September 11, 2017

Submitted via http://www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1676-P; CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B

Dear Administrator Verma:

The Alliance for Connected Care (the "Alliance") appreciates the opportunity to respond to 2018 Proposed Physician Fee Schedule solicitation of comments related to expanding telehealth and remote patient monitoring. We appreciate your leadership and continued work to modernize Medicare.

The Alliance is a 501(c)(6) organization supporting policy that enables the use of evidence-based, safe, high-quality telehealth and remote patient monitoring services. Our members are leading health care and technology companies from across the healthcare spectrum. The Alliance works in partnership with an Advisory Board that includes more than 25 patient and provider organizations.

Telehealth and remote monitoring enable clinicians to reach and monitor patients outside of institutional settings; engage beneficiaries; expand access to care; improve population health management; and increase care coordination, all of which are key to successfully transforming care and improving quality while reducing costs. As noted in your request for information, the regulatory frameworks for telehealth and remote patient monitoring are different. When we refer to "telehealth," we mean real-time communication between clinicians and patients while "remote patient monitoring" is asynchronous monitoring of patients' biometric data through technology. Telehealth is subject to 1834(m) restrictions while remote patient monitoring is not. Below are our recommendations for action CMS can take to enable greater access among seniors to both types of technology.

I. Telehealth Recommendations

There is significant evidence that telehealth usage can replace more expensive care and prevent costly medical interventions in the long-run. The Agency for Healthcare Quality and Research, Government Accountability Office and the Veterans Administration have issued reports, and there are many peer reviewed studies showing telehealth's efficacy. We commissioned our own actuarial study and found that replacing in-person acute care services with telehealth visits, reimbursed at the same rate as a doctor's office visit, could save the Medicare program an estimated $45/visit. The study also found telehealth visits resolved the problem 83% of the time, meaning no follow up care was necessary. The study found that a

majority of the replacement was coming from urgent care visits, which we assumed cost $116 per visit compared to $83 for a virtual visit.

Because reimbursement is only available in Medicare for certain services if a beneficiary receives care at an "originating site" located in a rural Health Professional Shortage Area (HPSA) or a county outside a Metropolitan Statistical Area (MSA), the vast majority of providers in Medicare fee-for-service do not utilize telehealth.

A. *Use waiver authority under Section 1899(b)(2)(G) of the [Social Security] Act to waive 1834(m) restrictions for all ACOs in the MSSP Program*.

The Alliance believes the most impactful telehealth expansion CMS can make within your authority in the Medicare fee-for-service program is a waiver of 1834(m) restrictions for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program. A waiver of section 1834(m) is supported by authority in section 1899(b)(2)(G) of the [Social Security] Act.

This waiver is appropriate for several reasons. First, telehealth tools align with the quality metrics for ACOs. From patient and caregiver engagement to preventive health and re-admission avoidance, telehealth facilitates improvement. Telehealth enables communication between patient and providers outside of the walls of the office, thereby increasing meaningful communication and contributing to the ability of providers to follow up with patients. For example, all of the following CAHPS measures can be achieved through telehealth: timely care, appointments and information; access to specialists; health promotion and education; shared decision making; health and functional status assessments; stewardship of patient resources.

Telehealth is also a tool for expanding access to primary care, which is the dominant use of telehealth in the commercial and VA market today. The HHS Office of Inspector General released a report two weeks ago evaluating the ACO program. They found that ACOs were able to reduce Medicare costs by $3.4 billion with a net savings to the Medicare program of $1.1 billion (accounting for incentive payments). Of the 428 ACOs analyzed, 36 ACOs accounted for half the savings, or $1.7 billion. The OIG dubbed these ACOs "high performing" and analyzed how they approached care. They found that "high performing" ACOs provided the highest number of primary care visits compared to other ACOs in the program.

B. Weigh in with Congress to Give the HHS Secretary More Waiver Authority over 1834(m)

There is legislation being considered in Congress that will give the HHS Secretary authority to waive 1834(m) restrictions as long as the CMS Actuary certifies that the service can improve quality or reduce costs. In the House, it's H.R. 3482, and in the Senate it's Section 11 of the CONNECT for Health Act (S. 1016). Currently, the agency's authority only extends to ACOs. We believe that if there is an appropriate level of evidence showing cost savings or quality improvement that the Secretary should have the ability to waive restrictions for any Part B code.

As currently envisioned, the process could be rolled into the established annual Physician Fee Schedule rulemaking process. Currently, outside organizations are able to submit requests annually to CMS for Part B telehealth modifiers permitting delivery of services via telehealth for services currently covered in-person. CMS evaluates the clinical evidence submitted in support of such requests based on established criteria. CMS then includes its proposed decision on whether to allow the service to be delivered via telehealth as part of the larger annual proposed Medicare Physician Fee Schedule. If CMS decides to

permit delivery via telehealth, this is communicated in the final rule for the next cost year and providers utilize a modifier to establish it was delivered virtually.

The existing process could be augmented by allowing outside organizations to also submit a request to waive some or all 1834(m) restriction(s) along with data for review by the Actuary showing impact on quality and cost for a code. In addition to annually deciding what additional in-person codes are covered when delivered via telemedicine, CMS could decide whether the codes under consideration are subject to any or all of the 1834(m) limitations after evaluating the submitted evidence provided by requestors. Use of the existing process would allow the Agency to provide an initial determination whether or not the restrictions will be waived and to receive public comment including additional relevant data. CMS could then determine whether sufficient data had been provided. If the Agency determines the data is insufficient, the codes remain subject to the 1834(m) limitations until sufficient data is available. The Actuary could start the process by evaluating codes that are already approved by Medicare.

Data: In terms of data, we see several possibilities:

- The CMS Actuary is in a good place to evaluate data because he/she has access to Medicare and Medicaid data. He or she can also evaluate other potential savings such as prevention of other CMS costs over time.
    - Medicare data—while limited (given the inherent problem of 1834(m) restrictions), there are emerging sources of Medicare data such as in CMMI Next Gen, CPC+, and other models that lift some of restrictions.
    - Medicaid data—Every state now has expanded telehealth services under Medicaid and states, for the most part, continue to expand these services. Medicaid is not limited by the same 1834(m) restrictions and therefore has more flexibility in coverage (also in Medicaid, telehealth is simply seen as another *modality* of care versus a new service). Medicaid patients are also arguably at least as (if not more) complex as Medicare patients, making them potentially comparable in terms of studies. The CMS Actuary could access this data more easily than most others, and could also look at budgetary impact in those states that lifted certain restrictions.
- Other federal data:
    - VA: There is a large (and rapidly growing) body of data at the VA. Given the medical complexity and diversity of this patient population, the number of studies, and the fact that CBO had been open to looking at VA data if Medicare data were inadequate (see blog post here), this would be a likely source of supporting evidence.
- Outside data:
    - Twenty-one health systems and 13 insurers sent letters to CBO and MedPAC last year offering raw telehealth data for cost and quality analysis. The CMS Actuary could access this data.
    - AHRQ/C-TEL reviews: There are some published overarching reviews of telehealth, notably from AHRQ and forthcoming from C-TEL.
    - Numerous academicians have studied telehealth and are willing to share their data.
    - The American Medical Association will issue a forthcoming set of in-depth comparative surveys of key health systems that have improved patient outcomes, patient-centered care, and reduced costs through provision of care in lower cost

sites of care, increased efficiencies in chronic care management, and reduced readmissions.

Examples: In terms of how this process could work with data, here are some hypothetical examples:

- Existing codes:
  - The codes for "Smoking cessation services" are already covered as telehealth services in Medicare (see list here). If a stakeholder, i.e. American Lung Association, has evidence that these services should have the 1834(m) restrictions lifted, it could submit, during the annual Physician Fee Schedule process, data to show why. Commercial entities who have data could also submit data. The data might come from its member physicians that have used telehealth to provide these services already in rural areas consistent with existing 1834(m) restrictions – these data could be studied to see whether the budget models are consistent with expansion. Medicaid and VA data could also be studied to see the impact of such smoking cessation services over telehealth (depending on whom is using these services over telehealth currently).
  - Because the American Heart Association (AHA) has evidence that telestroke services save substantial money and improve patient health outcomes, AHA could submit a request during the Physician Fee Schedule process requesting a waiver of 1834(m) geographic and originating site restrictions. The CMS Actuary could also see whether any new CMMI data or Medicaid/VA data would support the use of these codes.
  - Numerous peer-reviewed studies have been published on primary care visits via telehealth. These data could be supported to life geographic and site limitations for Codes 99201-99205, which are on the approved telehealth list for Medicare patient.
- New codes: Another example is the Association of American Medical Colleges and five academic medical schools implemented a collaborative to study e-consults with compelling results of savings and improved care coordination and patient outcomes. Under this scenario they would be able to request coverage of e-consults as a covered telehealth benefit while also seeking waiver of geographic restrictions. The codes for interprofessional telephone/internet consultations (e-consults) are demonstrated to improve the accuracy of a patient's diagnosis, result in faster implementation of appropriate treatment protocols (before disease progression and care in more costly sites of care) and shortens the diagnostic journey (and specialty visits) a Medicare patient may pursue to obtain a correct diagnosis as communications between providers enhanced.

Overall, we think that the CMS Actuary is uniquely equipped to make annual determinations based on code specific requests for waiver of some or all 1834(m) restrictions and authority should be delegated to the Actuary for the following primary reasons:

- He or she can waive some or all 1834(m) limitations based on individual codes (describing services) based on the evidence (which would be challenging for Congress to pass so many sequential bills).
- He or she has unfettered and ongoing access to Medicare and Medicaid data.

- The CMS Actuary plays a similar role to CBO in terms of high-quality budget analysis and projection.

We are hopeful that CMS would be willing to support efforts to give the HHS Secretary broad waiver authority over 1834(m).

II. Remote Patient Monitoring Recommendations

As you noted in the language of the Physician Fee Schedule, remote monitoring is not subject to the 1834(m) restrictions and CMS has broad authority to implement the remote monitoring of biometric data. There is payment for a limited number of remote monitoring services, mainly related to cardiac monitoring, but there is not widespread reimbursement for remote patient monitoring of physiologic data derived from home-use or mobile medical devices such as weight scales, blood pressure monitors, pulse oximeters, glucometers, thermometers, asthma inhaler sensors, etc.

The Alliance commissioned a systematic review of the literature by a preeminent telehealth researcher, Dr. Rashid Bashshur of the University of Michigan. The study[1] found that congestive heart failure (CHF) patients who received telemonitoring had a 15-56 percent reduction in mortality as compared to patients who did not receive the intervention. The same review found that use of telestroke interventions for stroke patients reduced the risk of mortality by 25 percent in the first year after an event, and that the use of telehealth for patients suffering from CHF, chronic obstructive pulmonary disease (COPD), and stroke generally resulted in lower rates of hospital admission and readmission, shorter lengths of stay.

The Veterans Administration studied their Care Coordinator Home Telehealth Program, which provides monitoring devices to veterans with chronic diseases such as COPD, diabetes, CHF, depression or PTSD. A care coordinator (usually a nurse or social worker) is the point of contact for a patient using a home telehealth device with a VA hospital. Care coordinators are able to link with the Providers to arrange treatment changes, set-up clinic appointments or arrange hospital admissions. The VA found that the program reduced bed days of by 25%, hospital admissions by 19%. It also increased patient satisfaction by 86%.

The Agency for Healthcare Quality and Research reviewed large volume of research and reported that telehealth interventions produce positive outcomes when used for remote patient monitoring, broadly defined, for several chronic conditions and for psychotherapy as part of behavioral health.[2] The agency stated that there is consistent benefit reported when telehealth is used for communication and counseling or remote monitoring in chronic conditions such as cardiovascular and respiratory disease, with improvements in outcomes such as mortality, quality of life, and reductions in hospital admissions.

A. Unbundle 99091

The Alliance was very pleased to see your request for information regarding the unbundling of code 99091. Changing the procedure status and allowing separate payment or this code would be the most impactful action CMS could take to expand access to remote monitoring for seniors and their medical providers. You have asked about utilization assumptions, and our understanding is other stakeholders such as the American Medical Association have modeled assumptions. We would like to point you to an

[1] The Empirical Foundations of Telemedicine: Interventions for Chronic Disease Management, E-Health and Telemedicine (Sept. 2014)

[2] https://effectivehealthcare.ahrq.gov/topics/telehealth/technical-brief/

Avalere study published in 2016 showing a $3 billion savings to the Medicare program over a 10 year period associated with a policy in which "Medicare would cover RPM for all FFS physicians and practitioners, regardless if they participate in the quality and value improvement programs or not." The policy evaluated defines the eligible population beneficiaries with chronic conditions specified using criteria that the Centers for Medicare & Medicaid Services (CMS)' Office of the Actuary determines will produce no net increase in Medicare expenditures resulting from the proposals. Avalere assumed 2.2 million users with COPD and CHF (15% of Medicare population) in the first year after enactment of this policy, but we believe there are likely to be far fewer users given the provider education and workflow changes that would need to occur in the early years. However, we also believe the more users, the greater the savings to the Medicare program resulting from reduced inpatient admissions and re-admissions.

While we believe that simply unbundling the code is the best course of action, if CMS wanted to add additional parameters around eligibility for use, we recommend patients with two or more chronic conditions with at least two hospital admissions in the past 12 months. CMS could also limit use of the code to specific chronic diseases, but that restricts the decision making of the physician about what is best for the patient.

If you are interested in speaking with a public institution that implemented RPM effectively and saved money, we recommend the University of Mississippi Health System. Either their current leadership or Kristi Henderson formerly of the University of Mississippi who lead the implementation of the RPM program several years ago.

B. Generate New G-Codes from the October CPT Committee Recommendations

There are very few specific codes associated with remote patient monitoring. To remedy this, in 2014, the AMA created a Telehealth Services Workgroup (TSW) to recommend solutions for the reporting of non-telehealth services when provided remotely utilizing telehealth technology. That work lead to the convening of the Digital Medicine Payment Advisory Group (DMPAG), a volunteer body of clinical subject matter experts with decades of experience utilizing digital medicine services and tools in clinical practice. As a result, several formal coding applications requesting the additions of new codes for physiologic monitoring and management have been submitted by the DMPAG to the CPT Editorial Panel for consideration during its upcoming September 2017 meeting. These applications include two for physiologic monitoring and management. One application requests the addition of a code to report the physician/provider services of chronic care monitoring/management of a patient using remote monitoring technology, the other addresses the technical component and set up.

C. Take RPM out of the MA manual

CMS policies related to remote monitoring are causing confusion in the marketplace. CMS requires MA plans to cover all Part A and B services, but "telemonitoring," "remote access technologies," and "Enhanced Disease Management" are listed as examples in the supplemental benefits section of the Medicare Advantage manual. Despite the use of remote monitoring for delivery of Part B CCM services, MA plans have to submit these technologies as supplemental benefits, which creates unnecessary administrative complexity. We encourage CMS to take out the sections on Enhanced Disease Management (Rev. 121, Issued 04-22-16), and Remote Access Technologies. This will make clear that MA plans can offer RPM as a basic benefit, which mirrors the permissiveness and coverage of RPM in FFS.

Conclusion

We look forward to continuing to work with CMS to increase access to high quality connected care for Medicare beneficiaries. If you have additional questions, please do not hesitate to contact us.

Sincerely,

Krista Drobac
Executive Director
Alliance for Connected Care