ALLIANCE *for*
CONNECTED CARE

February 6, 2015

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-1461-P Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Administrator Tavenner,

The Alliance for Connected Care ("Alliance") appreciates the opportunity to provide comments on the *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule* ("Proposed Rule"). We are pleased that the Centers for Medicare and Medicaid Services (CMS) recognizes the significant value that telehealth brings to the Medicare Shared Savings Program, and we thank you for requesting information from accountable care organizations ("ACOs") and other stakeholders about the use of telehealth technologies to coordinate care for beneficiaries.

The Alliance is a 501(c)(6) organization that was formed to advocate for the creation of a statutory and regulatory environment that enables every provider in America to deliver and be adequately compensated for providing safe, high-quality "connected care" at his or her discretion, regardless of care delivery location or technological modality. Our members are leading health care and technology companies from across the health care spectrum, representing insurers, retail pharmacies, telehealth platform providers, and health care entrepreneurs. The Alliance works in partnership with an advisory board of representatives from a broad spectrum of national patient and provider groups.

As acknowledged by CMS in the Preamble to the Proposed Rule, "connected care" encompasses a range of technologies that are used to support real-time, electronic communication between a patient and a provider, including telehealth, remote patient monitoring, and secure e-mail communication between clinicians and their patients. As Medicare continues to move toward new care delivery models, including ACOs, connected care will play an increasingly important role in their success. From empowering Medicare beneficiaries and caregivers to become more engaged in their health care, to giving Medicare providers the technology to better coordinate care across settings, connected care can help improve health care outcomes and generate savings to the Medicare program. Although this letter focuses specifically on telehealth technologies and services subject to section 1834(m) of the Social Security Act, the Alliance supports the use of and reimbursement for all connected care technologies, including remote patient monitoring.

ALLIANCE *for*
CONNECTED CARE

In the proposed rule, CMS asks stakeholders to weigh in on a number of important questions related to the use of telehealth services in ACOs. While we believe that telehealth services should be available to *all* Medicare beneficiaries, including those receiving care from *any* ACO, we have focused our comments below on how telehealth services could be used to support two-sided models to be responsive to CMS' requests for input. Our comments focus first how a waiver of section 1834(m) restrictions on telehealth reimbursement will help two-sided ACOs achieve the Shared Savings Program's goals of improved health outcomes and reduced costs, and then on specific operational considerations with respect to such a waiver.

I. Using Telehealth to Achieve Shared Savings Program Goals

Like CMS, the Alliance believes that a waiver of section 1834(m) is "supported by section 1899(b)(2)(G) of the [Social Security] Act" and agrees that such a waiver may be "necessary and appropriate" to "increase ACOs' willingness to participate in the Shared Savings Program under two-sided performance-based risk arrangements to increase quality and decrease cost growth."

As outlined in detail below, telehealth services can be used to not only improve outcomes and reduce costs, but also to increase patient "stickiness" to the ACO thus creating some of the additional certainty and stability needed to encourage continued program participation and greater uptake of two-sided models. To date, however, the restrictions included in section 1834(m), have severely limited the use of telehealth technologies among Medicare ACOs by creating a disincentive for the vast majority of ACO providers – many of whom are located in urban and suburban areas – to use this type of technology. Because reimbursement is only available 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 ACOs that are unable to receive reimbursement for telehealth services are faced with the difficult decision of assuming financial risk by providing care for free. For many physician-led and smaller ACOs, assuming that risk is not financially feasible.

A waiver of section 1834(m) would give ACOs seeking to take on or transition to two-sided risk an additional tool to use to drive improved health and reduced costs in their patient population. A growing body of evidence, including evidence from a number of CMS' own demonstration programs as noted in the Preamble, shows how telehealth can be used to positively impact health care outcomes for patients. A recent systematic review of the literature by Bashshur and Shannon[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,

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

and fewer emergency department visits. A number of other recent studies have demonstrated similar positive results with the use of telehealth.[2]

Moreover, the savings to be gained from the provision of telehealth services and resultant enhanced care coordination may make it more likely that ACOs will be willing to accept two-sided risk. A recent actuarial analysis 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.[3] The same report also found that patient issues are resolved in the initial telehealth visit almost 90 percent of the time, disproving the idea that telehealth services may lead to additional downstream care or utilization.

Finally, as noted by CMS in the Preamble, with respect to ACOs, a waiver of FFS requirements is appropriate when incentives are geared toward improving quality and reducing costs (similar to Medicare Advantage) rather than generating service volume. However, outside ACOs, we continue to believe we need reimbursement in fee-for-service as we transition to value-based models.

We agree with CMS that the incentives for an ACO with two-sided performance-based risk are similar to the incentives in a capitated environment, and note that CMS currently allows Medicare Advantage plans to offer telehealth services to beneficiaries as a mandatory supplemental benefit, further bolstering the case for a waiver of section 1834(m) for ACOs with two-sided performance based risk.[4]

Given the above, the Alliance believes that CMS should exercise its authority under section 1899(b)(2)(G) to waive section 1834(m) requirements for ACOs with a two-sided, risk-based model (both Track 2 and Track 3). We have included additional thoughts outlining how CMS might operationalize such a waiver below.

II. Operationalizing a Waiver of Section 1834(M) Restrictions

Although we do not believe that each ACO should have to go through a separate waiver process to be able to provide telehealth services to their patients, we have included some thoughts on how to operationalize such a process here in case CMS disagrees.

We recognize that there a number of issues that CMS takes into account when determining how to implement a waiver of an existing FFS requirement, including which ACOs should be eligible for the

---

[2] American Telemedicine Association, *Examples of research outcomes: telemedicine's impact on healthcare cost and quality.* Available at: http://www.americantelemed.org/docs/default-source/policy/examples-of-research-outcomes—telemedicine'simpact-on-healthcare-cost-and-quality.pdf. (April 2013). See also Uscher-Pines, L., and Mehrotra, A., *Analysis of Teladoc Use Seems to Indicate Expanded Access to Care for Patients Without Prior Connection to a Provider,* Health Affairs 33:12 (2014): 258-264.

[3] Yamamoto, D.H., *Assessment of the Feasibility and Cost of Replacing In-Person Care with Acute Care Telehealth Services* (Dec. 2014). Available at: http://www.connecwithcare.org/studiesreports.

[4] One of the Alliance's members, Anthem, began offering telemedicine services to its Medicare Advantage beneficiaries in October 2014.

waiver, how the services subject to the waiver should be defined, and what protections should be put in place to ensure appropriate use of the waiver. We have touched on each of these issues below, offering a number of recommendations for CMS' consideration. We would be happy to provide additional information about our recommendations in each of these areas if needed.

a. Eligible ACOs

The Alliance believes that a waiver of section 1834(m) should apply to any beneficiary assigned to an ACO with two-sided performance-based risk. As such, we believe that a waiver of section 1834(m) should be available in ACOs in both Tracks 2 and 3. While we understand that CMS is concerned that the retrospective assignment methodology used in Track 2 may make it difficult for these ACOs to know definitively which beneficiaries are covered by the waiver, we believe that the compelling policy-based reasons for extending a waiver of section 1834(m) to all risk-based ACOs outweigh the operational issues.

First, as discussed in detail above, the Alliance believes that telehealth offers clear benefits that should be realized by all Medicare beneficiaries. Although we would like to see expanded reimbursement across the Medicare program, we agree that risk-based ACOs provide a unique opportunity for a waiver of section 1834(m) for a subset of Medicare beneficiaries. Limiting a waiver to ACOs in Track 3, however, would unnecessarily deprive beneficiaries in Track 2 ACOs of services that could both improve their health and reduce their costs.

Second, along with other changes to the attribution model, allowing Track 2 ACOs to use telehealth to provide services could reduce the rate of patient "churn" out of the ACO and ensure that patients who otherwise would have fallen out of attribution remain attributed to the ACO at the end of the year. Waiving section 1834(m) requirements would increase the feasibility and convenience of continuing to receive care from the ACO for many patients, thus likely increasing their "stickiness."[5] Medicare beneficiaries living in urban and suburban areas may prefer telehealth services for some of their health care needs. They may otherwise have limited access to their health care providers due to difficulties associated with a lack of accessible transportation systems, an inability to afford transportation costs, a reluctance to travel in inclement weather, or even the safety concerns about traveling to their physicians' offices or other health care service settings. Patient satisfaction with telehealth services has also consistently been very high, with studies finding that approximately 98 percent of commercial patients are happy with their services. All of these factors could be helpful to Track 2 ACOs in preventing leakage of patients outside the ACO and reducing the rate of "churn."

Finally, as mentioned above, the Alliance believes there are ways to mitigate the operational challenges associated with use of a waiver in the event of retrospective attribution. If a Track 2 ACO uses telehealth to provide care to a beneficiary who does not end up being attributed to the ACO at the end of the year, they may still seek Medicare FFS reimbursement if care was provided to the beneficiary at an originating site in a qualifying location. If Medicare FFS reimbursement is not available, the ACO would be

[5] For example, patients who move to areas with warmer climates during the winter may fall out of the ACO if they seek in-person care from a provider in the area where they are temporarily located. However, if their providers from home were able to use telehealth, those patients may continue to consult with ACO professionals using technology, thus ensuring that they remain attributed to the ACO.

responsible for the costs associated with the care under the terms of their agreement with their telehealth vendor. ACOs could take steps to mitigate the financial risk associated with unreimbursed care by putting contractual guardrails in place and/or by creating guidelines that limit the use of telehealth services to patients that are not "at risk" of de-attribution (to the extent that is known).

b. Definition of "Telehealth Services"

As noted in the Preamble to the Proposed Rule, Section 1834(m)(4)(F)(i) of the Social Security Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary when furnished via a telecommunications system. The list of services eligible for reimbursement as a telehealth service is reviewed by the Secretary through CMS staff each year and updated as needed in the Medicare Physician Fee Schedule.

Rather than continuing with this services-based approach, the Alliance believes that CMS should adopt a definition of "telehealth" in the Shared Savings Program that focuses on "what" the technology does rather than "how" it does it. As such, we recommend that CMS define "telehealth" in the following manner for purposes of the Shared Savings Program: "*Telehealth is the use of electronic information and telecommunications technologies to support remote patient health care*." A waiver of section 1834(m) in the Shared Savings Program would be applied to technologies captured by this definition only insofar as applicable (we note, for example, that section 1834(m) does not apply to some types of technology including remote patient monitoring platforms).

This proposed definition is a modified version of an existing definition in the Public Health Service (42 U.S.C.S. § 254c-16). We believe that a functionality-focused approach is consistent with other technology-based definitional frameworks in use throughout the Department, including the approach to defining "meaningful use" used in CMS' EHR Incentive Programs and the risk-based framework for regulating health IT proposed by the Food and Drug Administration, the Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC).

Although we are only recommending use of this definition in the Shared Savings Program at this time, we note that CMS could choose to adopt it throughout the Medicare program through additional rulemaking at a later date. Use of a common definition across the program would allow CMS to efficiently and transparently communicate with policy makers, providers and patients, and would allow for innovation and the introduction of new technologies in the future.

c. Safeguards to Protect Beneficiaries and the Medicare Trust Fund

We have included a number of safeguards that CMS could consider implementing to prevent abuse of a waiver below. These suggestions are adapted from the discussion of the skilled nursing facility (SNF) 3-day rule waiver in the Proposed Rule and are grouped into three specific areas: 1) application/documentation requirements; 2) telehealth provider quality reporting requirements; and 3) requirements to promote transparency and prevent abuse of the waiver.

Application/Documentation Requirements. ACOs are currently required to submit a robust application to CMS when applying to participate in the Shared Savings Program, and CMS has proposed a similar application process for ACOs seeking to renew their participation for a second performance period. We believe that CMS could require ACOs to submit information to demonstrate that they have the capacity and infrastructure to deliver care via telehealth during the application process. CMS could require ACOs to submit information such as the following:

- A written plan outlining how the ACO will use telehealth to meet the clinical needs of patients within the ACO, including information on the ACO's staffing capacity and business processes related to the provision of telehealth services;
- Letter(s) of intent to contract from a telehealth provider(s);
- Documentation that the ACO governing body has approved the use of telehealth and will comply with all requirements for the provision of telehealth services; and
- Financial information demonstrating that the ACO has the funds to provide the startup costs and pay for ongoing/recurring implementation costs associated with their providers' provision of telehealth services.

Quality Reporting Requirements. The Alliance recognizes that high quality care is a pillar of the Shared Savings Program and believes that telehealth providers working with ACOs under a waiver of section 1834(m) should share in the responsibility of collecting and reporting relevant quality measures.

While ACOs will be responsible for reporting 37 quality measures on patient/caregiver experiences, care coordination/safety, preventive health, and clinical care measures for those at risk of depression, diabetes, hypertension, ischemic vascular disease, heart failure and coronary artery disease, we recognize that it may not be appropriate for telehealth providers to report on all of these measures given the nature of the services they are likely to provide.

As such, we recommend that CMS require telehealth providers to report on a subset of these measures – the patient and caregiver experience measures (ACO-1 through ACO-7 and ACO-34) – in the same manner as ACOs, while requiring telehealth providers to cooperate with ACOs, to the extent feasible, in meeting the ACOs' responsibilities for collecting other quality measure reporting requirements from the telehealth patients they serve.

We believe that these reporting responsibilities will allow ACOs to evaluative the patient and caregiver experience of their telehealth providers, and will provide the fullest picture to CMS and its evaluators of the role that telehealth services play in the Shared Savings Program.

Requirements to Promote Transparency and Prevent Abuse of the Waiver. We appreciate CMS' concerns about abuse of any waiver of FFS requirements, and agree that waivers should be implemented in a transparent manner that protects both beneficiaries and the Medicare Trust Fund. We fully support implementation of the types of protections that are in place or have been suggested for other waivers, including the right to deny, revoke, audit, or even withdraw the waiver if CMS were to determine that abuse of the waiver existed. Other recommended protections include:

- CMS has the right to deny or revoke the waiver for the provision of telehealth services at any time;
- ACOs must post a copy of the waiver on the dedicated ACO Web page;
- The use of the telehealth waiver would be documented by the ACO and the documentation retained;
- The telehealth waiver would be effective on the start date of the ACO's participation agreement and would not extend beyond the end of the ACO's participation in the Shared Savings Program;
- CMS would retain the right to monitor and audit ACOs' use of the telehealth waiver; and
- Practitioners providing telehealth services should follow all applicable licensure laws and could be required to provide documentation of appropriate licensure upon request.

In addition to these protections, we recommend that CMS require telehealth providers to have a mechanism in place to electronically transmit a record of the telehealth encounter to the patient's primary care provider when the eligible telehealth provider is not the patient's primary care provider. We also recommend that CMS consider the impact of telehealth services in its ongoing evaluations of the ACO program so that we will learn best practices as well as any challenges that ACOs face in the provision of telehealth services, how telehealth services enhance care coordination, and how these services contribute to improvements in health outcomes and cost savings.

* * * * *

Thank you for the opportunity to provide comment on the Proposed Rule. The Alliance appreciates CMS' consideration of all of its recommendations and looks forward to the agency's implementation of telehealth services in the ACO Shared Savings Program without any of the current restrictions in Section 1834(m). Telehealth can and will help ACOs achieve the cost, quality, access, and patient engagement goals for which they strive. It is time to lift the section 1834(m) restrictions on the coverage and reimbursement of telehealth services so ACO providers can have another important tool in realizing the potential of new care delivery models.

Please do not hesitate to contact me if you or your staff have any questions.

Sincerely,

Krista Drobac

Krista Drobac
Executive Director
Alliance for Connected Care