Partnership to Advance Virtual Care

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Submitted electronically via www.regulations.gov

December 23, 2020

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Regulatory Relief to Support Economic Recovery; Request for Information (RFI)

Dear Secretary Azar,

The Partnership to Advance Virtual Care (Partnership) appreciates the opportunity to respond to the Department of Health and Human Services' (HHS) request for information (RFI) on the costs and benefits of the regulatory changes beyond the COVID-19 public health emergency (PHE) and which actions should be made permanent. The Partnership is composed of health systems, health IT vendors, innovators, chronic care specialists, and primary care stakeholders who are committed to ensuring patients who receive care via telehealth have access to the highest quality care. As a coalition representing leaders across the telehealth space, we appreciate the opportunity to provide comments on the RFI on Regulatory Relief to Support Economic Recovery.

We applaud the broad and swift action taken by HHS and the Centers for Medicare and Medicaid Services (CMS) in response to the pandemic to make certain Medicare beneficiaries continue to have access to necessary care. During the pandemic numerous waivers and flexibilities were issued to ensure access to telehealth services as an alternative modality to in-person care. Prior to the pandemic, telehealth services were limited in scope and utilization. However, out of necessity, the pandemic forced the healthcare system to explore how care can be effectively provided through alternative modalities.

The Partnership recognizes that outside of the current PHE, the agency's authority to eliminate or waive certain telehealth requirements, such as originating and distant site requirements is limited by current statute. To fully realize the value and benefit of telehealth, the Partnership recommends that Congress remove all telehealth site of service limitations and allow Medicare beneficiaries to access telehealth services from all hospitals, healthcare facilities, and patients' homes or other locations deemed appropriate by a clinician. Absent such changes, the uptake and utility of telehealth will be limited.

Responding to the agency's request and specific questions on the telehealth flexibilities that should continue beyond the pandemic, the Partnership's comments address the continued need for broad telehealth flexibilities that will facilitate empirical data collection to inform more permanent care delivery transformation. In addition, we provide specific comments on the following regulations as listed in Appendix A of the RFI:

- *Action 4: Notification of Enforcement Discretion for Telehealth Remote Communications*
- *Action 111: Communication Technology-Based Services (CTBS)*

- *Action 113: Telephone Evaluation and Management (E/M) Services Codes*
- *Action 125: Payment for Medicare Telehealth Services Under Section 1834(m) of the Act*
- *Action 143: Payment for Remote Physiologic Monitoring (RPM) Services*
- *Action 149: Updating the Medicare Telehealth List on a Sub-regulatory Basis*
- *Action 189: Allow use of audio-only equipment to furnish audio-only telephone E/M, counseling, and educational services*
- *Action 201: Practitioner Locations*
- *Action 210: Remote Patient Monitoring Reporting*
- *Action 230: Medicare Provider Enrollment Relief*

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All Actions: Continued Need for Broad Telehealth Flexibilities to Inform Permanent Care Delivery Transformation

The emergence of COVID-19 accelerated the transformation of care delivery across the United States. This dramatic transformation was the result of necessity – to meet the immediate needs of the population – as well as the rapid removal of regulatory and statutory requirements that limit the scope and design of practice. While these requirements were designed with the intention of protecting beneficiaries, in many instances they had become a barrier to innovation and transformation in care delivery. The dramatic evolution of care delivery over the past nine months is a clear example of how requirements have limited such transformation.

The Partnership recognizes that permanent changes to our current regulatory frameworks should be informed by empirical data demonstrating that virtual care is used when clinically appropriate and that outcomes achieved through virtual care are at least equivalent, or non-inferior, to standard brick and mortar care. **An extension of established flexibilities through calendar year 2022 would provide health services researchers the opportunity to collect such data.** To do so successfully, economists and health services researchers across the United States need the opportunity to develop sound methodologic analyses that incorporate collection of utilization and outcome data during a timeframe where telehealth flexibilities remain in place, but beneficiary behavior is not driven by the effects of the pandemic. This will not occur in 2021. Population-wide vaccine delivery will not occur until late spring or early summer, and pent-up demand or otherwise unpredictable and unstable care utilization patterns are expected in the months immediately preceding population-wide vaccination. At the earliest, care patterns will stabilize in calendar year 2022.

As such, calendar year 2022, is expected to be the first opportunity to collect data that reflects utilization behavior and patient outcomes in a stable care delivery system and public health environment. Terminating current flexibilities at the end of the PHE or at the end of calendar year 2021 forgoes the opportunity to generate empirical data that would allow evaluation of the impact of virtual care delivery and that would inform future policy making. It would be a failure to benefit from a non-reproducible moment in time, and perhaps result in a dramatic step backwards in care delivery innovation. **Given the unique circumstances of the PHE, the Partnership urges HHS to maintain all current telehealth flexibilities through 2022 to provide health services researchers the opportunity to evaluate virtual care delivery models in a stable environment.**

Action 4: Notification of Enforcement Discretion for Telehealth Remote Communications

As part of the regulatory relief provided during the pandemic, the HHS Office of Civil Rights (OCR) waived Health Insurance Portability and Accountability Act (HIPAA) compliance requirements for digital platforms

used to furnish telehealth services. This flexibility permitted providers to leverage existing platforms well-known to patients, such as FaceTime or Zoom, so that telehealth services could be delivered without delay to patients during a critical time. Familiarity to both patients and providers was important for immediate adoption.

As the pandemic endures, providers continue to leverage telehealth to ensure the health of the nation and to respond to continued COVID-19 outbreaks. Flexibility in compliance requirements for digital platforms used for telehealth services remains critical. After the pandemic ends, HIPAA requirements should be enforced once again for digital platforms to ensure patient security and to protect patient privacy. The Partnership supports enforcement of standards for HIPAA compliant platforms. However, we are concerned about the impact of an abrupt return to enforcement on beneficiary access as providers will need time to obtain and implement new platforms. As such, **the Partnership urges HHS to provide a temporary extension of this HIPAA flexibility beyond the pandemic. This flexibility should be extended for at least 12 months after the end of the PHE to allow sufficient time for implementation of HIPAA compliant platforms.** This extension will ensure beneficiary access to care is maintained and provide adequate time for practices and their beneficiaries to transition to HIPAA compliant telehealth platforms.

Action 111: Communication Technology-Based Services (CTBS) & Action 211: Remote Evaluations, Virtual Check-Ins & E-Visits.

For the duration of the COVID-19 PHE, important flexibilities were issued by CMS to ensure patients maintained appropriate access to CTBS, such as permitting CTBS to be furnished to both new and established patients and allowing consent to receive these services to be documented by auxiliary staff under general supervision at the same time the service is furnished. CMS addressed some of these flexibilities in the recent CY 2021 Medicare Physician Fee Schedule (PFS) final rule. However, the Partnership urges HHS to take additional action.

Established Patients

CTBS services are important to ensure continuity of care and provide additional support for chronic disease management. Not every patient requires an in-person or telehealth visit. During the PHE, CMS permitted CTBS to be furnished to both new and established patients. **In the CY 2021 Medicare PFS final rule, CMS finalized, post PHE, a return to previous policy which allows CTBS services to be furnished to established patients only. The Partnership urges HHS to reconsider this position and to extend permanently the flexibility allowing CTBS to be furnished to both new and established patients. Moreover, if current coding for current CTBS services is limited to established patients, we recommend implementing new codes that are specific to new patients.** Data show that patients from underserved communities have less access to care and are less likely to have a primary care physician. These factors as well as others contribute to significant disparities in health outcomes. Establishing CTBS codes for new patients, while not a panacea, will minimize certain barriers to care by allowing patients to access care they may not otherwise seek.

Additionally, it remains unclear to the Partnership whether an E/M service furnished via telehealth is sufficient to establish a relationship with a patient, such that a physician furnishing a new patient E/M office visit (e.g., 99203) via telehealth may subsequently bill a CTBS service for the same patient. Currently, all states allow a physician to establish a relationship with a new patient via telehealth, though state laws may differ. **The Partnership requests that HHS clarify that, consistent with any applicable state laws, a physician may establish a relationship with a patient through services furnished via telehealth and that services that require an established relationship, such as CTBS services, may subsequently be provided to these patients**.

Both CTBS and telehealth services work in conjunction to ensure continuity of care and provide a modality for patients to remain engaged with their providers to manage complex chronic diseases.

As the nation evaluates how telehealth will fit into the healthcare landscape outside of the context of a pandemic, CTBS services will continue to play an important role in managing diseases. Continuity of care can improve health outcomes and reduce complications that lead to more expensive in-person care.

Obtaining Patient Consent

CMS issued flexibilities in the manner and timing of receiving beneficiary consent for CTBS services. Specifically, CMS indicates that the consent from the patient to receive these services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. The issued flexibilities in obtaining patient consent provide administrative relief for providers. In the CY 2021 Medicare Physician Fee Schedule (PFS) final rule, CMS affirms these policies. **The Partnership appreciates the Agency's recognition that the timing or manner in which beneficiary consent is acquired shouldn't interfere with the provision of these services and we ask CMS to confirm that consent documented by auxiliary staff under general supervision or by a single billing practitioner in a group practice extends to all clinicians in the group practice.**

Action 113: Telephone Evaluation and Management (E/M) Services Codes

For the duration of the PHE, CMS expanded access to care by permitting certain services to be furnished via audio-only technology. In addition to covering certain services when delivered via audio-only, CMS also provided coverage and payment for telephone evaluation and management (E/M) services, establishing payment at rates, comparable to office or outpatient visits for established patients. Specifically, CPT codes 99441, 99442, and 99443, which were previously non-covered, were crosswalked to CPT codes 99212, 99213, 99214, respectively. This resulted in payment for audio-only E/M services consistent with services furnished in-person or via telehealth during the PHE.

After the PHE, 99441, 99442, and 99443 will once again be non-covered. In the CY 2021 Medicare PFS Final Rule, CMS established on a temporary basis a single code, G2252, for audio-only assessment. Payment for G2252 was crosswalked to 99442 (telephone E/M visit describing 11-20 minutes of discussion). This policy will result in a significant decrease in payment for audio only services once the PHE ends. Moreover, this decrease is inconsistent with the amount of physician work described by the service and how similar physician work is valued for other services. For example, 99212 when using time for code selection, requires 10-19 minutes of total time spent on the date of the encounter. In contrast, G2252 requires 11-20 minutes of medical discussion with the patient (Table 1).

Table 1

HCPCS	Descriptor	Work RVUs
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. **When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter**	0.70
G2252	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an	0.50

	E/M service or procedure within the next 24 hours or soonest available appointment; **11-20 minutes of medical discussion**	

Audio-only visits have been essential to ensuring continuity of care for Medicare beneficiaries and to promoting equity in access during the PHE. Many beneficiaries do not have access to a smart device capable of audio-visual technologies, do not understand the technology and/or are unable to navigate the application, or don't have access to broadband internet to support audio-visual technology, and while these concerns were exceedingly prevalent during the pandemic, they will remain beyond the PHE. In these circumstances, telephone visits were able to supplement care provided. Similarly, text-based care provides the opportunity to further augment care availability to beneficiaries without broadband or those that cannot engage in audio visits due to caregiving or work responsibilities. And while the Partnership appreciates CMS's nod to the role audio-only E/M services have played during the PHE as well as the agency's willingness to maintain payment for such services, the temporary addition of G2252 is insufficient. As such, **the Partnership urges HHS to extend permanently coverage and payment for audio-only E/M services. Additionally, work RVUs for these services should be consistent with the work RVUs for the corresponding E/M service - 99212, 99213 or 99214.** Alternatively, HHS could extend the policy temporarily and require CMS to develop additional audio-only visit codes that are appropriately valued.

Action 125: Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

The Partnership applauds the agency's immediate actions to expand beneficiary access to telehealth services during the pandemic. The rapid expansion of telehealth services has dramatically changed the telehealth landscape. In comments to the CY 2021 Medicare PFS proposed rule, the Partnership urged CMS to continue coverage and payment for the expanded list of services on a Category 3 basis. However, CMS finalized on a Category 3 basis continued coverage and payment for only 57 of the 139 services added during the PHE. **The Partnership urges HHS to extend temporarily coverage and payment for all 139 services added during the PHE.**

CMS finalized that services added on a Category 3 basis remain on the list of Medicare telehealth services until the end of the calendar year in which the PHE expires. If the PHE expires in January, services added on a Category 3 basis remain on the list of Medicare telehealth services until December 31, 2021. Such an outcome provides an eleven month temporary transition period. However, if the PHE expires on July 1, 2021, services added on a Category 3 basis would be provided only a six month temporary transition period as these services would also remain on the list of Medicare telehealth services until December 31, 2021. Such an outcome would not achieve the objective of providing a sufficient transition period that allows for additional evidence to be collected to support permanent addition to the telehealth services list. **The Partnership asks HHS to reconsider the policy finalized by CMS and to extend the transition period such that services added to the Medicare telehealth services list on a Category 3 basis expire, at the earliest, at the end of the calendar year that follows the year in which the PHE expires.** Such a revision ensures that stakeholders have additional time to obtain the necessary evidence to demonstrate, that when delivered correctly, that such services may be furnished fully, effectively and safely via telehealth under a high value paradigm and therefore should be added permanently to the list of telehealth services.

Action 143: Payment for Remote Physiologic Monitoring (RPM) Services

During the PHE, CMS waived requirements that 16 days of data be collected within 30 days to meet requirements to bill CPT codes 99453 and 99454. In the CY 2021 Medicare PFS final rule, CMS finalized the agency's intent, when the PHE ends, to again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454. CMS indicates that such a policy is

consistent with the CPT prefatory language for the CPT codes describing these services. Although CMS sought comments on whether current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients and whether additional RPM codes might be necessary, the agency took no steps to provide coverage for RPM services of shorter duration post PHE.

RPM services are frequently used for shorter durations to manage Medicare beneficiaries during acute illnesses. For example,

- A 75 year old Medicare beneficiary with a history of asthma and chronic obstructive pulmonary disease diagnosed with the flu during an office visit may have their vitals and oxygen saturation levels monitored remotely. Such remote monitoring has detected declining oxygen levels allowing the patient to be placed on home oxygen via a nasal cannula and avoiding a potential hospital admission as the patient further decompensated.

Shorter duration of RPM services has also been used in the context of managing patients diagnosed with COVID-19.

- Patients with heart failure have been managed through COVID-19 infections through remote monitoring of blood pressure and heart rate, which has allowed for real-time tracking of heart and respiratory rates. Via remote monitoring of these patients, real-time medication adjustments were made to avoid a heart failure related admission. The duration of RPM services in these clinical situations is typically less than seven days.

RPM services are also being used increasingly to support early patient discharge.

- In early patient discharge programs, patients are discharged home with four days of remote monitoring as a minimum requirement. Early discharge assists hospitals capacity levels and the ability to care for additional and more acutely ill patients in need that might otherwise overflow into the Emergency Department. These examples highlight certain clinical scenarios where shorter durations of RPM services are warranted, but there are more.

The Partnership urges HHS to extend permanently coverage for RPM services where data is collected for fewer than 16 days. Moreover, if current coding is restricted to RPM services where data is collected for longer durations, we request HHS implement new codes that apply to clinical scenarios where data is collected for shorter durations.

Action 149: Updating the Medicare Telehealth List on a Sub-regulatory Basis

Prior to the PHE, CMS had an established mechanism in which the agency annually accepted recommendations from stakeholders for additions to the Medicare telehealth services list for inclusion in the annual Medicare Physician Fee Schedule. However, during the PHE, CMS modified the process for adding or deleting services from the Medicare telehealth services list to allow for an expedited process during the PHE that does not involve notice and comment rulemaking.

The Partnership supports the permanent implementation of a new sub-regulatory process for updating the Medicare telehealth services list. Creating a new pathway for codes to be added to the Medicare telehealth services list will ensure that the agency can more appropriately respond to changes in care delivery and technology ensuring beneficiary access to services. It will be important that CMS continues to engage with stakeholders and ensure appropriate feedback is obtained by interested parties and Medicare beneficiaries.

Additionally, **CMS should make permanent the Category 3 basis for adding services temporarily to the Medicare telehealth services list. Doing so would provide a pathway for permanent addition to the Medicare telehealth services list for services that the agency believes may be delivered effectively and safely via telehealth, but for which CMS seeks additional evidence.** The pathway could be limited to services that would be considered for permanent addition on a Category 2 basis, under which evidence on outcomes is generally required for approval. Moreover, CMS could make addition on a Category 3 basis time limited. Making the Category 3 basis permanent would allow providers to conduct the kinds of review or to develop the kinds of evidence that CMS believes necessary. **The Partnership would also urge CMS to use sub-regulatory processes to add services to the Medicare telehealth services list on a Category 3 basis.** Services could be added on an interim basis as requests are granted, where approval date signals the beginning of the temporary period supporting evidence generation for permanent addition to the list.

Action 189: Allow use of audio-only equipment to furnish audio-only telephone E/M, counseling, and educational services

Audio-only services are important to ensure beneficiary access to care. In responding to the PHE, CMS waived requirements for video technology for certain services allowing E/M, behavioral health counseling and educational services to be furnished via audio-only technology.

The Partnership encourages CMS to allow permanently behavioral health counseling and educational services to be furnished via audio-only technology. These services do not inherently require video technology and can be completely provided using audio. **As discussed above, the Partnership also encourages HHS to extend permanently coverage and payment for audio-only E/M services.**

Action 201: Practitioner Locations

Licensure requirements are a barrier to increased access to telehealth services. In a country where patients are demanding virtual care no matter where they live, it is currently burdensome and difficult for providers to be able to provide this care across state lines. This was particularly enhanced in the early days of the pandemic. To provide additional flexibilities for providers and to ensure patients have continued access to care, CMS waived requirements that out-of-state providers be licensed in the state in which they are providing services when they are licensed in another state. This flexibility provided immediate regulatory relief and was essential to ensure providers could support networks and patient demand for telehealth services across state lines. **The Partnership is grateful for the flexibilities provided and have seen the benefits of these licensure flexibilities and encourages HHS to extend temporarily licensure requirements that providers be licensed in the state which they are providing services, so long as they are licensed in another state.**

In the absence of an extension, licensure requirements will immediately be a barrier to telehealth access, cutting off access to care for certain patients. Continued flexibility will ensure equitable access to specialty care for all Medicare beneficiaries. Moreover, an extension would provide Congress and States an opportunity to take action to address barriers that may require legislative action.

Action 210: Remote Patient Monitoring Reporting

CMS allowed RPM to be offered to new and existing patients during the public health emergency, however in the CY2021 Medicare PFS final rule, CMS stated that outside of the PHE, RPM may only be initiated for existing patients. **We urge HHS to extend temporarily flexibilities allowing RPM services to be initiated by providers for both new and existing patients until such time as the agency creates new codes that capture the full range of patients for whom RPM services are clinically beneficial, including new patients, patients with both acute and chronic conditions and patients with only one disease.**

Above, the Partnership outlined several clinical scenarios in which patients benefit from short duration RPM services. These benefits apply to new and existing patients. **Further, the Partnerships urges the agency to clarify that, where permitted by state law, a telehealth visit can create a relationship between a provider and patient for purposes of providing RPM services.**

Action 230: Medicare Provider Enrollment Relief

For the duration of the COVID-19 PHE, CMS waived certain enrollment requirements, including those necessitating a written application and enrollment of practitioner home addresses as a practice location. As a result, healthcare providers delivering care via telehealth were able to serve a vital public health role in mitigating the case of infectious disease spread as well as provide safe access to routine care and behavioral health services to all who needed it, including 33 million seniors and people with disabilities on Medicare. With estimates projecting health professional and primary care shortages to reach 100,000 and 55,000 in the next decade, **the Partnership urges HHS to continue to extend Medicare provider enrollment relief throughout the PHE**. This will ensure that there is enough provider capacity to support the healthcare needs of Medicare beneficiaries and to leverage telehealth to divert non-COVID-19 related illnesses outside of overburdened hospitals and medical facilities and limiting the spread of the virus.

Additionally, CMS should modify existing Medicare regulations to modernize and streamline enrollment requirements and processes for telehealth practitioners and ensure updated MAC guidance. Modifications should include necessary regulatory changes and/or revisions to CMS and MAC guidance regarding the definition of practice location, which are necessary to exempt telehealth practitioners from enrolling a practitioner home as a practice location.

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Thank you for your consideration of these comments. Please contact Mara McDermott at (202) 487-1393 or mmcdermott@mcdermottplus.com if you have any questions.

Sincerely,

Mara McDermott
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The Partnership to Advance Virtual Care

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