



December 22, 2020

Admiral Brett Giroir
Office of the Assistant Secretary for Health
Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations

Dear Admiral Giroir,

The American Telemedicine Association (ATA) appreciates the opportunity to provide feedback on the Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations issued in the Federal Register on November 10, 2020. On behalf of the ATA, and the over 400 organizations we represent, I am writing to request that you consider our recommendations to accelerate the benefit of these digital health tools for individuals living with chronic conditions.

The ATA is committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA represents a broad and inclusive network of technology solution providers, delivery systems and payers, as well as partner organizations and alliances, working together to advance adoption of telehealth, promote responsible policy, advocate for government and market normalization, and provide education and resources to help integrate virtual care into emerging value-based delivery models.

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. Today more than six in ten adult Americans are living with chronic conditions, with four in ten living with two or more chronic condition¹. It's estimated that 180 million Americans are living with mental health challenges². According to a 2017 RAND Corporation Study, 90 percent of US

¹ National Center for Chronic Disease Prevention and Health Promotion, <https://www.cdc.gov/chronicdisease/about/index.htm>

² According to National Alliance on Mental Illness approximately 180 million are living with behavioral health issues.



healthcare spending is on chronic conditions³, this includes \$327 billion on diabetes⁴ and \$131 billion for the treatment of hypertension⁵.

We must reorient our healthcare system and make virtual care solutions the center of our modernization strategy. It is critical to recognize that most individuals spend 99.9 percent of their time outside of the healthcare system, left on their own to manage their health. 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. In order to fully engage and empower patients, we need to ensure that public policy does not impede innovation nor put up roadblocks in the use and aggregation of data sets and health signals.

Digital health technologies provide an opportunity to operate more efficiently and effectively at all levels including for payers, providers, and patients. Given Medicare and Medicaid's importance in the healthcare marketplace, we encourage you to seize opportunities to take a leadership role embracing the full potential of digital health. We welcome the chance to help inform the *Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations* (the RFI) to ensure that policies are in place to facilitate digital health solutions to improve the treatment and prevention of chronic conditions.

A. Barriers and Opportunities for Technology-Driven Solutions

1. What barriers (e.g., privacy concerns, other clinician and patient barriers) and opportunities are most relevant for bringing technology-driven solutions to aging populations in underserved areas?

Availability of internet connectivity

Recent research published in the Journal of the American Medical Association⁶ found that 26.3% of Medicare beneficiaries did not have digital access in their homes (smart phone or broadband internet) which prevented them from using audio/video communications. The proportion of those without digital access was higher among those

³ C. Buttorff, T. Ruder, and M. Bauman, "Multiple Chronic Conditions in the United States." Santa Monica, CA: RAND Corporation, 2017.

⁴ US Spending on Personal Health Care and Public Health, JAMA, 2016 Statistics About Diabetes, American Diabetes Association, 2018

⁵ Vital Signs: ...of Uncontrolled Hypertension (MMWR), CDC, 2012

⁶ Roberts, E. and Mehrotra, A., 2020. *Assessment Of Disparities In Digital Access Among Medicare Beneficiaries And Implications For Telemedicine*. [online] Available at: <<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768771>> [Accessed 21 September 2020].



with lower socioeconomic status, those older than 85 and those residing in communities of color.

Cost of care, including Cost-sharing Requirements

Health care costs remain a challenge for many Americans and for those with chronic conditions, while they may be interested in leveraging digital health, financially it be infeasible. The current copay structure is an impediment to beneficiary adoption and continued use of remote patient monitoring and other innovative digital health tools. A recurring monthly copay for beneficiaries living with high-cost chronic conditions can serve as a deterrent to using remote patient monitoring technologies which are proven to improve health outcomes. We applaud the Administration's policy to not enforce cost-sharing requirements for digital health during the pandemic and encourage the reexamination of cost-sharing requirements for remote patient monitoring and other chronic condition management technologies moving forward.

Health and technology literacy

There is great potential for telehealth, remote monitoring, and digital health technologies to help meet the needs of patients and families across the country, especially in rural America. Healthcare providers have sought to deliver virtual care at scale for years, but many beneficiaries and caregivers are in need of training and education on how to interact with providers during a telehealth visit and on the value of other digital health solutions like remote patient monitoring. The diverse range of stakeholders are in need for education and training resources that account for age-related, and other social factors, that may result in differences in how beneficiaries interact with technology.

Some individuals most in need of digital health solutions face the greatest challenge in both understanding and using the technology. For example, patients with dementia or others that relinquish their medical power of attorney, digital health could be critical in providing 24/7 access to care and wellness services, yet patient and caregiver education is need but remains a significant challenge. Community health workers and other personnel should be funded to assist at the point of care for training and education.

Provider reimbursement

Our healthcare system must embrace virtual care, including telehealth and remote patient monitoring, widely as to disrupt the cycle of allowing outdated reimbursement models to dictate policy, all to the detriment of Americans, especially those with chronic conditions that could benefit from opportunities to evaluate their conditions more



frequently than the current healthcare system allows. We must lean into the technological revolution and move on from intransigent, outdated models.

Patient and Providers trust

Transparency of the data gathered, stored, and shared is paramount to both address patient and provider hesitations, as the healthcare system transitions to one anchored in artificial (or augmented) intelligence powered by data. For patients, a clear, concise and non-legalistic interpretation of how and when their data is being used is necessary. Similar to clinician needs, patients also will expect transparency. This allows clinical and personal decisions (on accepting or rejecting the guidance) to be made with clear knowledge of how the algorithm works.

For providers, user friendly interfaces are necessary to easily show where the data is sourced, how the data is used, and where the data is stored. Providers must also be able to articulate how and with whom the data is shared. In many cases, these standards are nascent, and setting standards will be beneficial to ensure model developers are following best practices. We do not expect physicians to rely on an algorithm blindly as liability in clinical decision-making rests with the physician of record.

Privacy

We now face a new challenge because empowering patients doesn't just mean harnessing advanced artificial intelligence capabilities in healthcare but addressing questions of privacy and having American patients think differently about privacy. There is immense value in being able to interpret and extract the drivers of behavior change on a personal, member-by-member level, something that has become intrinsic to the online commercial 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. If privacy concerns are addressed effectively, patients should feel that they are in control of their data, and comfortable with how it is being used to enhance the delivery of their healthcare.

2. What federal policies currently limit the capacity to deploy and scale technology-driven solutions for aging populations?

Patient responsibility (Cost-sharing requirements)

Virtual healthcare technologies are designed to drive efficiencies in the healthcare system through improved outcomes and healthier patients. However, under current



cost-sharing requirements, the patient is the one that shoulders the monthly cost burden via copays to use digital health solutions. Many individuals that meet the parameters of this RFI may be living on a fixed income, and a monthly copay could serve as a deterrent to adoption. Moreover, when remote monitoring data is gathered or reviewed outside of the context of an office visit, members often do not view this as something that should generate a copayment, even though it is high-value work that a provider performs on their behalf. It is critical that the existing cost-sharing requirements be revisited for individuals living with chronic conditions, including those on both Medicare and Medicaid and those in rural communities. Digital health solutions should be available to all, not just those of more financial means.

Outdated Reimbursement Policies

It is critical to recognize the need to enable greater reimbursement for providers that leverage digital health and remote patient monitoring services in the treatment regimens of patients. Reimbursement structures need to continue to support remote patient monitoring and chronic disease management such that time can be proactively spent on these activities (and decrease time requirements for synchronous 1:1 provider/patient care.)

Using current remote patient (or physiologic) monitoring reimbursement in fee-for-service Medicare as an example, requirements around the frequency of remote monitoring for provider reimbursement are burdensome and may not be a reasonable match for the underlying clinical need. For example, a member with well-controlled hypertension may not need to monitor their blood pressure more frequently than once every two weeks, but this frequency may not support reimbursement when a provider reviews the data. Or if a patient has multiple chronic conditions that could benefit from multiple devices (i.e. diabetes and hypertension), providers can only get reimbursed for the practice expense codes associated with one of the remote patient monitoring devices.

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 in-person care, so if proper payment mechanisms are established to enable clinicians to maximize efficiencies, additional burdens can be reduced.

Worth noting is that the Medicare statute does not directly address coverage of digital health technologies nor does the statute specifically limit or prohibit coverage of digital health technologies within the program's benefit categories. Under the status quo, with the absence of an explicit benefit category or categories, digital health technologies may



be eligible for reimbursement by Medicare under existing benefit pathways for either “direct” coverage and payment, or “indirect” coverage as an allowable cost of service provision. In both direct and indirect payment pathways, incentives to use the technology are dependent on adequate coverage and reimbursement policies under Medicare. We emphasize the importance of updating Medicare’s coverage pathways to accommodate advances in technologies that improve the standard of care and patient engagement. While the statutory and regulatory provisions for Medicare’s benefit categories establish coverage parameters, there are numerous regulatory opportunities to improve coverage of digital health technologies.

Interoperability

The prolific adoption of electronic health records has resulted in the digitization of unprecedented amounts of clinical data. However, this data is not ubiquitously liquidated and shared among providers. For algorithms and AI to be accurate, providers will need to have access to as much data on a single patient as possible, not just limited to what may be hosted within one provider practice or health system. Data sharing must transcend health system boundaries and continue to be an area of priority for policymakers. As a further step towards patient empowerment, we must also ensure that people can share their data with whomever they wish within their care team. Additionally, standards have not been routinely adopted to govern the sharing of sensitive data. Robust data sharing standards must continue to be a focus of efforts to spur nationwide interoperability.

Another interoperability challenge exists pertaining to patient access of data generated by their medical device. Additional policy or enforcement actions should be considered to improve patient access to data from their medical devices. Device makers are currently left to decide on their own what level of data access is necessary to provide to patients.

3. What new federal policies could facilitate the success of technology-driven solutions for aging populations?

Modernize provider reimbursement

Our reimbursement structures must be revamped to reflect this revolution of value-based care. 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.

The Administration should consider ways to incorporate opportunities for clinicians to utilize digital health and novel technologies in their existing reimbursement or regulatory requirement. Considering how adoption of these technologies could be captured as an Improvement Activity under the Merit-base Incentive Payment System (MIPS) or quality measures to include use of virtual care for chronic disease management or for post-discharge follow-up.

Connectivity challenges

We encourage you to be very aggressive in supporting policies to improve broadband and 5G access across the nation. Additional funding is necessary to support the physical infrastructure necessary for deployment on a broad scale. We would also encourage you to explore other ways to address internet access issues, such as incentives for equipping senior living facilities, senior centers or community centers with high-speed internet as tackle head-on some of the communities that are widely-known to be impacted disproportionately by access challenges.

Standards setting and adoption

Stated simply, a lack of recognized standards could erode trust in new technologies. In considering the potential of AI to transform health outcomes, we must acknowledge that proper standards and protocols are necessary to ensure the reasonable creation and use of algorithms. Transparency is a critical element of this discussion and it is clear that an algorithm is useful, mitigates biases, and is honest about its limitations. Given the speed at which innovation is occurring, it will be vital the standard be regularly reviewed and revised.

4. What are the ways in which technology-driven solutions are manifested (e.g., software platforms, wearables, robotics, etc.) and how is the integrity of data collected ensured (e.g., fidelity, and accuracy of data)?

Solutions can manifest as member facing or provider facing. These can be active member/provider interactions (i.e. applications (apps), webpages, dashboards) or passive data collected in the background (i.e. wearables or voice transcription services.)

Technology-driven solutions include, but are some limited to: software platforms (dashboards, decision support tools,) wearables, robots, mobile devices (phones, tablets,) medical devices (glucometers, thermometers,) distributed smart devices (motion sensors, cameras.)



The integrity of the data collected is usually ensured by using a collection of rules including algorithms at the time of collection, transmission, storage and provider or member consumption.

Additionally, the fidelity of the data requires verification of a person's identity and review of other values to determine outliers or data to differentiate patients that may be sharing devices. An individual's identification must be established upon connection and frequently verified throughout use of the technology. Ideally any patient biometric data from consumer devices or FDA-approved medical devices is also reviewed against clinically measured data (e.g. in-patient/ambulatory/nurse home health sample/data collection) to compare values from at-home and internet/cellular connected devices

5. How will training data sets be established and implemented to drive effective technology solutions that improve chronic disease outcomes for aging populations in rural areas?

Typically datasets are use-case driven and the effectiveness of dataset is evaluated by comparing performance on targeted populations. Device data, survey/self-reported data, and interaction data (with platform and providers) together with demographic data and data from public sources can be used to create training datasets. Often limited data sets are created with appropriate features and split for model development, model testing, and model validation.

It will be critical for the evidence base for novel technologies that leverage artificial intelligence to continue to grow. It would be invaluable for digital health solutions to be incorporated into federal research efforts.

6. How will AI solutions be validated? What metrics will be used to evaluate the effectiveness of AI/machine learning algorithms?

The AI solutions will be evaluated based on measures including: engagement, clinical outcomes (i.e. reduction in HbA1c), reduction in gaps in care, long-term risk reduction. Randomized control tests (with and without AI) and observational studies are conducted in tandem to understand treatment heterogeneity so as to understand the efficacy of the AI solution on various individual groups. Accuracy measurements may include: sensitivity, specificity, positive predictive value and negative predictive value.

7. How will healthcare team and patient trust in technology solutions be addressed? How will legal and ethical issues be addressed for technology solutions designed for improving chronic disease outcomes?

As more data is generated and exchanged to aide in the adoption of novel technologies or facilitated by the adoption of novel technologies, ethical use and privacy protections



must be a central focus of discussions. We believe patients will trust the solutions if they offer measurable improvement in their condition and the healthcare providers team would trust the technology if it provides for genuine and correct insight on a member level basis and assist them to provide high-quality care with increased efficiency. Legal and ethical issues will be addressed by carefully following the Health Insurance Portability and Protect Act (HIPAA), HITECH and other applicable privacy regulations.

At the heart of our AI solution, which supports our remote patient monitoring solutions, is a core set of technologies and capabilities that aggregate, interpret, apply and iterate. Today we join dozens of data sets together and combine them with the signals from our own devices, coaches, providers 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 a private and secure manner.

8. How will bias and variance be addressed in machine learning algorithms for this application? How will supervised versus unsupervised learning be used to develop inferences and patterns from data sources? What will be the challenges and proposed solutions for data cleansing and transformation?

Bias and variance will be addressed with the standard processes of cross-validation and hyperparameter tuning in the training set, in the supervised learning context.

Modeling risk, likelihood of outcomes, likelihood of engagement and modeling key biometric signals (i.e. blood glucose after a meal) are some of the supervised learning examples. These supervised learning examples are modeled using a variety of signals including medical history, engagement/interaction history, other behaviors and demographic data. The unsupervised algorithms are useful for segmenting and extracting hidden/latent variables.

9. Will AI deep learning and neural networks approaches and solutions be appropriate and used for chronic disease improvement for aging populations?

There are many use cases where AI deep learning and neural networks would help aging populations, some of which include: understanding vocal and facial patterns to decipher mental and emotional change as well as inferring vitals, understanding effects of various medication, activity and food changes to help keep sugar levels and hypertension under control.

This will require transparency and the recognition of best practices. Outset limits may be necessary on "unsupervised" models to items with no risk to patient health or care. Unsupervised models adapt quickly and many developers are yet to be completely



“transparent” (the so-called “black box”) to the user on how the algorithm arrived at the predictive conclusion.

10. What are the per-person-costs of technology-driven solutions in the context of this RFI?

Solutions cost will vary by the complexity and what tools (devices) may be necessary to support the individual.

B. Key Indicators & Data Sources of Technology-Driven Chronic Disease Management

1. What key indicators or data sets will be used to perform measure outcomes (e.g., racial, ethnic, gender, and socioeconomic disparities)?

Along with various indicators like age, race, ethnicity, gender and socioeconomic status, the outcomes would also be quantified based on medical history and behavioral data points like physical activity (sedentary/active,) nutritional habits and alcohol consumption.

All components must be viewed to determine if there are unintended consequences to models and inherent biases in data. Any intended outcome must also be viewed through balancing measures, some examples are provided below.

- Reducing unnecessary antibiotic prescriptions may lead to missing more opportunities when antibiotics may be appropriate and may increase patient dissatisfaction/trust in health care system.
- Conclusions that sexually transmitted infections (STI)/sexually transmitted diseases (STD) rates are higher in certain racial/ethnic populations may be more to do with the system of care and the social determinants of health rather than to race itself. Low income status affects more minorities; lack of income may necessitate the need to utilize federally quality health clinics (FQHCs) which are more likely to have robust clinical quality processes than private practices and thus screen more for STI/STDs; thus lack of income (poverty) may be more of a driver than race or ethnicity itself.

2. What existing methods, data sources, and analytic approaches are being used to assess and monitor technology-driven solutions (e.g., AI) in healthcare systems?

Technology-driven solutions must first determined to be safe/meeting the requirements through validation in simulation domains/datasets (past data, curated examples.) Once deemed to meet the safety/regulatory requirements technology-driven solutions are further accessed using various experimentation methods such as A/B testing and



observational studies. In addition to this various real-time monitoring of the deviations from desired effects due to drifts in the system are used to trigger retraining and deployments to correct for it. Transparency with regard to data and methods is critical to evaluation and to establish trust.

Further we would highlight the value of federally collected data as a critical resource to support analysis around biases and ensure social determinants of health are properly considered, this may include census data on race, income and employment status.

3. What selected health conditions should be addressed as priority conditions to assess technology-driven capacity to influence access, timeliness, and quality of healthcare treatment and preventive services to aging populations living in rural areas?

We enthusiastically support the recognition of the value of ensuring access to technologies that improve outcomes, enhance quality, promote healthy behaviors and assist with 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. We would encourage you to consider the following conditions:

1. Diabetes Mellitus
 - Two VA studies of telemedicine in patients with diabetes (many in rural areas) demonstrate equivalence of virtual primary care (VPC)/virtual endocrinology care in glycemic outcomes, and improvements in patient satisfaction, cost savings and reduced travel time (Xu, Sood)^{1,2}
2. Hypertension
3. Chronic Kidney disease
4. Heart Failure
5. Elevated Atherosclerotic Cardiovascular Disease (ASCVD) risk
6. Established atherosclerotic cardiovascular disease (ASCVD). This includes coronary artery disease, stroke, and peripheral artery disease
7. Tobacco use
8. Depression
9. Anxiety



C. Examples of Health Promotion using Technology-Driven Solutions

1. Describe novel technology-driven approaches (e.g., AI) that may prevent the onset, progression, or escalation of chronic disease states in patients who have decreased frequency of health system interaction during the COVID-19 pandemic, such as aging Americans living in rural areas.

Outlined below are clinical use cases for combining biometric monitoring with AI-driven real-time feedback and proactive delivery of telemedicine services when needed.

- For diabetes care, a member can use a cellular-connected glucometer to receive real-time, personalized feedback and self-management support. Remote monitoring data from the glucometer can feed into a telehealth service to proactively deliver visits to address detected needs regarding medication optimization or behavior change support.
 1. Studies of telehealth in people living with type 1 diabetes suggest that increased frequency of contact between a person living with diabetes and the health system (particularly to manage insulin recommendations) is associated with improved glycemic control. AI-driven recommendations are non-inferior to physician recs (Nimri, Joubert)^{3,4}
 2. Continuous glucose monitoring (CGMs) can be used in many segments of the population:
 - Prevent progression of disease: use CGM as educational tool, paired with remote visits to providers (primary care physician (PCP)/Endocrinologist/coach) or with digital coaching. Even intermittent use can result in A1c improvement without treatment intensification (Vigersky)⁵
 - Remote monitoring tool for high risk populations: defined segments with complications (hypoglycemia unawareness, suboptimal control) or healthcare utilization related to diabetes management could proactively be given CGM with closer monitoring in high risk transition periods (Vettoretti)⁶
 3. Smart Insulin Pens - data capture and integration with glucose data can allow patients and providers to safely, accurately assess insulin dosing. Applications would include timely optimization of glucose control (decrease clinical inertia), and also proactive outreach to high risk groups (e.g. focus on patients frequently missing insulin boluses, or those with dangerous bolus administration) (Adolffson)⁷



4. Integrated bolus calculators for people with diabetes on intensive insulin therapy can aid numeracy and safety in insulin bolus delivery (Zeigler)⁸. Aggregated device data (insulin pen, glucose data) allows providers and AI tools to make data-driven recommendations.
 - For hypertension, a member with access to a cellular-enabled blood pressure cuff could receive personalized feedback and self-management support based on their blood pressure readings. Remote monitoring data could drive a telehealth service with outreach and medication titration to bring blood pressure under control without the need for in-office services. This approach has been demonstrated to be feasible and effective by Fisher and colleagues, who were able to achieve high rates of hypertension control and rapid medication titration in a pilot program.
 - For Heart failure, the use of remote monitoring devices and virtual interactions with a care navigator team can lead to improved adherence to appropriate therapy. In a case control study, Desai et al found that remote titration of guideline-directed medical therapy by navigators using encoded algorithms increased use of appropriate medications among patients with heart failure with reduced ejection fraction (HFrEF) relative to usual care delivered by office-based Cardiologists. Navigators contacted participants remotely to direct medication adjustment and conduct longitudinal surveillance of laboratory tests, blood pressure, and symptoms under supervision of a pharmacist, nurse practitioner, and heart failure cardiologist. There were significant improvements in the use of renin-angiotensin system antagonists and Beta blockers.

Our research has shown that solutions combining remote patient monitoring with real-time telehealth management have been proven to reduce use and spending for office-based services. A recent study in the *Journal of Medical Economics*⁷ showed that at 12-months, people active in the a remote patient 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 is that the remote patient monitoring programs serve as a substitute for office-based care. As outlined above, studies support improved diabetes self-management through digital health programs

⁷ 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



that include contact with healthcare professionals and allow for increased communication.

1.Outline programs leveraging novel technology-driven approaches that may prevent increases in morbidity and mortality due to deferred care for acute medical conditions (e.g., exacerbation of heart failure, decompensated lower respiratory tract disease).

There are many examples of how technology-driven approaches may prevent increases in morbidity and mortality, as solutions including telehealth and other remote care modalities can combat deferred care for acute medical conditions. Below are a few examples:

1. To prevent acute volume overload (which occurs in a heart failure exacerbation or among people with severe chronic kidney disease), members with heart failure and/or chronic kidney disease could utilize connected devices in the home to detect episodes. For example, members could use a cellular-connected scale to detect rapid weight gain that would trigger outreach from a qualified clinician via telehealth.
2. To promote early identification and early management of diabetes associated complications, members could employ remote-screening of microvascular complications (e.g. remote retinopathy screening [Strul, Jani], at-home diabetic foot ulcer monitoring [Smith-Strom, Hazenberg].)

2.What is the established evidence or evaluation supporting proposed benefits, and the evaluation of potential harms of AI-driven solutions such as increased racial bias?

There is no doubt that our health system has racial bias, but we believe that a broader introduction of AI as well as other digital health solutions could begin to reduce existing biases. Many individuals living with chronic conditions may be in a disproportionate need for improved access to care, and thus the introduction of AI and additional digital health resources could begin to bridge the access divide and begin to alleviate existing bias.

D. Public-Private Partnerships

1.Provide ideas of the form and function of a public-private partnership model to leverage the adoption of technology-driven solutions to improve outcomes for at-risk populations such as aging Americans living in rural areas.

Partnerships with Industry



HHS should consider risk-based arrangements directly with industry, including digital health solution providers. These arrangements should hinge on reporting key metrics, that if met, incentives could be offered to individuals to adopt technologies (such as waiving cost-sharing requirements.) If metrics are not met, the solution provider would need to payback program fees to HHS.

We could also see creative thinking employed to establish programs to address provider deserts. For example, a digital health provider could “adopt a zip code” to address some of the structural access issues by introducing new health resources via virtual care. Or “opportunity zones” in healthcare that may have underperformance in healthcare outcomes and allow virtual care providers the opportunity to introduce additional resources into these communities.

Administration task force on digital health technologies

We encourage you to consider the establishment of an inter-agency task force to explore policies to improve access and coverage for digital health technologies, including coordination across federal and state agencies. It should serve to coordinate policy agendas and regulatory activity on digital health across agencies including CMS, the Food and Drug Administration and the Office of the National Coordinator for Health Information Technology (ONC.)

Public-Private Consortium on the use and diffusion of digital health technologies

A Public-Private Consortium with involvement from CMS and the FDA, should include payers, manufacturers and developers of digital technologies, providers, patients, and trade associations. Its goals would be to develop common methodologies, metrics, and approaches to assessing data on the impact of digital health technologies on quality, health outcomes, and total costs of care.

2. What organizations, groups, and/or, associations should HHS engage as part of such a collaborative effort?

We encourage HHS to take an inclusive approach to collaboration. The Department should look to balance the expertise of innovators and technology-solution developers and suppliers, with patients, clinicians, payers, academics and regulators.

The ability to leverage technology and digital health solutions, including remote monitoring and telehealth, with the application of artificial intelligence be immensely valuable as we establish a new standard of care for all Americans in the future. We appreciate the Administration’s willingness to consider applications of innovative solutions moving forward, for Medicare and Medicaid beneficiaries.



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 to offer our perspective, and we look forward to serving as a resource. If you have any questions, please contact the ATA Director of Public Policy Kyle Zebley at kzebley@americatelemed.org.

Kind regards,

A handwritten signature in black ink, appearing to read "Ann Mond Johnson", followed by a period.

Ann Mond Johnson
CEO
American Telemedicine Association