

March 19, 2020

The Honorable Nancy Pelosi
Speaker of the House
U. S. House of Representatives
1236 Longworth House Office Building

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
317 Russell Senate Office Building

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
2421 Rayburn House Office Building

The Honorable Charles Schumer
Minority Leader
U.S. Senate
322 Hart Senate Office Building

Dear Speaker Pelosi, Leader McCarthy, Leader McConnell, and Leader Schumer:

We applaud your leadership in developing bipartisan legislation in response to COVID-19, also known as coronavirus. We recognize the work you accomplished to ensure that patients can receive care via telehealth and urge you to build on these efforts. In the first two COVID-19 response packages, you provided an important waiver authority for the Department of Health and Human Services (HHS) to bypass statutory restrictions on Medicare coverage of live voice and video (telehealth) interactions between providers and patients. But the work does not stop there. We urge you to include a few additional measures in the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

In-Person Requirement. In the Qualified Provider restrictions for Medicare telehealth services, an in-person visit is generally required to begin a patient-provider relationship for coverage purposes. In the increasingly digital healthcare system, this requirement makes less sense and certainly during the COVID-19 crisis, clinicians will need to quickly establish relationships with sick patients they have never seen before. Ideally, clinicians would be able to establish those relationships with patients over live voice or video in order to fully benefit Medicare patients, during the COVID-19 emergency, but also in the future. We strongly support the provision in the CARES Act proposal authorizing HHS to waive Qualified Provider restrictions in Section 1834(m) of the Social Securities Act, including the requirement for an in-person visit to establish the provider-patient relationship and allow patients receiving care via telehealth to establish that relationship via telehealth. Similarly, we strongly support the Senate's proposal to waive the in-person visit requirement that appears in the statutory provision covering telehealth for home dialysis Medicare patients.

Telehealth from Federally Qualified Health Centers (FQHC) and rural health clinics (RHC). We also support the Senate's proposal in the CARES Act to require HHS to pay for Medicare telehealth services furnished by FQHCs and RHCs. These providers need to be able to access their Medicare patients quickly and efficiently, especially during the COVID-19 crisis, and should not have to deal with mountains of red tape in order to ensure their Medicare patients' telehealth services are covered.

Anti-Kickback Statute. As clinicians remotely monitor patients at home who may have COVID-19, there is a lingering concern that any equipment or access to software platforms provided without charge may inadvertently trigger liability under the Anti-Kickback Statute (AKS). The operative definition for “remuneration” in this statutory provision, at 42 U.S.C. 1320a–7a(i)(6), is broad, and we recommend directing the HHS Office of Inspector General (OIG) to enable the provisioning of remote physiologic monitoring (RPM), telehealth, and other tech-driven healthcare tools without triggering AKS liability. Alternatively, we urge you to include Section 11 of the CONNECT for Health Act of 2019 (S. 2741) in the CARES Act, which would carve the provision of certain RPM and telehealth technologies out of the definition of “remuneration” for the purposes of AKS.

Co-pays. Another hurdle to the use of RPM and telehealth for Medicare patients is the mandatory 20 percent co-pays. Providers should not be in a situation during this crisis where regulations require them to charge the patient for remote monitoring that becomes necessary to keep the patient at home to avoid the risk of spreading the deadly disease. Therefore, we urge you to direct HHS OIG to provide flexibility to providers so that they can choose to waive or reduce co-pay charges for telehealth and RPM services.

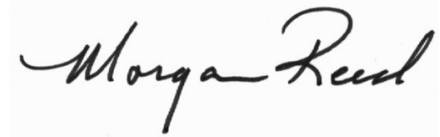
RPM coverage clarification. The Centers for Medicare and Medicaid Services (CMS) took a significant and important step when it adopted RPM codes 99453, 99454, 99457, and 99458 to support RPM services for Medicare patients. Now more than ever, providers should clearly understand that those codes can be billed for the monitoring of acute conditions—such as, but not limited to, COVID-19—in addition to chronic conditions. Therefore, we urge you to require CMS to clarify that these codes cover the monitoring of patients with acute conditions, including the review of pulse oximetry data for patients with conditions such as COVID-19. We do not seek a change to CMS’ policy with respect to RPM codes, we are specifically asking for Congress to ensure that CMS provides clear guidance that the codes cover the monitoring of acute conditions.

Privacy rules. Recently, HHS’ Office of Civil Rights (OCR) announced enforcement discretion with respect to the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations. Importantly, the enforcement discretion clarifies that the use of private, secure telehealth tools that are not part of the provider’s official offerings will not draw a penalty, as long as the provider alerts the patients to the risks. The CARES Act should direct OCR to continue this enforcement discretion until the national emergency and the national public health emergency have lapsed. However, we also urge you to direct OCR to issue guidance clarifying that certain telehealth tools that are end-to-end encrypted are mere “conduits” and thus not required to enter business associate agreements (BAAs). The guidance should clarify that the providers of such telehealth services should only store data about the patient that is necessary to support the service, for a period of time necessary to support the service.

Federal Communications Commission (FCC) COVID-19 Connected Care. The FCC recently asked appropriators to include funding to support a COVID-19 Connected Care pilot at the FCC. We fully support the appropriation of these funds, and we are strong supporters of the FCC’s broader connected care pilot.

Thank you for considering our request. We look forward to working with you on the extremely important and bipartisan task of responding to the COVID-19 pandemic.

Sincerely,

A handwritten signature in black ink that reads "Morgan Reed". The signature is fluid and cursive, with the first letters of "Morgan" and "Reed" being capitalized and prominent.

Morgan Reed
Executive Director
Connected Health Initiative

The Connected Health Initiative (CHI), an initiative of ACT | The App Association, is the leading multistakeholder spanning the connected health ecosystem seeking to effect policy changes that encourage the responsible use of digital health innovations throughout the continuum of care, supporting an environment in which patients and consumers can see improvements in their health. CHI is driven by its Steering Committee, which consists of the American Medical Association, Apple, Bose Corporation, Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, Otsuka Pharmaceutical, Podimetrics, Proteus Digital Health, Rimidi, Roche, Spekt, United Health Group, the University of California-Davis, the University of Mississippi Medical Center (UMMC) Center for Telehealth, the University of New Orleans, and the University of Virginia Center for Telehealth.

For more information, see www.connectedhi.com.