



March 17, 2020

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Draft 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker,

We welcome the opportunity to provide comment on the draft *2020-2025 Federal Health IT Strategic Plan*.

Our company, Livongo, is based in Mountain View, California and has large footprints in Denver and Chicago. Livongo has more than 600 employees and is considered a leader in digital health technology. Livongo offers a whole person approach to help people better manage chronic conditions. We started with diabetes and now provide an integrated solution for people to manage their hypertension, prediabetes, weight, and behavioral health. As of December 31, 2019, over 222,000 people use Livongo for Diabetes and over 804 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, and Medicaid managed care plans. In October 2019, Livongo was also selected to provide the Livongo for Diabetes solution to eligible members covered by the Federal Employees Health Benefits Program (FEHBP) who are living with Type 1 or Type 2 diabetes.

Our goal at Livongo is to empower people with chronic conditions to live better and healthier lives. In fact, even with all the advances in health data and technology, the daily life of a person with chronic conditions hasn't improved much at all in the last few decades. Every day, more people are diagnosed with chronic conditions, which can be debilitating to people and their families. It also carries a great economic cost. These health conditions are driving up costs for these individuals and their families while costing the federal healthcare system billions of dollars.

The statistics are staggering:

- Six-in-ten adults in the U.S. have a chronic condition – four-in-ten have more than one chronic condition.¹

¹ Livongo. "Empowering People with Chronic Conditions to Live Better and Healthier Lives." Investor Presentation. 2019.



- Approximately 90 percent of annual American health costs are attributable to chronic conditions.²
- Chronic conditions cost the U.S. economy \$3.7 trillion each year.³

We welcome the chance to help inform the *Federal Health IT Strategic Plan* (the plan) to ensure that policies are in place to facilitate digital health solutions to improve the treatment and prevention of diabetes and other chronic conditions.

We applaud your commitment to a fully connected health system that empowers patients, caregivers, and their healthcare providers to use and share electronic health information. To realize the stated goal of patient empowerment it will be critical for incentives to be aligned with policies that will facilitate the continued development and adoption of digital health tools. At this point in time, we believe there is tremendous value in broadening the framework beyond EHR data capture and exchange. We urge the Administration to ensure Americans have broad access to digital health tools and that these tools can share data that is of value to both the user as well as their care team.

We have provided feedback on specific elements of the plan below.

Challenges in Healthcare

The plan includes discussion of critical challenges facing healthcare including increasing costs, poor outcomes, increasing rates of mental illness and substance use disorders, access to care and access to technology. Livongo shares your concerns about these challenges and urges you to consider the value proposition of robust adoption of digital health and virtual care as key solutions.

The prevalence of chronic conditions and the inability of our current acute care-focused health system to treat them is a demonstration of poor outcomes and a source of the significant financial duress the system faces today. As previously stated, today more than 147 million Americans are living with chronic conditions. It's estimated that 180 million Americans are living with mental health challenges⁴. According to a 2017 RAND Corporation Study, 90 percent of the US healthcare spend is on chronic conditions⁵, this includes \$327 billion on diabetes⁶ and \$131 billion for the treatment of hypertension⁷. We must reorient our healthcare system. We must recognize that most individuals spend 99.9 percent of their time outside of the healthcare system, left on their own to manage their conditions. Digital health has the potential to break the mold, to empower people, improve access and allow those Americans already living with these chronic conditions a chance at a happier, healthier life.

² Livongo. "Empowering People with Chronic Conditions to Live Better and Healthier Lives." Investor Presentation. 2019.

³ Livongo. "Empowering People with Chronic Conditions to Live Better and Healthier Lives." Investor Presentation. 2019.

⁴ According to National Alliance on Mental Illness approximately 180 million are living with behavioral health issues.

⁵ C. Buttorff, T. Ruder, and M. Bauman, "Multiple Chronic Conditions in the United States." Santa Monica, CA: RAND Corporation, 2017.

⁶ US Spending on Personal Health Care and Public Health, JAMA, 2016 Statistics About Diabetes, American Diabetes Association, 2018

⁷ Vital Signs: ...of Uncontrolled Hypertension (MMWR), CDC, 2012



Opportunities in a Digital Health System

We commend the plan's recognition of the importance of patient empowerment, movement to value-based care, achieving interoperability, new technologies and available data, reducing regulatory and administrative burden, privacy of health information and security of health information. Livongo seeks to empower people with chronic conditions to live better and healthier lives. We enthusiastically agree that our system needs to be more person-centered and allow for robust access to innovative solutions. As noted, it will be important to ensure that reimbursement models and payment arrangements enable preventive care and disease management tools as a tactic to transform our acute care-focused system.

As more data is generated and exchanged, ethical use and privacy protections must be a central focus of the federal strategy. At the heart of Livongo's Applied Health Signal solution is a core set of technologies and capabilities called AI+AI: Aggregate, Interpret, Apply and Iterate. Today Livongo joins dozens of data sets together and combines them with the signals from our own Livongo devices, coaches, and web assets, to extract the drivers of behavior change. We then deliver actionable, personalized and timely recommendations through a broad set of applications to our Members. All this is done in AI+AI in a private and secure manner.

Goal 1: Promote Health and Wellness

Objective 1a: Improve individual access to health information

We agree that it is necessary to ensure individuals have access to their health information and can share it through the platform they prefer in a form that is useful for the individual and their care team alike.

Our members, through their blood glucose meter, app or portal can not only access their data but they can also share health summary reports directly with members of their care team by either text message, email or fax. Our Members can also easily download all of their blood glucose values and blood pressure readings.

Objective 1b: Advance health and safe practices through health IT

We enthusiastically support the recognition of the value of ensuring access to technologies that promote healthy behaviors and self-management. Advancing the use of evidence-based digital health solutions to help treat those living with chronic conditions will be paramount in a truly person-centered healthcare system.

Here's an example of the value that digital solutions offer people to manage their hypertension. According to the Centers for Disease Control (CDC), one in three adults in the United States have high blood pressureⁱ, and it's estimated that only about 54 percent of them have the condition under controlⁱⁱ. Every year, hypertension contributes to \$131 billion in health-care expendituresⁱⁱⁱ. Today, people with hypertension are



offered little guidance outside of the time they spend in a doctor's office. Without continued support, many people with high blood pressure do not understand how behavioral and lifestyle changes affect their blood pressure.

A March 2019 study presented at the American College of Cardiology's (ACC) 68th Annual Scientific Session showed that people with both diabetes and uncontrolled high blood pressure who used the Livongo for Hypertension solution saw significant declines in their blood pressure within six weeks. The Livongo for Hypertension solution includes a smartphone app that enables participants to monitor their blood pressure remotely, tips on healthful living, and the opportunity to connect with a health coach.

As outlined above, the evidence is robust. Unfortunately, antiquated reimbursement models and the lack of sustainable pathways to innovation to be a disrupter in the marketplace remain a limiting factor in adoption of new and promising practices.

Goal 2: Enhance the Delivery and Experience of Care

Objective 2a: Ensure safe and high-quality care through the use of health IT

We agree that federal policies must account for care delivered outside of traditional clinical settings, which should account for virtual care solutions and remote patient monitoring. As previously stated, people spend 99.9 percent of their time outside of a traditional care setting, and we need to ensure we are empowering them through digital health tools.

As an example of the potential impact of digital health, the heart of Livongo's Applied Health Signals solution is a core set of technologies and capabilities called AI+AI: Aggregate, Interpret, Apply and Iterate. These are the four pillars of the Applied Health Signals engine. Today Livongo joins dozens of data sets together and combines them with the signals from our own Livongo devices, coaches, and web assets, to extract the drivers of behavior change. We then deliver actionable, personalized and timely recommendations through a broad set of applications to our members. All this is done through Livongo's AI+AI engine. Applying advanced capabilities such as machine learning and artificial intelligence can enable improved personalization of care decisions as Livongo has demonstrated through our Applied Health Signals Solution.

Objective 2b: Foster competition, transparency and affordability in healthcare

The plan should ensure efforts to foster competition across the healthcare ecosystem which must encompass the digital health sector. This serves to enhance the experience of patients through access to effective digital health solutions. Ensuring access to digital health solutions must be a goal of the plan and of federal policies broadly. To date, Medicare has been slow to adopt innovative technologies. Pro-competitive policies should also be pursued by Medicare to enable greater opportunities for Medicare beneficiaries to access innovative therapies and digital health solutions.



To address technology access concerns, we encourage the consideration of alternative payment models that allow for greater consumer empowerment. One consideration would be to foster plan redesign in government-sponsored care to share benefits directly with consumers/beneficiaries for use of digital health. This could be in the form of lower co-payments for the medications they need to treat their chronic disease or lower co-payments when they do need to see a provider who would in turn have access to better data. The traditional model which only pays providers and relies on doctors to prescribe digital health is one that has yet to take hold – and interposes a middleman between the payor and the beneficiary.

Objective 2c: Reduce regulatory and administrative burden on providers

The plan acknowledges the need for person-centered care, and digital health technologies will be critical in the modernization effort of our healthcare system. The plan must also recognize the need to enable greater reimbursement for providers that leverage digital health and remote patient monitoring services in the treatment regimens of patients. Ensuring reimbursement policies mimic the evolution of care delivery will be necessary to address regulatory and administrative burdens for providers. Digital health solutions are not meant to replace clinicians, so if proper payment mechanisms are established to enable clinicians to practice at the top of their license, additional burdens can be reduced.

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

Objective 3a: Advance individual- and population-level transfer of health data

We believe that, in order to fully engage and empower patients, we need to ensure that public policy does not throw up roadblocks in the use and aggregation of dozens of data sets. The 21st Century Cures Act fundamentally established a floor for the use of data sharing in healthcare. We believe that it is important to interpret and extract the drivers of behavior change on a personal, member-by-member level, just like an Amazon or Netflix experience. If we can continue to promote that and do so in a way that addresses privacy concerns, then we can deliver actionable, personalized, and timely recommendations to our members through a broad set of applications. As a further step towards patient empowerment, we must ensure that people can share their health data with whomever they wish within their care team.

Objective 3b: Support research and analysis using health IT and data at the individual and population levels

The ability to access, leverage and improve outcomes will hinge on the availability of data. Livongo's AI+AI engine is an example of how data can drive personalized care and improve outcomes. It will be critical for the evidence base to continue to grow. It would be invaluable for digital health solutions to be incorporated into federal research efforts moving forward. It would also be worthwhile for ONC to promote research on the effectiveness of digital health technologies as a means to improve outcomes, reduce cost and empower people. We are pleased to share some of key findings based on our research that validates the role virtual solutions can play in preventing and managing chronic conditions.

A [recent study](#) presented at the American Heart Association's 2019 Scientific Sessions showed that people with both diabetes and elevated blood pressure hypertension who used Livongo's integrated platform saw



sustained clinically-significant blood pressure reduction after only four weeks and experienced further improvements after using the program for twelve weeks.⁸ Users of our diabetes program have been able to significantly lower their HbA1c, a clinical metric that reflects blood glucose control. In a study presented at the 79th Scientific Session of the American Diabetes Association, research was conducted to understand the relationship between diabetes distress (DDS2), diabetes empowerment (DES-SF), and the Livongo program. Sixty-one percent of members had an improvement in DDS2 and DES-SF. Livongo program usage with higher blood glucose checking frequency was associated with higher likelihood of improvement in DDS2 and DES-SF.⁹

The savings are significant, as recognized by clients engaged in the movement from volume-based to value-based health care. A peer-reviewed study published in the *Journal of Medical Economics* showed people using Livongo reduced their medical spending by 21.9 percent, which included a 10.7 percent reduction in diabetes-related spending and 24.6 percent reduction in office-based services.¹⁰ Additionally, a [2019 Journal of Medical Economics study](#) found that the Livongo for Diabetes program delivered an \$88 per member monthly reduction in medical spending for Livongo clients, with employers experiencing a positive return on investment in just one year.¹¹

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Objective 4b: Establish transparent expectations for data sharing

Livongo sees the practical value add from having data accessible and available for sharing, just as Livongo's AI+AI solution is powered by data, so too are people living with chronic conditions as they are becoming better able to manage their condition more effectively with data. Livongo enables members to share their data with their care team, friends, and family members directly from their personal blood glucose meter, or mobile phone, with multiple transmission options. This is far from the norm. Many people living with diabetes are writing their values in a notebook and presenting them to their physicians months later, unable to benefit from intervention or recall why their values may have been out of their normal range.

Objective 4c: Enhance technology and communications infrastructure

We must ensure that geography or connectivity limitations do not impede anyone from being able to leverage digital health tools to improve their lives. In addition to promoting the adoption of infrastructure

⁸ Karen Xu, Roberta James, Wei Lu, Anoop Sangha, Bimal R Shah. "More Frequent Remote Home Monitoring Decreases Blood Pressure in an Unselected Population of People With Diabetes." *Circulation*. 2019. https://ahajournals.org/doi/abs/10.1161/circ.140.suppl_1.15430

⁹ JB Pollyky, S Painter, JL Poon, M Perez-Nieves, B Shah. "Connected Glucose Meter Plus CDE Coaching Improved Diabetes Patient Empowerment and Distress in Real-World Outcomes Setting." 79th Scientific Sessions American Diabetes Association. San Francisco, CA. 2019.

¹⁰ Livongo Health, Inc., Amendment No. 2 to Form S-9 Registration, SEC Commission, July 22, 2019, p. 145.

¹¹ Christopher M. Whaley, Jennifer B. Bolyky, Wei Lu, Stefanie Painter, Jennifer Schneider, Zhenxiang Zhao, Xuanyao He, Jennal Johnson & Eric S. Meadows. Reduced medical spending associated with increased use of a remote diabetes management program and lower mean blood glucose values, *Journal of Medical Economics*, 22:9, 869-877. 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31012392>



needed for telehealth, we must also acknowledge the need to support remote patient monitoring and virtual care solutions as well.

Objective 4d: Promote secure health information that protects patient privacy

We face a new challenge because empowering patients will mean not just harnessing advanced artificial intelligence capabilities in health care but will mean addressing questions of privacy and having American patients think differently about privacy. Let us be clear, we do not sell our Members' data and we truly believe, as stated above, that the data belongs to our Members and they have the right to share it with whomever they chose.

Member trust is our priority and we believe that good data stewardship is only way that we will be able to preserve the personalized care experience that we deliver to our Members. Unfortunately, misuse of data is rampant and will hinder the ability for data science to deliver new and innovative therapies as well as personalized care plans. Striking the balance between improved consumer privacy and not overwhelming businesses with additional red tape will be critical. Being too explicit and overly restrictive with privacy policies will have an impact on innovation and will add to the compliance burden, however, not acting is simply not an option.

We appreciate the opportunity to provide comments on the draft Federal Health IT Strategic Plan. We commend you for outlining a health IT landscape that transcends the electronic health record and instead allows for personalized care to be delivered using a variety of digital health solutions. Our healthcare system needs significant reforms in order to tackle the challenges you outline, including poor outcomes and high costs. We look forward to working with you on how we can ensure federal policies foster digital health solutions and truly put patients in control of their care.

We work every day to bring about a future where healthcare is easier for our Members and their complex chronic conditions. We appreciate the opportunity offer our perspective, and we look forward to serving as a resource.

Sincerely,

Zane Burke, Chief Executive Officer
Livongo

ⁱ Merai R, Siegel C, Rakotz M, Basch P, Wright J, Wong B; DHSc., Thorpe P. CDC Grand Rounds: A Public Health Approach to Detect and Control Hypertension. *MMWR Morb Mortal Wkly Rep.* 2016 Nov 18;65(45):1261-1264

ⁱⁱ Merai R, Siegel C, Rakotz M, Basch P, Wright J, Wong B; DHSc., Thorpe P. CDC Grand Rounds: A Public Health Approach to Detect and Control Hypertension. *MMWR Morb Mortal Wkly Rep.* 2016 Nov 18;65(45):1261-1264.

ⁱⁱⁱ [Vital Signs: ...of Uncontrolled Hypertension \(MMWR\), CDC, 2012](#)