, in order to help providers utilizing APMs to meet statutory requirements to reduce total costs, CMS should exercise its statutory authority under 42 U.S.C. 1315a(d)(1) (in the case of CMMI Models) and 42 U.S.C. 1395jjj(f) (in the case of the Medicare Shared Savings Program) to waive payment and program requirements as appropriate to allow for remote monitoring to be used to improve quality while reducing per capita total costs of care. Those entities using APMs would not utilize remote monitoring services unless total care costs would be reduced. Therefore, CMS' use of relevant waiver authority to allow payment for remote monitoring – including the unbundling of CPT Code 99091 as noted above – would enable the success of APMs.

# VII. CMS Should Permit Physician Flexibility in MIPS and APM Participation

We appreciate the complexities associated with the needed changes being made to the Medicare program. To ensure that the physicians who will rely on payment under MIPS and APMs, CMS should examine flexibility in the implementation of new programs under MACRA. We therefore request that CMS permit physicians to elect to extend their implementation of new rules under this rulemaking by 6-12 months in order to aid in the transitioning to a new and improved Medicare system that prioritizes quality over quantity.

# VIII. Conclusion

We appreciate the opportunity to submit comments to CMS on this matter and look forward to the opportunity to further work on these issues in more depth. Thank you for your consideration.

Sincerely,

Morga Reed

Morgan Reed

Acting Director Connected Health Initiative

Executive Director ACT | The App Association

# 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.

## http://www.va.gov/oig/pubs/VAOIG-13-00716-101.pdf

## 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. <u>http://online.liebertpub.com/doi/pdf/10.1089/tmj.2008.0021.</u> Supplemented with further data by Darkins, available at <u>http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf</u>

## 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."

"Whole System Demonstrator Programme, Headline Findings – December 2011", Department of Health, United Kingdom] <u>http://www.telecare.org.uk/sites/default/files/file-</u> <u>directory/secure\_annual\_reports/Publications/Effect%20of%20Telehealth%20on%20use%20of%20seco</u> <u>ndary%20care%20and%20mortality%20findings%20from%20the%20WSD%20cluster%20randomised%2</u> <u>Otrial.pdf</u>

## **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.

David C. Grabowski and A. James O'Malley, "Use of Telemedicine Can Reduce Hospitalizations of Nursing Home Residents and Generate Savings for Medicare," *Health Affairs*, 33, no. 2 (2014): 244-250.

# 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."

J Am Coll Cardio: 2009;54:1683-94 <u>http://content.onlinejacc.org/article.aspx?articleid=1140154</u>

## **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] http://www.careinnovations.com/data/sites/1/downloads/Guide\_product/guide\_stvincent\_profile.pdf

## <u>Program Evaluation of Remote Heart Failure Monitoring: Healthcare Utilization Analysis in a Rural</u> <u>Regional Medical Center</u>

"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 Shardelll, 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<sup>™</sup> 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

## RESPIRATORY AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE MANAGEMENT

## Content-Driven Telehealth System Coupled with Care Management: Study Size Medicare <u>patients</u> <u>enrolled in CMS' Health Buddy Program demonstration from 2006-2010</u>

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."

Au, DH, Macaulay, DS, et al. Impact of a telehealth and care management program for patients with chronic obstructive pulmonary disease. *Ann Am Thorac Soc.* 2015 Mar;12(3):323-31. Doi: 10.1513/AnnalsATS.201501-042OC. <u>http://www.ncbi.nlm.nih.gov/pubmed/25642649</u>

## 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)

Segrelles CG, et al. A home telehealth program for patients with severe COPD: the PROMETE study. *Respir Med.* 2014 Mar; 108(3):453-62. Doi: 10.1016/j.med.2013. 12.003. Epub 2013 Dec 16. <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=A+home+telehealth+program+for+patients+with+COPD%3A+The+PROMETE+study">http://www.ncbi.nlm.nih.gov/pubmed/?term=A+home+telehealth+program+for+patients+with+COPD%3A+The+PROMETE+study</a>

## 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."

Vitacca M, Bianchi L, et al. Tele-assistance in chronic respiratory failure patients: a randomized clinical trial. *Eur Respir J.* 2009 Fed:33(2):411-8. Doi: 10.1183/09031936.00005608. Epub 2008 Sep 17. http://www.ncbi.nlm.nih.gov/pubmed/18799512

# 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 ( $0.41 \pm 1.68$ ,  $0.15 \pm 1.65$ , and  $0.56 \pm 2.3$ , respectively; all with p < 0.01)."

Alrajab S, Smith TR, et al. A home telemonitoring program reduced exacerbation and healthcare utilization rates in COPD patients with frequent exacerbations. *Telemed J E Health.* 2012 Dec; 18(10):772-6. Doi: 10.1089/tmj.2012.0005. Epub 2012 Oct 19. http://www.ncbi.nlm.nih.gov/pubmed/?term=Alrajab+S%2C+Smith+TR%2C+et+al

## 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  $\pm$  26 vs. 58.3  $\pm$  25, 59% reduction; p < 0.0001)."

Munafo D, Hevener W, et al. A telehealth program for CPAP adherence reduces labor and yields similar adherence and efficacy when compared to standard of care. *Sleep Breath.* 2016 May;20(2): 777-85. doi: 10.1007/s11325-015-1298-4. Epub 2016 Jan 11.

http://www.ncbi.nlm.nih.gov/pubmed/?term=Munafo+D%2C+Hevener+W%2C+et+al.

## 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."

Bell, RC, Yager PH, et al. Telemedicine Versus Face-to-Face Evaluations by Respiratory Therapists of Mechanically Ventilated Neonates and Children: A Pilot Study. <u>http://rc.rejournal.com/content/61/2/149:abstract</u>

## **MEDICATION ADHERENCE FOR CHRONIC CONDITIONS**

## <u>Case Study: Medication Adherence and mHealth: The George Washington University and Wireless</u> <u>Research Pill Phone Study</u>

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."

Study designed, conducted and analyzed by George Washington University Medical Center; Qualcomm Wireless Reach Initiative was the primary funder of this study. <u>http://www.qualcomm.com/media/documents/files/wireless-reach-case-study-united-states-pill-phone-english-.pdf</u>

# **BLOOD PRESSURE MANAGEMENT**

<u>Using simple telehealth in primary care to reduce blood pressure: a service evaluation</u> (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."

[Elizabeth Cottrell, Ruth Chambers, Phil Connell. BMJ Open. 2012;2:e001391. Doi:10.1136/bmjopen-2012-001391] http://bmjopen.bmj.com/content/2/6/e001391

#### APPENDIX B: CONNECTED HEALTH INITIATIVE REDLINE EDITS TO CPIA INVENTORY (TABLE H)

Subcategory	Activity	Weighting	
Expanded Practice Access	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as telehealth or remote monitoring, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.	High	Deleted: e-visits
Expanded Practice	Use of telehealth or remote monitoring services and analysis of data for quality improvement, such	High	Deleted: Medium
Access	as participation in remote specialty care consults/supervision, or telehealth and remote monitoring,		Deleted: audiology
Expanded Practice Access	Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.	Medium	
Expanded Practice Access	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (e.g., investment of on-site diabetes educator).	Medium	

Population Participation in a systematic		
· antisipation a cyclomatic	remote monitoring program (clinic, patient self-reporting program,	High
Management patient self-management pro	gram) for 60 percent of practice patients in year 1 and 75 percent of no receive medications.	

-	Deleted: anticoagulation
1	Deleted: coagulation
	Deleted: anti-coagulation
	<b>Deleted:</b> (warfarin or other coagulation cascade inhibitors)

Subcategory	Activity	Weighting	1	
Population	MIPS eligible clinicians and groups who prescribe oral therapy must attest that, in the first	High		Deleted: Vitamin K antagonist
Management	performance year, 60 percent or more of their ambulatory care patients receiving such oral therapy,			Deleted: (warfarin)
	are being managed by one of more of these clinical practice improvement activities.			Deleted: warfarin
	Patients are being managed by a management service, that involves systematic and coordinated			Deleted: n anticoagulant
	and patient communication of results and dosing decisions;			
	Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions;			
	Patients are managed using remote monitoring or telehealth options that involve systematic and			<b>Delatad:</b> For rural or remote patients, p
	coordinated care, incorporating comprehensive patient education, systematic INR testing, tracking, follow-up, and patient communication of results and dosing decisions; and/or			
	For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self- testing (PST) or patient-self-management (PSM) program.			
	The performance threshold will increase to 75 percent for the second performance year and onward.			
	Clinicians would attest that, 60 percent for first year, or 75 percent for the second year, of their			
	ambulatory care patients receiving <u>such oral therapy</u> participated in a management program for at least 90 days during the performance period			Deleted: warfarin
				Deleted: n anticoagulation

Subcategory	Activity	Weighting
Population Management	Participating in a Rural Health Clinic (RHC), Indian Health Service (IHS), or Federally Qualified Health Center in ongoing engagement activities that contribute to more formal quality reporting, and that include receiving quality data back for broader quality improvement and benchmarking improvement which will ultimately benefit patients. Participation in Indian Health Service, as a CPIA, requires MIPS eligible clinicians and groups to deliver care to federally recognized American Indian and Alaska Native populations in the U.S. and in the course of that care implement continuous clinical practice improvement including reporting data on quality of services being provided and receiving feedback to make improvements over time.	Medium

Activity	Weighting
For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and groups must attest to having:	High
For the first performance year, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that:	
a) Takes into account patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and	
b) Is reassessed at least annually.	
The performance threshold will increase to 75 percent for the second performance year and onward.	
Clinicians would attest that, 60 percent for first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.	
Take steps to improve health status of communities, such as collaborating with key partners and stakeholders to implement evidenced-based practices to improve a specific chronic condition. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist MIPS eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.	Medium
	Activity   For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and groups must attest to having:   For the first performance year, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that:   a) Takes into account patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and   b) Is reassessed at least annually.   The performance threshold will increase to 75 percent for the second performance year and onward.   Clinicians would attest that, 60 percent for first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.   Take steps to improve health status of communities, such as collaborating with key partners and stakeholders to implement evidenced-based practices to improve a specific chronic condition. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.

Subcategory	Activity	Weighting
Population Management	Take steps to improve healthcare disparities, such as Population Health Toolkit or other resources identified by CMS, the Learning and Action Network, Quality Innovation Network, or National Coordinating Center. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.	Medium
Population Management	Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.	High
Population Management	Participation in CMMI models such as Million Hearts Campaign.	Medium
Population Management	Participation in research that identifies interventions, tools or processes that can improve a targeted patient population.	Medium
Population Management	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).	Medium

Subcategory	Activity	Weighting
Population Management	Implementation of regular reviews of targeted patient population needs which includes access to reports that show unique characteristics of eligible professional's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources, such as data analytics and predictive modeling to identify the patients with increased needs and potential for admission.	Medium
Population Management	Empanel (assign responsibility for) the total population, linking each patient to a MIPS eligible clinician or group or care team. Empanelment is a series of processes that assign each active patient to a MIPS eligible clinician or group and/or care team, confirm assignment with patients and clinicians, and use the resultant patient panels as a foundation for individual patient and population health management. Empanelment identifies the patients and population for whom the MIPS eligible clinician or group and/or care team is responsible and is the foundation for the relationship continuity between patient and MIPS eligible clinician or group care team that is at the heart of comprehensive primary care. Effective empanelment requires identification of the "active population" of the practice: those patients who identify and use your practice as a source for primary care. There are many ways to define "active patients" operationally, but generally, the definition of "active patients" includes patients who have sought care within the last 24 to 36 months, allowing inclusion of younger patients who have minimal acute or preventive health care.	Medium

Subcategory	Activity	Weighting	
Population Management	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following:	Medium	
	Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; plan of care for chronic conditions; and advance care planning (such as through partnership with Specialty Organizations);		
	Use condition-specific pathways for care of chronic conditions (e.g., hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target;		
	Use pre-visit planning, telehealth, and remote monitoring to optimize preventive care and team management of patients with chronic conditions;		
	Use panel support tools (registry functionality) to identify services due;		
	Use reminders and outreach (e.g., <u>telehealth, remote monitoring</u> , <u>postcards</u> , <u>patient portals and</u> community health workers where available) to alert and educate patients about services due; and/or Routine medication reconciliation.		Deleted: phone calls, emails

Subcategory	Activity	Weighting
Population Management	Provide longitudinal care management to patients at high risk for adverse health outcome or harm that could include one or more of the following:	Medium
	risk stratification into actionable risk cohorts. Monitor the risk-stratification method and refine as necessary to improve accuracy of risk status identification;	
	Use a personalized plan of care <u>and continuous monitoring</u> for patients at high risk for adverse health outcome or harm, integrating patient goals, values and priorities; and/or	
	Use on-site practice-based or shared care managers to proactively monitor and coordinate care for the highest risk cohort of patients, such as using telehealth and remote monitoring.	
Population Management	Provide episodic care management, including management across transitions and referrals that could include one or more of the following:	Medium
	Routine and timely follow-up to hospitalizations, ED visits and stays in other institutional settings, including symptom and disease management via telehealth and remote monitoring, and medication reconciliation and management; and/or	
	Managing care intensively through new diagnoses, injuries and exacerbations of illness.	

Subcategory	Activity	Weighting
Population Management	Manage medications to maximize efficiency, effectiveness and safety that could include one or more of the following:	Medium
	Reconcile and coordinate medications and provide medication management across transitions of care settings and eligible clinicians or groups;	
	Integrate a pharmacist into the care team; and/or Conduct periodic, structured medication reviews.	
Care Coordination	Performance of regular practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology (e.g., mobile technology in care transtions).	Medium
Care Coordination	Timely communication of test results defined as timely identification of abnormal test results with timely follow-up, via such means as telehealth, patient portals, postcards, etc.	Medium
Care Coordination	Implementation of at least one additional recommended activity from the Quality Innovation Network- Quality Improvement Organization after technical assistance has been provided related to improving care coordination.	Medium
Care Coordination	Participation in the CMS Transforming Clinical Practice Initiative.	High
Care Coordination	Membership and participation in a CMS Partnership for Patients Hospital Engagement Network.	Medium

Subcategory	Activity	Weighting
Care Coordination	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (e.g., documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).	Medium
Care Coordination	Implementation of regular care coordination training.	Medium
Care Coordination	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).	Medium
Care Coordination	Implementation of practices/processes to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s).	Medium
Care Coordination	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (e.g., staff involved, <u>use of telehealth and remote monitoring</u> in support of transition, accompaniments, navigation actions, home visits, patient information access, etc.).	Medium

I

**Deleted:** phone calls conducted

Subcategory	Activity	Weighting		
Care Coordination	Establish standard operations to manage transitions of care that could include one or more of the following: Establish formalized lines of communication with local settings in which empaneled patients receive care to ensure documented flow of information and seamless transitions in care; and/or Partner with community or hospital-based transitional care services.	Medium		
Care Coordination	Establish effective care coordination and active referral management that could include one or more of the following: Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; Track patients referred to specialist through the entire process; and/or Systematically integrate information from referrals into the plan of care.	Medium		
Care Coordination	Ensure that there is bilateral exchange of necessary patient information to guide patient care that could include one or more of the following: Participate in a Health Information Exchange if available:	Medium		elated: and/or
	Use structured referral notes: and/or			cicicu. and/or
	Utilization of telehealth or remote monitoring,		D	eleted:

Subcategory	Activity	Weighting
Care Coordination	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; and/or Provide a guide to available community resources.	Medium
Beneficiary Engagement	In support of improving patient access, performing additional activities <u>such as remote monitoring</u> that enable capture of patient- <u>generated</u> reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.	Medium
Beneficiary Engagement	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.	Medium
Beneficiary Engagement	Engagement with a Quality Innovation Network-Quality Improvement Organization, which may include participation in self- management training programs such as diabetes.	Medium
Beneficiary Engagement	Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health or blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about <u>treatments</u> , <u>relevant biometric</u> <u>data</u> , medication changes and adherence.	Medium

Subcategory	Activity	Weighting
Beneficiary Engagement	Enhancements and ongoing regular updates and use of websites/tools that include consideration for compliance with section 508 of the Rehabilitation Act of 1973 or for improved design for patients with cognitive disabilities. Refer to the CMS website on Section 508 of the Rehabilitation Act https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS- Information-Technology/Section508/index.html?redirect=/InfoTechGenInfo/07_ Section508.asp that requires that institutions receiving federal funds solicit, procure, maintain and use all electronic and information technology (EIT) so that equal or alternate/comparable access is given to members of the public with and without disabilities. For example, this includes designing a patient portal or website that is compliant with section 508 of the Rehabilitation Act of 1973.	Medium
Beneficiary Engagement	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	High
Beneficiary Engagement	Participation in a QCDR, that promotes use of patient engagement tools.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.	Medium
Beneficiary Engagement	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes implementation of patient self-action plans.	Medium

Subcategory	Activity	Weighting
Beneficiary Engagement	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.	Medium
Beneficiary Engagement	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.	Medium
Beneficiary Engagement	Use evidence-based decision aids to support shared decision- making.	Medium
Beneficiary Engagement	Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms.	Medium
Beneficiary Engagement	Engage patients and families to guide improvement in the system of care.	Medium
Beneficiary Engagement	Engage patients, family and caregivers in developing a plan of care and prioritizing their goals for action, which could include patient-generated health data and documented in the certified EHR technology.	Medium
Beneficiary Engagement	Incorporate evidence-based techniques to promote self- management into usual care, using techniques such as goal setting with structured follow-up, teach back, action planning, telehealth, remote monitoring, or motivational interviewing.	Medium
Beneficiary Engagement	Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).	Medium
Beneficiary Engagement	Provide peer-led support for self-management.	Medium
Beneficiary Engagement	Use group visits for common chronic conditions (e.g., diabetes).	Medium

Subcategory	Activity	Weighting
Beneficiary Engagement	Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community.	Medium
Beneficiary Engagement	Provide self-management materials at an appropriate literacy level and in an appropriate language.	Medium
Beneficiary Engagement	Provide a pre-visit development of a shared visit agenda with the patient.	Medium
Beneficiary Engagement	Provide coaching between visits with follow-up on care plan and goals.	Medium
Patient Safety and Practice Assessment	Participation in an AHRQ-listed patient safety organization.	Medium
Patient Safety and Practice Assessment	Participation in Maintenance of Certification Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.	Medium
Patient Safety and Practice Assessment	For eligible professionals not participating in Maintenance of Certification (MOC) Part IV, new engagement for MOC Part IV, such as IHI Training/Forum Event; National Academy of Medicine, AHRQ Team STEPPS®.	Medium
Patient Safety and Practice Assessment	Administration of the AHRQ Survey of Patient Safety Culture and submission of data to the comparative database (refer to AHRQ Survey of Patient Safety Culture website http://www.ahrq.gov/professionals/quality-patient- safety/patientsafetyculture/index.html)	Medium

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.	Medium
Patient Safety and Practice Assessment	Consultation of Prescription Drug Monitoring Program prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than 3 days.	High
Patient Safety and Practice Assessment	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.	Medium
Patient Safety and Practice Assessment	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the Surgical Risk Calculator.	Medium
Patient Safety and Practice Assessment	Completion of the American Medical Association's STEPS Forward program.	Medium
Patient Safety and Practice Assessment	Completion of training and obtaining an approved waiver for provision of medication -assisted treatment of opioid use disorders using buprenorphine.	Medium
Patient Safety and Practice Assessment	Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).	Medium
Patient Safety and Practice Assessment	Participation in designated private payer clinical practice improvement activities.	Medium

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Participation in Joint Commission Ongoing Professional Practice Evaluation initiative.	Medium
Patient Safety and Practice Assessment	Participation in other quality improvement programs such as Bridges to Excellence.	Medium
Patient Safety and Practice Assessment	Implementation of an antibiotic stewardship program that measures the appropriate use of antibiotics for several different conditions (URI Rx in children, diagnosis of pharyngitis, Bronchitis Rx in adults) according to clinical guidelines for diagnostics and therapeutics.	Medium
Patient Safety and Practice Assessment	Use decision support and protocols to manage workflow in the team to meet patient needs.	Medium
Patient Safety and Practice Assessment	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following: Train appropriate staff on interpretation of cost and utilization information; and/or	Medium
	Use available data regularly to analyze opportunities to reduce cost through improved care.	

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Measure and improve quality at the practice and panel level that could include one or more of the following:	Medium
	Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group(panel); and/or	
	Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.	
Detient Sefety and	Adapt a formal model for quality improvement and create a sulture in which all staff activaly	Madium
Practice Assessment	participates in improvement activities that could include one or more of the following:	Medium
	Train all staff in quality improvement methods;	
	Integrate practice change/quality improvement into staff duties;	
	Engage all staff in identifying and testing practices changes;	
	Designate regular team meetings to review data and plan improvement cycles;	
	Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or	
	Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.	

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: Make responsibility for guidance of practice change a component of clinical and administrative leadership roles;	Medium
	Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or	
	Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.	
Patient Safety and Practice Assessment	Implementation of fall screening and assessment programs to identify patients at risk for falls and address modifiable risk factors (e.g., clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).	Medium
Achieving Health Equity	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare.	High
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.	Medium

Subcategory	Activity	Weighting
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for promoting use of patient- reported outcome (PRO) tools and corresponding collection of PRO data (e.g., use of PQH-2 or PHQ-9 and PROMIS instruments).	Medium
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (e.g., use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF- 12/VR-12 functional health status assessment).	Medium
Achieving Health Equity	Participation in State Innovation Model funded activities.	Medium
Emergency Response and Preparedness	Participation in Disaster Medical Assistance Teams, or Community Emergency Responder Teams. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and MIPS eligible clinician groups must be registered for a minimum of 6 months as a volunteer for disaster or emergency response.	Medium
Emergency Response and Preparedness	Participation in domestic or international humanitarian volunteer work. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must be registered for a minimum of 6 months as a volunteer for domestic or international humanitarian volunteer work.	Medium
Integrated Behavioral and Mental Health	Diabetes screening for people with schizophrenia or bipolar disease who are using antipsychotic medication.	Medium

Subcategory	Activity	Weighting
Integrated Behavioral and Mental Health	Tobacco use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including tobacco use screening and cessation interventions (refer to NQF #0028) for patients with co-occurring conditions of behavioral or mental health and at risk factors for tobacco dependence.	Medium
Integrated Behavioral and Mental Health	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Depression screening and follow-up plan: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including depression screening and follow- up plan (refer to NQF #0418) for patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including suicide risk assessment (refer to NQF #0104) for mental health patients with co-occurring conditions of behavioral or mental health conditions.	Medium
Integrated Behavioral and Mental Health	Integration facilitation, and promotion of the colocation of mental health services in primary and/or non-primary clinical care settings.	High

Subcategory	Activity	Weighting
Integrated Behavioral and Mental Health	Offer integrated behavioral health services to support patients with behavioral health needs, dementia, and poorly controlled chronic conditions that could include one or more of the following:	High
Wentar ricatin	Use evidence-based treatment protocols and treatment to goal where appropriate;	
	Use evidence-based screening and case finding strategies to identify individuals at risk and in need of services;	
	Ensure regular communication and coordinated workflows between eligible clinicians in primary care and behavioral health;	
	Conduct regular case reviews for at-risk or unstable patients and those who are not responding to treatment;	
	Use of a registry or certified health information technology functionality to support active care management and outreach to patients in treatment; and/or	
	Integrate behavioral health and medical care plans and facilitate integration through co-location of services when feasible.	
Integrated Behavioral and Mental Health	Enhancements to an electronic health record to capture additional data on behavioral health (BH) populations and use that data for additional decision-making purposes (e.g., capture of additional BH data results in additional depression screening for at-risk patient not previously identified).	Medium