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May 28, 2020

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

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma,

We appreciate the opportunity to provide comment on the *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule with Comment*. We are encouraged by the steps the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) has taken to facilitate the use of telehealth and Remote Patient Monitoring (RPM) in the nation's response to COVID-19. We request that you consider our recommendations to accelerate the benefit of these digital health tools for Medicare beneficiaries.

Livongo offers a whole person approach to help people better manage chronic conditions, and we are considered a leader in digital health technology. We started with diabetes and now provide an integrated solution for people to manage their hypertension, prediabetes, weight, and behavioral health. As of March 31, 2020, over 328,000 people were using Livongo for Diabetes and over 1,252 employers, hospital systems, and health plans are clients, including four of the seven largest health plans. Livongo's clients utilize different types of plans: fully-insured, administrative services only (ASO), Medicare Advantage (MA), and Medicaid managed care plans. Additionally, more than 6.5 million individuals have access to Livongo for diabetes through their Federal Employee Health Benefits Program plan (FEHBP.)

Our mission at Livongo is to empower people with chronic conditions to live better and healthier lives. Even with all the advances in health data and technology, the daily life of a person with chronic conditions has improved very little in the last few decades—people are still left mostly navigating day-to-day on their own. Every day, more people are diagnosed with chronic conditions, which can be debilitating to the individuals and their families –from a physical and economic well-being perspective. These health conditions are driving up costs for these individuals and their families while costing the federal healthcare system billions of dollars.

Top-level recommendations as outlined in the body of this letter include:

- Continue to leverage authorities to expand access to remote monitoring and digital health resources for Medicare beneficiaries, especially those with chronic conditions.
- Provide necessary clarity on the remote monitoring codes to facilitate expanded use during and beyond the public health emergency.
- Modernize the quality measurement policies to include remotely-generated data including eHbA1cs and electronic blood pressure readings.
- Explore any flexibilities available to postpone the bid filing date to allow MA plans additional time to assess remote patient monitoring and telehealth strategies.

Telehealth and remote patient monitoring are at the forefront of the new standard of care that must be available to all Americans, especially Medicare beneficiaries. We applaud the important initial steps CMS has taken to expand access to RPM services as a piece of the nation's COVID-19 response through the Interim Final Rule and subsequent regulatory actions.

While telehealth has proven effective at providing convenient care and reducing the need for people to travel to their hospital or healthcare provider, telehealth by itself does not help us scale to meet our healthcare needs or solve the challenges presented by the COVID-19 pandemic. Remote monitoring solutions like Livongo add the layer of care that people with chronic conditions need by providing 24x7x365 support through digital and telehealth coaching capabilities at the exact moment the individual needs it as well as sharing real time biometric data with the caregiver.

A recent CDC report shows that 78% of people who were admitted to the intensive due to COVID-19 had at least one pre-existing health condition[1]. This statistic shows the dire need to implement remote monitoring solutions for people with chronic conditions.

Remote monitoring solutions for people with chronic conditions are in the unique position of providing services to populations at the greatest risk of COVID-19 -- those living with chronic conditions like diabetes and cardiovascular conditions. Although these platforms are not meant to treat COVID-19 directly, they do provide people with COVID-19 specific digital coaching based off of the unique individual biometric data, delivered through "Health Nudges" in our company's case, and are coupled with access to certified health coaches with the latest information from the Centers for Disease Control and Prevention (CDC) and expertise from industry experts including the American Diabetes Association (ADA), American Heart Association (AHA), and Juvenile Diabetes Research Foundation (JDRF.) Additionally, RPM that includes the use of two-way cellular communication provides the ability to share glucose checks and alerts with

[1] Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020. MMWR Morb Mortal Wkly Rep 2020;69:382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6913e2external icon.

family/friend networks. This is especially critical in isolation or quarantine situations where people cannot maintain regular check-ins and contact with their caregivers and network.

As the Administration has acknowledged, remote monitoring enables beneficiaries to remain safely in their home where they can be properly supported to manage their conditions while also reducing the strain on the healthcare system. We look forward to sharing more about how we are working with health systems and provider groups to provide support for their high-risk patients during the pandemic. Below we have provided feedback on specific policies outlined in the interim final rule.

Communication Technology-Based Services (CTBS)

CMS reiterated that Medicare routinely pays for many kinds of services that are furnished via telecommunications technology but are not considered Medicare telehealth services. These communication technology-based services (CTBS) include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), and interpretations of diagnostic tests when furnished remotely. As stated by CMS, these services like remote monitoring and virtual check-ins are different than the kinds of services specified in section 1834(m), in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

Livongo appreciates that in recent years CMS has embraced reimbursement pathways for additional remote monitoring and technology-based services. We request that CMS continue to take a comprehensive approach to care for Medicare beneficiaries, which should include digital health tools beyond the definition of telehealth under1834(m) during and following the COVID crisis.

Remote Physiologic Monitoring

Our experience is consistent with CMS' assertion that Remote Physiologic Monitoring (RPM) or remote monitoring, services support the CDC's goal of reducing human exposure to the novel coronavirus while also increasing access to care and improving patient outcomes. We applaud the important steps taken by CMS in response to COVID-19 including: allowing RPM services to be provided to new patients as well as established patients, ability to leverage RPM for chronic and acute condition management, and important amendments to the patient consent policies to initiate RPM services for beneficiaries.

A recent study in the Journal of Medical Economics[2] serves to validate CMS' actions. It showed that at 12-months, people active in the a remote monitoring program demonstrated a statistically significant 25% reduction in office-based visits (which translated in a reduction of an average of 2.5 visits/year) compared to people with diabetes not on a remote patient monitoring program. One explanation offered by the authors is that the remote monitoring programs serve as a substitute for office-based care. The study

[2] Whaley CM, Bollyky JB, Lu W, et al. Reduced Medical Spending Associated With Increased Use of a Remote Diabetes Management Program and Lower Mean Blood Glucose Values. Journal of Medical Economics. 2019;0(0):1-9. doi:10.1080/13696998.2019.1609483

supports that improved diabetes self-management through digital health programs that include contact with healthcare professionals and allow for increased communication.

RPM Coding Modifications

In recent years, CMS finalized payment for seven CPT codes in the Remote Physiologic Monitoring (RPM) code family. We appreciate CMS' recognition of the value of remote monitoring for Medicare beneficiaries, especially those with chronic conditions.

In the 2019 Physician Fee Schedule Final Rule, CMS stated that many commenters recommended CMS should clarify certain elements in the scope of service and code descriptors of the RPM codes. CMS indicated a willingness to issue appropriate sub-regulatory guidance but has yet to do so. Given that CMS has reduced barriers to use of the remote monitoring codes to drive additional utilization, we would urge CMS to offer clarity on the terms for reimbursement for these codes.

99454 (Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days)

As it relates to code 99454, we interpret programmed alert(s) transmission to include messages pushed from the beneficiaries' care team members to the beneficiaries with reminders and wellness tips as well as real-time interventions. These programmed alerts can both be sent directly to the device used for remote monitoring as well as supporting cellphones, tablets or web portals. Additionally, we interpret monitoring to include food logging, mobile app usage, member portal logins, or member support calls. We would encourage CMS to include such clarifications in subsequent rulemaking or subregulatory guidance.

99457 (First 20 minutes of monitoring and treatment management that includes interactive communication with the patient or caregiver during the calendar month; base code)

Similar in nature to the proposed change to code 99454 to enable remote monitoring to be used for less than 16 days made in the Interim Final Rule with Comment issued by CMS on April 30th, we encourage CMS to consider decreasing the time threshold for data review by the qualified health care professional (QHCP) associated with code 99457.

If the device used for remote monitoring can easily collect data and the accompanying solution can produce reader-friendly interpretations of the data captured, providers should not have to redesign workflows just to satisfy a certain time threshold. Today, providers and other QHCPs need to be maximizing their time spent caring for patients, and instead, remote monitoring solutions that lead to ease in data review should be rewarded. CMS should consider decreasing the 20-minute minimum review time threshold associated with code 99457 to reflect efficiencies gained through streamlined reporting and real-time data feeds.

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Further, we would reemphasize the value of leveraging certified health educators, such as certified diabetes educators, credentialed by the National Certification Board for Diabetes Educators (NCBDE.) In recent rulemaking CMS has allowed to additional professionals to provide telehealth services, including physical therapists and speech pathologists. We similarly suggest that health educators be included in the definition of a qualified health care professional (QHCP) and able to provide telehealth and remote monitoring services for the duration of the Public Health Emergency and beyond. For additional perspective, we have shared the certification criteria for Certified Diabetes Educators from NCBDE:

1. Minimum of 2 years (to the day) of professional practice experience in the discipline under which the individual is applying for certification; and
2. Minimum of 1,000 hours of diabetes education (DE) experience earned within 4 years of application date, with a minimum of 40% of those hours (400 hours) accrued in the most recent year preceding application.
3. Includes 15 hours of continuing education
4. Renewal necessary every five years.

Innovation Center Models

CMS stated that they intend to permit certain beneficiaries to obtain the set of Medicare Diabetes Prevention Program (MDPP) services more than once per lifetime, increase the number of virtual make-up sessions, and allow certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis for those programs underway as of March 1, 2020. Under these temporary flexibilities, the requirement for in-person attendance at the first core-session will remain in effect. As a result, if beneficiaries are prohibited from attending the first core session in person, suppliers will be unable to start any new cohorts with MDPP beneficiaries.

In contrast with a number of other flexibilities included in the IFC and waivers released by CMS, which leverage innovative technology solutions to improve access and quality, the agency's temporary policy changes for the MDPP stymy an opportunity to further develop and enhance the program to support Medicare beneficiaries. CMS' recognition of the importance of inclusion of additional virtual diabetes prevention program sessions during the public health emergency is a first step, but we urge the permanent inclusion of CDC-recognized virtual Diabetes Prevention Program (DPP) providers eligible for reimbursement in the Medicare DPP (MDPP) expanded model. Moreover, through the widespread use of virtual DPP providers, there would not need to be a disruption in starting such programming for any new cohorts of MDPP beneficiaries.

As we have seen in recent news reports, the Medicare Diabetes Prevention Program (MDPP) has fallen woefully short on the promise of helping patients in preventing diabetes. Even though projections showed that as many as 110,000 people would be served by the MDPP annually, just over 200 people used the program in 2018.[3] Recognizing this shortcoming, last year several Senate offices asked CMS to explore

[3] Darius Tahir. "Medicare diabetes prevention program helps a few hundred instead of hundreds of thousands." *Politico*. October 22, 2019.

whether the agency has the authority to include digital providers in the MDPP[4] and more recently a similar group of Senators asked CMS to expand the opportunity for virtual DPP providers to serve Medicare beneficiaries during the PHE and beyond[5][6].

HHS should ensure that digital platforms are included in the scope of DPP services, both during the public health emergency and beyond, because they support people-centric models of care while addressing affordability of care. At a time when Americans need support, we must ensure that we are not turning them away.

Additionally, it would be valuable for virtual providers and digital solutions to be considered for the Medicare Part B Diabetes Self- Management and Training (DSMT) program. Like MDPP, CMS has restricted use of virtual tools in the DSMT program to a limited number of make-up sessions and for a small cohort of Americans living in rural communities. The ability for ongoing training to empower individual beneficiaries to better understand how to manage their complex condition is important in a person-centered approach to care. The Livongo model that combines technology and support from our coaches has proven valuable to improve clinical outcomes and we urge you to consider this model for Medicare beneficiaries living with diabetes. Now more than ever, CMS must take all steps possible to integrate virtual care offerings for all Medicare beneficiaries, especially those with chronic conditions.

Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

CMS acknowledged the challenges posed to Star Ratings, Healthcare Effectiveness Data and Information Set (HEIDS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) calculations, thus proposing to use the 2020 measure-level stars and scores for the missing HEDIS and CAHPS data provides the best approximation of performance in 2019. We appreciate CMS' willingness to decrease regulatory burdens and recognition that quality measurement programs must be reevaluated given the public health emergency.

As CMS notes, the bid deadline is set by the statute, as the first Monday in the June prior to the coverage year, but we encourage CMS to explore any flexibilities available to postpone the bid filing date to allow MA plans additional time to assess remote patient monitoring and telehealth strategies. There is much to learn that is applicable to the potential for the expanded use of digital health tools for the COVID-19 response, and we believe it would be valuable to enable plans have additional time to evaluate lessons learned and opportunities for improvement.

We would also highlight the importance of allowing plans in cases of unforeseen circumstances to amend their benefits package. The ability to amend, if in place now, would allow additional Medicare Advantage

[4] Letter from Senators to HHS Secretary Alex Azar and CMS Administrator Seema Verma, October 30, 2019. https://www.scott.senate.gov/imo/media/doc/20191029161543864.pdf

[5] Letter from Senators to HHS Secretary Alex Azar and CMS Administrator Seema Verma, April 16, 2020.

[6] Letter from House Diabetes Caucus Co-chairs to Secretary Alex Azar and CMS Administrator Seema Verma, May 21, 2020.

plans to make telehealth and remote patient monitoring services available to beneficiaries. This could reduce reliance on in-patient care, improving the health and safety of beneficiaries.

We recommend that CMS begin to take steps to ensure that Star Ratings measures can incorporate remotely-generated data. This should include diabetes outcomes based on eHbA1c (estimated hemoglobin A1c) and remotely generated blood pressure readings, rather than mandating an in-person blood draws and blood pressure checks. It is important that reimbursement for treatment of diabetes and hypertension not hinge on an in-person procedure, the blood draw to facilitate the generation of the HbA1c or a manual blood pressure check.

According to industry literature, eHbA1c's are an effective proxy for a blood-drawn HbA1c check. Traditionally, doctors and payors measure outcomes for people living with diabetes by their HbA1c, which warrants blood draw and a trip to a lab or clinician office. We should consider allowing the estimate of HbA1cs, gathered in the real-world using thousands of data points, to be counted as a quality indicator, rather than insisting on lab-based, in person HbA1cs.

Cost-sharing Requirements

Under current CMS flexibilities, Medicare Advantage plans may waive cost-sharing for plan enrollees on a uniform basis for remote monitoring, telehealth services, and other services to address the outbreak. Additionally, the Office of the Inspector General (OIG) is allowing for cost-sharing of telehealth services under enforcement discretion for Medicare Part B. CMS should build on these policies and support Medicare patients in the Part B program by waiving beneficiary copayments, deductibles, and coinsurance costs for remote patient monitoring and telehealth services during the remainder of the public health emergency and beyond leveraging existing authorities wherever possible Those managing chronic conditions likely face significant financial costs thus policies must be pursued that remove barriers to solutions and services that will not only improve outcomes but also reduce overall healthcare spending. We understand the role of cost-sharing requirements in Medicare, but in this case, this outdated policy significantly impacts enrollment of Medicare beneficiaries in remote monitoring programs

Incentives for Beneficiaries to Use Digital Health

We encourage you to consider including incentives for Medicare beneficiaries to use digital health tools. At the outset we must ensure that Medicare's coverage and reimbursement policies are aligned with the FDA's clearance process for digital health tools. In the same way that the Administration has moved to reimburse providers for in-person and virtual visits at the same rate to spur use of telehealth during the public health emergency, a similar incentive-based approach should be considered for beneficiaries during and beyond the pandemic response. For example, if a beneficiary elects to use remote monitoring solutions, which decreases their need for in-patient care and optimizes their medication adherence, they too should receive credit. Medicare should explore options including reduced deductibles, decreased coinsurance costs or lower prescription drug expenses.

ACA Enrollment Period

While we are encouraged that some of our clients and partners have continued to offer benefits to their recently laid-off or furloughed employees for an extended period, we know that many Americans have lost their health insurance or face significantly different financial circumstances. We encourage the Administration to consider allowing a special enrollment period for healthcare.gov.

The ability to leverage technology and digital health solutions, including remote monitoring and telehealth, will both be valuable in the nation's response as well as we establish a new standard of care for all Americans in the future. We appreciate the Administration's ongoing efforts to respond to the COVID-19 pandemic and willingness to employ innovative solutions, especially for those at greatest risk if they fall ill.

We work every day to bring about a future where healthcare is easier for our Members so they can live happier, healthier lives. We appreciate the opportunity offer our perspective, and we look forward to serving as a resource.

Sincerely,

Zane Burke
Chief Executive Officer
Livongo