

April 15, 2016

The White House  
Domestic Policy Council, Rural Affairs  
Washington, DC 20500

To Whom It May Concern:

ACT | The App Association appreciates the opportunity to provide input to you in follow-up to the March 30, 2016-held White House Convening on Rural Telehealth. ACT | The App Association's Connected Health Initiative represents an established – and growing – diverse consensus spanning the healthcare and technology communities which holds that telehealth and remote patient monitoring (RPM) solutions improve patient care, reduce readmissions, and improve care coordination. Further, we strongly agree that statutory and regulatory restrictions have limited the range of telehealth and RPM technologies that may be offered to American patients and have long been a deterrent to advancement and adoption. For example, due to the chosen approach by the Center for Medicare & Medicaid Services (CMS), Medicare coverage for telehealth is shockingly lacking,<sup>1</sup> while support for RPM is non-existent and denies reasonable reimbursement for the monitoring of patient-generated health data (PGHD).

A well-established, and ever-growing, body of clinical evidence suggests that interoperable remote monitoring improves care, reduces hospitalizations, helps avoid complications, and improves satisfaction, particularly for the chronically ill.<sup>2</sup> However, in the context of telehealth, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. As notable examples, Section 1834(m) of the Social Security Act has resulted in significant restrictions on telehealth services;<sup>3</sup> further, remote patient monitoring, independent of telehealth services, is unreasonably restrained by CMS' decision to bundle it with other codes, resulting in a lack of reimbursement for remote patient monitoring. We urge CMS (and other Federal actors) to utilize every opportunity to work towards a connected healthcare system by removing such barriers to the utilization of advanced technologies.

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<sup>1</sup> For example, according to the Centers for Medicare & Medicaid Services (CMS), Medicare telemedicine reimbursement totaled a mere \$13.9 million in Calendar Year 2014. See <http://ctel.org/2015/05/cms-medicarereimburses-nearly-14-million-for-telemedicine-in-2014/>.

<sup>2</sup> See, e.g., U.S. Agency for Healthcare Research and Quality (AHRQ) Service Delivery Innovation Profile, *Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>. See also an appended list of studies

<sup>3</sup> See 42 CFR § 410.78.

Despite these over-burdensome restrictions, remote monitoring of PGHD is increasingly being proven as an important aspect of any healthcare system. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.<sup>4</sup> A vivid example of the use of virtual chronic care management is by the Department of Veterans Affairs who reported a substantial decrease in hospital and emergency room use.<sup>5</sup> Telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are all up-and-coming technologies that are revolutionizing remote patient monitoring (including asynchronous technologies) and the medical care industry, representing a significant opportunity.<sup>6</sup> There is also a growing body of potential cost savings, noted most recently by a study predicting that remote monitoring will result in savings of \$36 billion globally by 2018, with North America accounting for 75% of those savings.<sup>8</sup> RPM has the potential to positively engage patients when addressing chronic and persistent disease states to improve management of chronic conditions.<sup>7</sup> The Hackensack Alliance in New Jersey reduced readmission rates from 28% to 5% for congestive heart failure patients.<sup>8</sup> Christus Health reduced the average cost for congestive heart failure readmissions from \$12,937 compared to \$1,231 per re-admission after implementing a remote patient monitoring system.<sup>9</sup> Further, we have appended to this letter a non-exclusive list of studies demonstrating the value of telehealth and RPM to patients with chronic conditions.

Based on the above, we believe that the implementation of MACRA presents an enormous opportunity for CMS to take meaningful steps to improve millions of American's lives through the use of RPM in subsidized medicine consistent with the following recommendations:

## **I. CMS Should Provide a Bridge to the Full Implementation of MACRA Through the Use of Existing Waiver Authority**

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<sup>4</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 Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>.

<sup>5</sup> See Darkins, *Telehealth Services in the United States Department of Veterans Affairs (VA)*, available at <http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf>.

<sup>6</sup> See Kalorama Information, *Advanced Remote Patient Monitoring Systems*, 8th Edition (2015), available at <http://www.kaloramainformation.com/redirect.asp?progid=87656&productid=9123949>.

<sup>7</sup> See Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), available at [http://www.juniperresearch.com/reports/mobile\\_health\\_fitness](http://www.juniperresearch.com/reports/mobile_health_fitness).

<sup>8</sup> [Use Case Study: Hackensack Alliance ACO - Remote Patient Monitoring for Chronic Disease. HIMSS. 2014](#)

<sup>9</sup> Use Case Study: Christus Health –Remote Patient Monitoring Solution, St. Michael Health System Expansion Program. HIMSS 2015 (demonstrating a return on investment of \$9.91 per \$1.00 invested in RPM and reduced costs over time).

Whether a provider takes the route of the Merit-Based Incentive Payment System (MIPS) or of an Alternative Payment Model (APM), and while the MACRA's 2019 implementation will bring greater support of telehealth and remote patient monitoring, we believe that a lack of adequate support for telehealth and RPM will result in a lack of a foundation amongst providers because, with limited coverage of telehealth services and no coverage for evidence-based RPM and a lack of leadership by CMS, there is little incentive for providers to invest in such advances.

CMS is well-positioned to take tangible steps to addressing this transition issue in the short-term by modernizing the Physician Fee Schedule. In the context of telehealth, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services that should be waived by the Secretary. Further, CMS should, using its existing authority, provide adequate reimbursement for collection and interpretation of physiologic data stored/transmitted by patient/caregiver by “unbundling” the relevant CPT code.<sup>10</sup> Such a practice would align with CMS' established approach to chronic care management in CPT 99490, where, because the challenges of preventing and managing chronic disease caused “the focus of primary care [to evolve] from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management,” CMS found that the reimbursement for chronic care management that had historically been included in evaluation and management (E/M) codes was insufficient; as a result, CMS concluded that chronic care management should be separately reimbursed, and noted its anticipation that increased reimbursement for chronic care management (CCM) will be more than offset by the corresponding reduction in more costly services.

## **II. CMS Should Include Provisions for Telehealth and Remote Patient Monitoring as Part of MIPS Clinical Practice Improvement Activities**

By including clinical practice improvement activities as one of the four domains included in the composite performance score under MIPS, Congress has signaled the importance it places on supporting providers through the transition from volume- to value-based reimbursement. The importance of assisted transitions (e.g., fee-for-service payments that reward practice transformation) should be fully appreciated, and we ask CMS to ease the administrative burden associated with fee-for-service care management and provide adequate reimbursement for those services. In addition, we support the inclusion of integrated use of telehealth and remote patient monitoring in providing direct patient care as part of any clinical practice improvement activities, most notably those identified by Congress in MACRA.

We appreciate CMS' request for input on the components that should comprise clinical practice improvement activities for the implementation of MIPS. Initially, we urge for CMS to ensure that its approach focuses on outcomes, rather than giving too much weight to quantitative measures (e.g., hours spent). Further, we suggest that CMS ensure robust

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<sup>10</sup> 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.

inclusion of evidence based consumer-oriented technologies used to monitor patients with chronic disease, care coordination, patient education, health coaching, and patient engagement. Specifically, we urge CMS to provide a menu of remote patient monitoring or consumer oriented information technology categories that primary care and specialties would use for care improvement, which include:

- Screening of patients with chronic conditions to determine if remote patient monitoring would provide benefit;
- Use of remote patient monitoring of biometric data for chronic condition management when screening determines it would be effective;
- Technology enabled health education based on condition management;
- Technology enabled communication for health coaching and health education; and,
- Electronic, two-way, communication between clinical staff and patient to support chronic conditions management.

### **III. CMS Should Include ‘Remote Monitoring of Patient-Generated Health Data’ as an Additional Subcategory of MIPS Clinical Practice Improvement Activities**

MACRA lists six subcategories of clinical practice improvement activities that contribute to the MIPS composite score: (1) Expanded practice access, (2) population management, (3) care coordination, “including use of remote monitoring or telehealth” (emphasis added), (4) beneficiary engagement, (5) patient safety and practice assessment, and (6) participation in an alternative payment model.<sup>11</sup> In defining the scope of the MIPS clinical practice improvement activity category, CMS may include one or more additional subcategories of clinical practice improvement activities beyond the six identified in the statute, but only if “relevant eligible professional organizations and other relevant stakeholders identify [the additional subcategory] as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.”<sup>12</sup> Based on the above-noted benefits associated with the integration of remote monitoring of PGHD into clinical practices, we strongly urge CMS to include *remote monitoring of patient-generated health data* as an additional subcategory of clinical practice improvement activities.

First, we urge CMS to ensure that the definition of PGHD contemplates advances in electronic remote monitoring technology which will allow for physiological data to be captured, transmitted, and evaluated in near real-time by clinicians who can respond immediately with clinically-guided support such as changes in treatment, medications,

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<sup>11</sup> MACRA Section 101(c)(2)(B)(iii)(III).

<sup>12</sup> 42 USC 1395w-4(q)(2)(C)(v).

and lifestyle.<sup>13</sup> We encourage CMS to share our vision of a continuum of care where this PGHD then can be automatically downloaded and stored in providers' networks or electronic health records where the data can be used to identify trends and to modify the care plan, if necessary.

We recognize that irrespective of strong evidence base reflecting the positive impact of remote monitoring of PGHD on the quality and cost of care, the new clinical practice improvement activity we propose must be objectively quantifiable to qualify as a subcategory for MIPS. Therefore, we propose that in order to determine whether an eligible professional (EP) is adequately engaging in the clinical practice improvement activity of remote monitoring of PGHD (counting towards a MIPS composite score), CMS use a variation on the PGHD measure in the Meaningful Use Stage 3 Final Rule.<sup>14</sup>

To satisfy these Stage 3 Rule requirements, an EP must, among other requirements, meet two of the three measures listed under *Objective 6 – Coordination of Care Through Patient Engagement*. One of the three measures concerns incorporation of PGHD or data from a nonclinical setting into the EP's electronic health record (EHR), with the denominator set as the number of unique patients seen by the EP and the numerator set as the number of patients in the denominator for whom such data is captured in the EHR during the reporting period. To satisfy this measure, the resulting percentage must be equal to or greater than five percent (5%).

For purposes of the remote monitoring of PGHD subcategory of clinical practice improvement activities that we propose, CMS should make specific modifications to this measure to focus on the EP's use of PGHD for clinical decision-making. Such modifications may include, for example, limiting the denominator to Medicare beneficiaries and/or patients with specific chronic conditions, limiting the numerator to PGHD (*i.e.*, not including data from non-clinical settings), or increasing the threshold percentage. In addition to this objective measure, CMS should require a written certification from the EP regarding their use of remote monitoring of PGHD to facilitate clinical decision-making and care coordination.

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<sup>13</sup> M. Shapiro, D. Johnston, J. Wald, and D. Mon, *Patient-Generated Health Data: White Paper Prepared for the Office of the National Coordinator for Health IT by RTI International* (April 2012) (available at <http://www.rti.org/pubs/patientgeneratedhealthdata.pdf>) (cited in M. Deering, *Office of National Coordinator for Health Information Technology Issue Brief: Patient-Generated Health Data and Health IT* (December 2013) (available at [https://www.healthit.gov/sites/default/files/pghd\\_brief\\_final122013.pdf](https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf))), defining PGHD as:

...health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (*i.e.*, care partners or those who assist them) to help address a health concern. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways. First, patients, not providers, are primarily responsible for capturing or recording these data. Second, patients direct the sharing or distributing of these data to health care providers and other stakeholders.

<sup>14</sup> See 80 Fed. Reg. 62,851-52 (Oct. 16, 2015).

#### **IV. Telehealth and Remote Patient Monitoring Should be Fully Embraced by APMs**

We also support Congress' goal of realizing innovative APMs, and continue to work across our diverse interests (e.g., medical specialties) towards eligible alternatives to MIPS. However, at a minimum, we strongly believes that APMs must effect the utilization of telehealth and RPM in a significantly expanded way, which promotes patient engagement, consistent with the above detailed views and discussion. Even today, we are very concerned with the lack of utilization of telehealth and RPM by CMMI in the Medicare Shared Savings Program.

##### **a. The Treatment of Telehealth in APMs**

Expanding the use of telehealth services and modern technologies will be an important step forward in improving Medicare beneficiaries' access to quality and cost effective care delivery systems. There is growing recognition among policy makers at the state and federal level that telehealth and related services are particularly relevant in addressing the consequences of health professional shortages, maldistribution, and provider participation in both private insurance, Medicaid and the Medicare program. Despite decades of efforts to entice health professionals to locate in or near underserved areas, the problems have generally gotten worse. The tools of telehealth, notably real-time and interactive video visits, can be of immediate benefit to Medicare APMs.

Currently, Medicare is failing its beneficiaries by its very restrictive rules concerning telehealth, such as the following:

- Requiring that a beneficiary with severe depression and other mobility-impairing conditions must leave their home and travel to get mental health counseling,
- Not covering a beneficiary in a metropolitan area for getting a time-critical diagnosis of an ischemic stroke so that disability-preventing clot busting medication can be administered merely because the stroke specialist is at a different location,
- Not covering a beneficiary who meets Medicare's definition of "homebound" from receiving any health care services from a physician using video,
- Requiring that a beneficiary needing physical rehabilitation must be at an inpatient facility or travel to an outpatient facility for all therapy services,
- Not covering a beneficiary receiving hospice services at home from receiving pain management or counseling from a physician using video,
- Not covering a beneficiary at-risk with multiple chronic conditions to have key health indicators monitored daily from their home, and
- Requiring that a beneficiary with diabetes travel to a scarce retinal specialist for an annual diabetic retinopathy exam to prevent blindness.

We have no doubt that paying for telehealth within an APM will increase the net savings from APMs for the Medicare program. Paying for telehealth within an APM will be the single most important step to date by CMS to advance the knowledge and experience of how best to use these technology tools. Using telehealth is how APM providers can create “value.”

We strongly support allowing APMs flexibility from the Medicare telehealth restrictions in Social Security Act section 1834(m). APMs, with their financial and operational incentives, can be prudent demonstrators of the best uses of telehealth tools. For this reason, we find the current restrictions of 1834(m) particularly inappropriate for such Medicare services. We urge that APMs be given the same flexibility to cover telehealth as has been the long-standing policy for Medicare Advantage plans. 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. In particular, we support a general waiver from the restrictions of 1834(m) for APMs.

Further, we support applying the same regulatory oversight to telehealth and related services that is required of the other similar components of care coordination and APM operations. The APM design and financial incentive structure encourages and promotes use of enabling technologies that create value to the care delivery system and contains the governance, infrastructure and necessary provider oversight to protect Medicare and beneficiaries from fraud and abuse. It is unnecessary and counter-productive to have special operational and data requirements that single out telehealth services and create burdensome regulatory requirements that will stifle innovation and discourage participation by APMs.

Telehealth services are necessary in a number of circumstances:

- Triaging for faster, appropriate specialist care
- Increasing provider productivity
- Relief for provider shortages
- Reduction in disparities to patient access
- Decreasing unnecessary variations in care
- Reducing in-person overuse, such as in emergency rooms and preventable inpatient admissions

We strongly support a waiver for APMs from the following specific, otherwise artificial Medicare restrictions in section 1834(m), up to any overall Medicare coverage limitations:

- Section 1834(m)(4)(C)(I)(II) to permit an APM to provide health services by video conferencing for Medicare beneficiaries who live in metropolitan counties.
- The last sentence of section 1834(m)(1) to permit an APM to provide and bill for health services provided by store-and-forward means (such as transmission of medical images) to beneficiaries who live outside of an Alaska or Hawaii demonstration site as of December 31, 2000.

- Section 1834(m)(4)(F)(i) to permit an APM to provide additional CPT and HCPCS codes for Medicare covered services provided via telehealth.
- Section 1834(m)(4)(C)(ii) to permit an APM to provide for telehealth services originating from a beneficiary's home, a hospice and anywhere else from which a beneficiary seeks service (without regard to an originating site fee).
- Section 1834(m)(4)(E) to permit a beneficiary in an APM to get the otherwise covered Medicare services of physical therapy, occupational therapy, speech-language pathology, audiology and other health professionals.

If APMs receive waivers from these five specific Medicare restrictions, particularly originating site and geographic restrictions, they can take the lead in demonstrating the value of telehealth remote patient monitoring and other technologies in innovating care delivery and improving access and efficient delivery of care in both rural and urban settings. The APM quality and performance measures and other participation requirements provide protection against fraud and abuse and Medicare's traditional fee for service utilization controls.

#### **b. The Treatment of Remote Patient Monitoring in APMs**

Additionally, an APM should have the flexibility to provide other telehealth services, such as remote patient monitoring for beneficiaries with 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 RPM to be used to improve quality while reducing per capita total costs of care. While CMS has expressed reluctance to do this in the past at least in part because of expected overutilization, those using APMs would not utilize RPM services unless total care costs would be reduced. Therefore, CMS' use of relevant waiver authority to allow payment for RPM – including the unbundling of CPT Code 99091 as noted above – would enable the success of APMs.

We look forward to continued engagement with CMS as this important alternative eligibility criteria is defined, including important aspects such as physician-focused payment models.



**V. CMS Should Closely Coordinate with the ONC's Ongoing Effort to Develop a PGHD Policy Framework**

Recently, the Office of the National Coordinator for Health IT (ONC) announced that it will develop a policy framework for identifying best practices, gaps and opportunities for the use of PGHD in research and care delivery through 2024. We are supportive of this effort within ONC, and encourage CMS to ensure that it closely coordinates with ONC in the development of this framework. The framework should include key standards and best practices, such as the Continua Health Alliance's Design Guidelines which define the interfaces that enable the secure flow of medical data among sensors, gateways, and end services, removing ambiguity in underlying healthcare standards and ensuring consistent implementation through product certification. However, based on the established benefits of PGHD's inclusion in the continuum of care as well as timeline realities (e.g., MACRA's 2019 implementation), we strongly urge CMS not to defer any activity related to PGHD until ONC's policy framework is completed in 2024.

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ACT | The App Association urges your consideration our stakeholder consensus which supports the wide use of telehealth and remote monitoring solutions to improve the United States' healthcare system, by promoting value by increasing quality and by reducing costs. We welcome the opportunity to work with you and your designees on such timely actions.

Respectfully submitted,

A handwritten signature in black ink that reads "Morgan Reed". The signature is fluid and cursive, with the first name "Morgan" and last name "Reed" clearly distinguishable.

Morgan Reed  
Executive Director  
ACT | The App Association