ALLIANCE for CONNECTED CARE

October 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1734-P)

Dear Administrator Verma:

The Alliance for Connected Care ("the Alliance") welcomes the opportunity to provide feedback on the Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule for calendar year (CY) 2021, which includes several important reforms with respect to telehealth. We appreciate the Center for Medicare and Medicaid Services early recognition of the value of telehealth and remote patient monitoring in responding to the COVID-19 pandemic and its prompt and continued efforts to ensure access to care during COVID.

The Alliance is dedicated to creating a statutory and regulatory environment in which insurers and providers can deliver, and be compensated for providing safe, high quality care using connected care technology. Our members are leading health care and technology companies from across the spectrum, representing health systems, health payers, and technology innovators. The Alliance works in partnership with an Advisory Board of more than 30 patient and provider groups, including many types of clinician specialty and patient advocacy groups who wish to better utilize the opportunities created by telehealth.

As reflected in the comments below, the Alliance applauds the inclusion of additional telehealth services as part of the Medicare Telehealth Services List. The Alliance is committed to leveraging telehealth and remote patient monitoring to improve the quality of care while also lowering costs and improving efficiency, and we believe this inclusion will serve all three of those aims.

The Alliance would like to emphasize four overarching priorities in advance of our more detailed response:

- A great deal of confusion continues to exist around the authority of the Administration to make longer-term telehealth changes. We encourage CMS to continue clearly communicating to

Congress and stakeholders that there are statutory limitations curtailing CMS's ability to allow continued access to telehealth for Medicare beneficiaries. Additionally, we urge you to continue collecting and publicly sharing data about telehealth utilization and inform a conversation with Congress around what statutory authorities CMS needs to make thoughtful, long-term policy.

- While we appreciate and support CMS's effort to create temporary category 3 codes, we do not believe these codes create the adequate stability and predictability needed for healthcare providers to make necessary investments and plan for care/care systems in the longer team. CMS should be making additional permanent changes within its authority, even if those changes may require revision at a future date. CMS should also aggressively leverage a much wider set of category 3 codes to help create a smoother, calendar year-aligned, "off-ramp" for those services which may not continue – rather than having an abrupt and unpredictable ending with the close of the public health emergency.

- We are particularly concerned with steps taken by CMS around remote patient monitoring. Specifically, the Alliance does not agree with CMS's interpretation of codes 99457 and 99458 and the proposed requirement that "interactive communication" consist of real-time synchronous two-way audio. Requiring real-time interaction is inconsistent with the opportunity and intent of remote patient monitoring technologies, which are effectively delivered using a mix of both synchronous and asynchronous modalities.

- While we strongly support a system-wide telehealth expansion, we note that there is no reason for CMS not to immediately leverage its full authority to permanently expand the use of telehealth flexibility within outcome-based alternative payment models. The concerns about long-term expansion expressed by CMS and others do not exist in models with aligned incentives and accountability for quality, cost, and patient satisfaction.

We also recognize there are statutory restrictions that limit the ability of CMS to permanently extend several longstanding and antiquated telehealth issues. We encourage CMS to explore opportunities and coordinate with Congress to expand the types of practitioners who may furnish and bill Medicare telehealth services, including for physical therapy, occupational therapy, and speech-language pathology services, which have proven both effective and necessary during the PHE.

Category 1 Codes

In the proposed rule, CMS makes permanent nine new codes – adding them to the list of Medicare telehealth services on a Category 1 basis for CY 2021. These codes were previously added on an interim basis for the duration of the COVID-19 public health emergency and would now be permanent. The

Alliance strongly supports the addition of all of these codes including the visit complexity E&M add-on code, prolonged E&M services code, home visit E&M services, group psychotherapy, neurobehavioral status exam, assessment and care planning for the cognitively impaired, and domiciliary services. These new Medicare telehealth services codes will help bolster patient and provider adoption of telehealth and advance access to care. CMS should strongly consider moving a significantly larger number of the codes leveraged during the PHE to permanent status.

Category 3 Codes

While we generally support CMS's proposal to retain codes on a category 3 basis for services enabled during the PHE, temporary changes do not provide the certainty necessary to drive market adoption and investment in telehealth. Many of these codes could be safely added on a permanent basis.

CMS should also strongly consider extending this list as broadly as possible to cover all telehealth services, or at least the majority of telehealth codes used during the pandemic. Even if a COVID-19 vaccine is successfully created in 2020, experts agree that it will be well into 2021 that the risks posed to Medicare beneficiaries by COVID-19 subside. CMS should be seeking to minimize the amount of change for strained providers at the end of the PHE. It would make the most sense and create the least administrative burden on the health system for CMS to attempt to smoothly transition from public health emergency-approved codes to physician-fee-schedule codes without significant changes (recognizing that CMS can only make these changes on some flexibilities). If CMS does not intend to continue all of the temporary PHE telehealth codes, they should seek to have all of those not made permanent end with the calendar year in which the PHE ends.

Finally, there are a number of priority codes left out of previous COVID-19 PHE actions that are needed by patient populations represented on the Alliance for Connected Care's Advisory Board. We recommend that CMS act to immediately add the following codes on a category 3 basis.

- 92526 (treatment of swallowing dysfunction and/or oral function for feeding)
- 92607 (evaluation for speech generating device; first hour)
- 92608 (evaluation for speech generating device; each additional 30 minutes
- 92609 (therapeutic services w/ speech generating device includes programming/modification)
- 92610 (evaluation of oral and pharyngeal swallowing function)

Other priority areas for category 3 codes include psychiatric and neuropsychiatric testing, end-stage renal disease, radiation treatment management, and intensive care services.

Furnishing Telehealth Visits in Inpatient Nursing Facility Settings, and Critical Care Consultations

CMS is seeking comment on whether it would be appropriate to maintain the flexibility during the PHE permitting physicians and nonphysician practitioners to perform required visits for nursing home residents via telehealth. CMS is seeking comment on whether the in-person visit requirement is necessary, or whether two-way, audio/video telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary. According to the Kaiser Family Foundation, there are roughly 15,500 skilled nursing facilities in the US. Telehealth services help provide necessary care to patients while minimizing the transmission of COVID-19, protecting both patients and frontline providers. Telehealth has the potential to improve nursing home care, as well as improve a SNF's financial stability and save Medicare dollars by saving money from reducing hospital readmissions thereby reducing costs. While we broadly believe that in-person visits are rarely necessary before a telehealth encounter, these visits are even less necessary in a facility-based environment where another healthcare professional is on-site.

Payment for Audio-only Telehealth Visits

CMS is not proposing to continue to recognize audio-only codes for payment under the PFS after conclusion of the PHE for the COVID-19 pandemic because, outside of the circumstances of the PHE, CMS is not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. CMS notes that the CARES Act allowed its emergency waiver of video technology requirements under 1834(m), which will cease at the end of the PHE.

The Alliance believes that audio-only telehealth has been a critical tool for many clinicians and patients during COVID-19. While we believe that audio-visual communication is the preferred modality for most telehealth, we strongly support continued flexibility for audio-only – when clinically appropriate and the meeting the need or request of the patient. These needs could include technology or broadband limitations or be limited to specific services (such as behavioral health) for which audio-only is demonstrated to be a clinically appropriate means of care delivery. The Alliance supports the addition of payment for audio-only visits, when a two-way, audio/video communication cannot be properly established. The Alliance would support the development of telephone-only payment codes for a specific set of clinically appropriate services if statutory barriers continue to be interpreted to prohibit a more flexible "as-needed and appropriate" approach.

Remote Patient Monitoring and Communication Technology-Based Services

The Alliance applauds CMS for many positive changes to remote patient monitoring and communication-technology based services. The Alliance is broadly supportive of all CMS efforts to facilitate the delivery of telehealth and remote patient monitoring services by all types of healthcare practitioners within the

scope of that practitioner's expertise. We also strongly support the proposal to allow consent to be obtained at the time that RPM services are furnished on a permanent basis.

As stated in previous years, the Alliance continues to believe that restrictions on payment for virtual-check-ins based on visits in the previous 7 days or following 24 hours to be significant limitation on the utility of these services. While these visits should not be billed when they would represent unnecessary utilization, the burden of tracking past and future visits does not happen before billing. Rather than risking a false claim over $14, providers just choose not to utilize virtual check-ins. There may also be clinically appropriate circumstances in which a virtual-check in could be used within 7 days of another medical procedure – and be a better value to the Medicare program than the visit which might be billed instead.

CPT Codes 99457 and 99458

CMS stated that "interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. CMS stated the interactive communication must total at least 20 minutes of interactive time with the patient over the course of a calendar month for CPT code 99457 to be reported. CMS stated that each additional 20 minutes of interactive communication between the patient and the physician/nonphysician practitioner/clinical staff is reported using CPT code 99458.

This is the first time CMS has addressed, in published guidance, the interactive communication requirement in the context of RPM. CMS's interpretation would appear to mean that the practitioner and clinical staff must use the RPM, analyze the data, assess it, update the care plan accordingly, and also spend at least 20 minutes talking on the phone or video with the patient each month. The proposed clarification does not include clinician and clinical staff time spent reviewing physiologic data, care management functions, educating the patient, and other aspects included in the description of procedures for 99457, which we believe should be included in addition to "interactive communication" with the patient/caregiver. For example, if a doctor spent 40 minutes overall doing these activities, but only 19 minutes of that time was actually talking on the phone/video with the patient, the doctor would not be eligible to bill CPT 99457. Such an interpretation does not seem consistent with the use of RPM technology. Nor does it sufficiently distinguish between RPM and chronic care management services, the latter designed to have more direct patient intervention/interaction.

Further, many of these elements can be most effectively delivered using a mix of both synchronous and asynchronous modalities, as opposed to strictly real-time, two-way audio interaction. This proposed change would greatly handcuff the efficiency of an RPM program, and drive up overall program expense. A more reasonable reading of the code descriptor and intent is that the interactive communication with the patient is part of the 20-minute minimum, but the practitioner can also include time spent reviewing and analyzing the patient's RPM data and determining how to change the care management accordingly.

CPT Codes 99453 & 99454

In the current CPT code explanatory language for CPT Codes 99453 & 99454 there is a requirement that, in order to bill these codes, the patient must have monitoring devices in use for at least 16 days in a 30-day period. CMS temporarily waived this requirement for those with a COVID-19 or suspected COVID-19 exposure. While this requirement is likely valid for the appropriate tracking and treatment of many chronic conditions, COVID-19 has highlighted the benefit of using RPM for acute conditions as well. In the proposed rule, CMS asks for input on removing the 16-day requirement despite the inclusion in the CPT code explanatory language. We believe that CMS should adopt distinct codes for RPM services for acute conditions and RPM services for chronic conditions; however, in the meantime, we urge CMS to remove the 16-day requirement from CPT Codes 99453 & 99454.

CMS also includes in the proposed regulation a limitation on how often codes CPT Codes 99453 and 99454 can be billed in a 30-day period. The current language only allows for billing the codes once per month per patient – even if a patient has multiple providers who use different (or even the same) device to track a multiple chronic condition (for example their cardiologist uses RPM to track heart disease/failure while their pulmonologist uses RPM to track COPD). We urge CMS to allow for more than one provider to bill per patient in a 30-day period, when necessary and clinically appropriate.

The Alliance also encourages CMS not to finalize the proposed requirement that RPM-supportive medical devices digitally upload patient physiologic data, thus barring the utilization of patient self-reported data. We believe that RPM can be successfully delivered through a mix of both devices with direct digital uploading and devices that incorporate additional steps. There are clinically appropriate situations in which a clinician could rely on manually uploaded or patient-reported data. Additionally, devices with direct digital upload may prove more costly or not be feasible in rural or underserved areas with limited broadband access.

The Alliance supports allowing auxiliary personnel (which includes other individuals who are not clinical staff but are employees, or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

CPT Code 99091

Currently, the explanatory language for CPT code 99091 states that "a physician or other qualified healthcare professional, qualified by education, training, licensure/regulation (when applicable)" can bill for the code. Unlike other RPM codes for which CMS has allowed clinical (non-physician) staff to bill under general supervision of a Medicare eligible provider, CMS has stated that *only* Medicare eligible providers can bill for CPT code 99091. The Alliance encourages CMS to align the language with other RPM codes to allow for clinical staff, as appropriate, to bill for CPT code 99091 under general supervision of a Medicare eligible provider.

Direct Supervision by Interactive Telecommunications Technology

For the duration of the PHE for the COVID-19 pandemic, CMS adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/ video real-time communications technology. CMS is proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021. The Alliance for Connected Care encourages the permanent extension of this policy, in recognition of the significant workforce changes enacted during COVID-19 that are affecting every industry – not just healthcare. Just as major corporations are adjusting to enable more flexible and remote workforces – healthcare organizations must also evolve. Remote supervision is a critical tool to extend the capability of the healthcare workforce and drive value across the healthcare system in the long-term.

CMS Authority to Support Other Types of Billers

Many critical access hospitals (CAHs) are not able to leverage these increased telehealth flexibilities from CMS. Under the standard payment methodology for CAHs, also known as "Method I," a CAH receives payment for outpatient services under a reasonable cost-based methodology. More specifically, the CAH as an institution receives payment for outpatient hospital services it furnishes to its patients and pays its medical staff according to its own internal policies. Because of this facility-based payment, Method I CAHs cannot leverage the telehealth benefit under section 1834(m) to ensure beneficiary access to outpatient hospital services furnished via telehealth. During the pandemic, CMS acted quickly to create a path for these facilities to deliver telehealth through its waivers of provider-based regulations under emergency authority – however, we believe there may be opportunity for CMS to address this challenge on a permanent basis.

CMS has the statutory authority to amend its provider-based regulations to allow Method I CAHs to designate a patient's home as provider-based, which would allow a CAH to furnish certain outpatient via telecommunications technology that are payable to the CAH under Method I. CMS can do this by simply adding a new clause (M) to 42 C.F.R. § 413.65(a)(1)(ii) that reads: "a beneficiary's home, when such beneficiary is under a plan of care for outpatient critical access hospital services (as defined in section 1861(mm)(3)) for behavioral therapy that are paid under 42 C.F.R. § 413.70(b)(2). We strongly encourage CMS to evaluate this option.

CMS Authority to Support Telehealth in APMs

While CMS needs additional statutory authority for many permanent telehealth policies, it has broad authority over alternative payment models. The Alliance was pleased to see CMS take steps to expand flexibility for telehealth in Medicare Advantage plans earlier this year. CMS now has a significant

opportunity to facilitate telehealth under Medicare Shared Savings Program (MSSP) and Center for Medicare and Medicaid Innovation (CMMI) models where it has broad statutory latitude. When a health organization agrees to take both financial and health outcome responsibility for patients, they should be allowed by CMS to provide care in a way that best serves their patients. CMS should provide participants in alternative payment models access to an expansive set of telehealth waivers – including waiving geographic and originating site restrictions, patient cost-sharing, additional modalities like telephone-only, supervision allowances, waivers on the frequency of telehealth visits, and rules around covered services, such as those with in-person care requirements. CMS should also seek to eliminate unnecessary telehealth barriers, such as Accountable Care Organization (ACO) restrictions on retrospective assignment.

Virtual Care in the Diabetes Prevention Program

The Alliance believes that one of the most appropriate uses of virtual care is for the management of ongoing chronic conditions. Therefore, we also provide comment on the proposed emergency policy for the Medicare Diabetes Prevention Program (MDPP) Expanded Model. The Alliance believes that virtual DPP programs have significant promise for ensuring the health of Medicare beneficiaries and should be covered by CMS. We believe that virtual MDPP can be offered to Medicare beneficiaries in a manner that aligns with CMS's stated goals for the MDPP benefit, and to further ensure that a greater number of Medicare beneficiaries who are eligible for the MDPP benefit can use it to reduce their risk of chronic disease.

We were disappointed with CMS's March decision not to allow virtual DPP programs to operate in Medicare during the COVID-19 PHE despite the flexibility given to in-person MDPP suppliers to transition their sessions to a virtual setting. The Alliance encourages CMS to expand access to virtual DPP -- CMS should undertake rulemaking to include a virtual DPP offering in the MDPP benefit at its earliest convenience, covering both non-emergent time periods as well as the current and future public health emergencies.

Additional Guidance Requested

The Alliance respectfully requests that CMS provide additional guidance for providers on the deletion of CPT code 99201 for CY2021. We request that CMS please confirm if there are any circumstances in which a practitioner who would previously have billed 99201 may not instead bill 99202. For example, we seek clarity that it is appropriate to bill 99202 for a new patient visit lasting significantly less than 20 minutes in time.

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The Alliance greatly appreciates CMS's leadership in working to ensure that seniors are able to realize the benefits of telehealth and remote patient monitoring. We appreciate the opportunity to provide feedback on the Medicare Physician Fee Schedule (PFS) Proposed Rule for calendar year (CY) 2021, and look forward to continuing to work with CMS to increase access to high quality connected care for Medicare beneficiaries. If you have any additional questions, please do not hesitate to contact Chris Adamec at cadamec@connectwithcare.org.

Sincerely,