

December 20, 2019

The Honorable Alex M. Azar  
Secretary  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 509F  
200 Independence Avenue, SW  
Washington, DC 20201

Re: PreventionX Request for Information

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments in response to the U.S. Department of Health and Human Services' (HHS) Request for Information (RFI) on effective prevention strategies for chronic conditions. The AMA has a long-term commitment to developing and implementing strategies to address chronic disease prevention and management. Specifically, since 2011, the AMA has partnered with local and national health, medical, government, and community organizations on preventing type 2 diabetes and improving hypertension control. Addressing lifestyle behavior change in individuals with prediabetes and patients with hypertension is a primary intervention to prevent disease. Ensuring that behavior change is lasting requires a multi-pronged approach. Efforts such as PreventionX are a path to collect and synthesize a variety of approaches.

### **Barriers and Opportunities to Effective Preventive Health**

#### **1. In your estimation, what have been the most significant barriers to more effective prevention and delayed progression of chronic health conditions in the US?**

The evidence base describing effective preventive interventions is fairly extensive, and numerous clinical guidelines and recommendations—e.g., from the United States Preventive Services Task Force (USPSTF), the Community Preventive Services Task Force (CPSTF), and others—encourage the use of specific interventions and services that are known to be effective. One excellent example of an evidence-based preventive intervention is the lifestyle change program which is part of the Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (DPP). Despite the evidence base and inclusion in clinical guidelines, all evidence-based programs are not equally accessible or implementable. Smoking cessation programs are readily covered by public and private insurance companies, but similar behavior change interventions like the DPP struggle to gain universal attention. Program providers like the YMCA must subsidize the program costs or identify grant dollars to cover program operations and to avoid charging participants. The cost savings of the DPP have demonstrated cost savings to health systems like Medicare, as well as to families. Medicare's own estimates show a cost savings of \$2650 per Medicare beneficiary enrolled in the DPP. Yet, the rate of private insurance coverage is not keeping pace with the rise in new cases of prediabetes and type 2 diabetes.

Lack of coverage for participants is not the only barrier associated with costs. Physicians and clinical teams face numerous barriers when attempting to implement referral to effective preventive services, particularly those included in Bucket 2. Physician practices and health care organizations frequently lack the infrastructure to systematically identify and connect patients to interventions that extend beyond the traditional clinical care environment. They struggle to identify which community-based organizations or digital health companies offer high-quality programs or solutions. Once they have identified preferred referral partners, physicians do not have ready access to seamless and secure information-sharing systems to send and receive referral information. Establishing this prevention infrastructure requires significant time and financial resources which are difficult to allocate given competing priorities driven by payment programs and associated requirements for quality measurement. Financial incentives cannot even be developed without methods for measuring the quality of preventive care, but few quality measures exist that directly address use of preventive services beyond screening. Therefore, physicians are not incentivized to discuss prevention with patients beyond a brief intervention.

When effective preventive programs are adopted by a health care organization or other service provider, the program is often a solitary offering. Participants are offered one often inflexible intervention. If the intervention is too long, or not available at a convenient time or location, then participant engagement is low. Organizations put all their energy and funds into that one intervention when offering a choice is sometimes all that is needed. The AMA has seen this firsthand in working with health care organizations on implementing a diabetes prevention strategy. The DPP lifestyle change program is based on the Diabetes Prevention Study that was published in the *New England Journal of Medicine* almost 20 years ago. That study showed that an intensive lifestyle change program reduced the incidence of type 2 diabetes by 58% in US adults 18 and older compared to placebo and outperformed Metformin. Much has changed in our society since then and providing a year-long program is a barrier to scaling the intervention. Intermountain Healthcare's diabetes prevention strategy is multi-layered, and patients are offered options. These options consider location, time, delivery mode, and patient preference. This approach has also resulted in increased engagement in their entire range of diabetes prevention offerings, including in the most intensive intervention, the DPP. The health care system has shown cost savings and reduced incidence of type 2 diabetes using this approach.

Digital health applications are often proposed as a solution to several of the previously-mentioned barriers. These solutions are frequently marketed to physicians with the idea that physicians should recommend them to their patients. AMA research has demonstrated that physicians are generally receptive to using digital health solutions, particularly where they may extend care (i.e., Bucket 2) or make clinical care more effective or efficient. However, physicians have four key questions that they consider before adopting digital health solutions:

- 1) *Does it work?* In other words, is there good quality evidence that the solution is effective? The evidence base for many preventive digital health solutions is of low quality or non-existent. One notable exception is the CDC-recognized virtual diabetes prevention programs. Even when there is evidence, physicians struggle to remain abreast of the latest evidence due to the sheer volume of solutions in the market.

- 2) *Will I be reimbursed?* Frequently this is not the case with solutions that fall into Bucket 2 as they represent care not delivered by the physician. This does not mean that physicians are averse to adopting these solutions, but they may need to prioritize other solutions that support revenue generation.
- 3) *Will I be liable?* Solutions that generate clinical data can create new liabilities for physicians that they are not equipped to assess and manage. Relatedly, issues of data security and privacy often represent a seemingly insurmountable barrier that many physicians and health care organizations do not feel comfortable navigating.
- 4) *Does it work in my practice?* This question speaks to issues around practical implementation of the solution, such as what practice workflow is needed to implement the solution. For example, how would the practice manage referrals to a virtual DPP provider? If the solution generates data that can support clinical care, how can that data be shared with the clinician in a seamless and actionable manner? Many digital health solutions are designed without critical input from physicians and care teams, and so they are very difficult to incorporate into workflows or do not fit the practice's precise needs. Oftentimes, these practical questions are numerous and feel insurmountable for a busy practice to deal with.

#### **4. Despite extensive evidence suggesting the health benefits of diet and behavior change in preventing chronic health conditions such as obesity and type 2 diabetes, many populations continue to see steady increases in the prevalence of these conditions. Why are more Americans not adopting diet and behavioral changes?**

There are many reasons why Americans struggle to adopt and sustain healthy behavior changes, but the simple answer is that it is confusing, challenging, and the environment does not support healthy behaviors.

First, the average person's understanding of healthy behaviors is poor. The scientific evidence is conflicting, incomplete, and continually changing. Physicians and experts in this field struggle to remain abreast of the current evidence, so it is understandable that lay individuals would struggle further. The confusing state of scientific evidence is compounded by significant misinformation in the public sphere. There are numerous diets discussed in the media or advertised on social media that have weight loss claims. Several other products (e.g., supplements) make unsubstantiated claims about achieving weight loss with minimal effort on the part of a consumer. Additionally, consumers are being bombarded with messages about digital apps and physical activity trackers on phones and watches, but the benefit of most of these solutions is questionable at best. Clear, accurate, trustworthy information about healthy behaviors is difficult for most Americans to obtain.

Even when people have understandable, accurate information about healthy behaviors, implementing and sustaining these behaviors are challenging for any individual. A recent study in the *Journal of the American Medical Association (JAMA)* suggests that a growing number of Americans are overweight and have obesity despite an increase in the number of people who are trying to lose weight. During the study period the percentage of people that were reported trying to lose weight went from 34.3 percent to 42.2 percent. But, participants' average weight and body mass index (BMI) increased regardless of whether they tried to lose weight. When one tries any number of these and doesn't see the rapid weight loss promised, the motivation to keep trying wanes, and self-efficacy is diminished.

Losing weight is a complex behavior change. It isn't just a matter of eating less or eating more nutrient-dense foods. According to a 1998 [study](#) in the *Journal of the American Dietetic Association*, factors that predict adult eating habits include taste, cost, nutrition, convenience, pleasure, and weight control. Successful policy and program interventions need to take one or more of these into consideration. In addition to these factors, people have [emotional connections](#) with food that determine choices and quantities. For some people, food is a reaction to a situation or feeling. People overeat when they are depressed or under undue stress. For others these situations result in loss of appetite and weight loss without adopting a healthier diet. Helping people make lasting lifestyle changes must start with an understanding of why people, on an individual level, overeat, or make poor choices. Given this, it is worth noting that the CDC's NDPP lifestyle change program does address individualized causes of unhealthy habits, stress, and the need for support mechanisms and coping strategies.

The environment in which one lives has a major influence on our eating habits. Much has been studied on food deserts and lack of access to fresh fruits and vegetables. Even in environments where access is not an issue, the food environment is often supportive to overeating and poor dietary choices. Fine dining restaurants offer entrees that exceed daily calorie requirements. Retailers position calorie-dense nutrient-poor foods near the front of the store. Unhealthy choices make up the bulk of items sold in most stores and are frequently sold at a lower price than healthier options. Our built environment discourages or limits people's ability to walk, bike, and be more physically active. Today's workplaces and types of work require less physical activity and demand more sedentary behavior. The healthier choices are rarely the easier (or more pleasant) choice in today's environment.

##### **5. What evidence-based insights from any domain have the potential to create entirely new classes of interventions in Bucket 2 and Bucket 3?**

Institutional, regulatory, and legislative policies that create environments supportive of making the healthier choice the default choice are proven to provide lasting and sustainable lifestyle changes. Policies, Systems, and Environmental changes (PSEs) go beyond programming to create the structures in which we work, live, and play. PSEs work hand-in-hand. For example, an environmental change may be furthered by a policy or system change. Similarly, a policy could be put in place that results in additional environmental changes. The process is not linear. This has been proven with tobacco control. Increases in tobacco excise taxes and enacting clean indoor air laws not only encouraged people to quit using tobacco products but prevented youth initiation. While both are technically considered policy changes, clean indoor air laws created environments that send a message to the public: no smoking is allowed here.

The successful PSE approach that has resulted in preventing diseases associated with tobacco use is also being applied to prevent diseases associated with obesity. Consumption of sugar-sweetened beverages (SSBs) and fast food have been significant contributors to increased caloric intake and higher body weight. SSBs have been identified as the leading source of added sugar and calories in the American diet. Taxes on SSBs have resulted in decreased consumption and an increase in revenue to support prevention programs. The data on health outcomes – fewer cases of diabetes and hypertension – is limited; however, they all conclude that there is a direct link to reduction in weight which is a risk factor for cardiovascular disease. Examples of environmental interventions include placement of fruits and vegetables near the registers in retail establishments and in school cafeterias, resulting in an increase in consumption.

**6. What are the key barriers to commercialization of effective prevention products, services, and other strategies with clear public health benefit?**

Companies that are attempting to commercialize effective preventive products appear to struggle with determining a sustainable business model. The intensive interventions that have a strong evidence base (e.g., DPP) can have a price of several hundred dollars to cover costs of developing and delivering the product. The average price of the DPP commonly cited is \$450. Several companies attempt a direct-to-consumer model, but quickly learn that the price is more than consumers are willing to bear entirely through self-pay. Many companies attempt to market their products to physicians and health care organizations under the assumption that these entities have an altruistic commitment to health and see potential financial benefit in the era of value-based care. However, health care organizations are held accountable for cutting costs, which results in prioritization of resources towards the costliest conditions rather than preventing conditions. The companies that are relatively successful in commercializing a preventive product are doing so by securing contracts with commercial payers and large self-insured employers. However, even in this scenario, these entities seek a return on their investment that is realized within two to three years. Preventive solutions that have a longer time frame to deliver a return on investment will not be considered by these purchasers.

Additionally, the start-up costs associated with research and development of a proven product/service/program are expensive and can take years to come to market. Even if a company is leveraging research funded or conducted by other entities (e.g., NIH), the translation of that research to a scalable product is still a costly endeavor that does not guarantee a viable product.

**PreventionX Theory of Change**

**1. What are some of the most effective, but not well-publicized prevention strategies (e.g., those found in CDC's 6|18 and HI-5 programs) within Buckets 2 and 3 (or anywhere on the continuum between them)? What has been their key to success? Specifically, we are also interested in interventions that have proven effective on a smaller (e.g., health system or community) scale and are candidates for further testing or expansion.**

The AMA collaborates with CDC and its public health partners on scaling its National Diabetes Prevention Program (NDPP) lifestyle change program. The AMA specifically has focused its resources on system level changes in clinical practice, including improving prediabetes screening and referral to the DPP. As a result, the AMA has been offering technical assistance to health systems that want to implement their own DPP and syncing it with care coordination. The most successful approach we have observed is when the clinical team utilizes the following strategy:

- Query the electronic health record to identify patients due for screening (per the USPSTF guideline for screening for abnormal glucose);
- Implement standing orders for screening labs;
- Engage with patients using brief counseling interventions and shared decision-making;
- Enter an electronic referral to a DPP provider;
- Outreach to the patient and enrollment is conducted by the DPP provider; and
- Reports on participant progress are transmitted to the referring clinical team.

This screening and referral strategy is most successful when there is an ongoing use of technology to communicate with the DPP program provider, clinical team, and program participants. This applies even if the DPP provider is a community-based organization such as the YMCA. Lacking in this strategy is a universal system or method to facilitate information-sharing across all stakeholders, so these stakeholders are forced to deal with multiple communication systems that do not interface with each other.

**3. What models or methods are available to accelerate the testing, piloting, validation and (if efficacious) scale-up of Bucket 2 and Bucket 3 interventions for common chronic health conditions?**

In our response to Question 1 we noted key questions that physicians ask before they can adopt preventive digital health solutions that would be included in Bucket 2. The AMA has put forth multiple initiatives to address these key questions and barriers:

- 1) [AMA's Physician Innovation Network](#)—An online platform with the mission to cultivate and connect the worlds of medicine and health care innovation to ensure solutions meet the needs of physicians, care teams, and patients. The Physician Innovation Network connects the health care innovation ecosystems to improve the development of emerging health care technology solutions.
- 2) [Xcertia](#)—A collaboration of over two dozen organizations including the AMA, American Heart Association, Healthcare Information Management Systems Society, and DHX Group to develop and disseminate mHealth app guidelines that can drive the value these products bring to the market and the confidence that physicians and consumers can have in these apps and their ability to help people achieve their health and wellness goals.
- 3) [AMA's Digital Health Implementation Playbook](#)—Months of research were compiled into a Playbook documenting the most efficient path to implement new digital health solutions including key steps, best practices, and resources to accelerate and achieve digital health adoption.

**Public-Private Partnerships**

**1. Are you aware of examples of effective public-private partnerships at any scale?**

The AMA partnered with the YMCA of the USA, as part of a Centers for Medicare and Medicaid Innovation (CMMI) demonstration project, to develop, implement, and evaluate innovative quality improvement strategies to increase routine screening, testing, and referral of Medicare patients with prediabetes to a CDC-recognized diabetes prevention program at local YMCAs. This partnership resulted in an economic model confirming the CMMI findings that enrolling Medicare beneficiaries would save CMS \$2650 per beneficiary over 15 months. The AMA/YMCA partnership resulted in CMS covering the lifestyle change program for all Medicare beneficiaries.

In 2015, the AMA began partnering with the CDC's National Diabetes Prevention Program. This partnership worked with other national health organizations, state and local medical societies, and health departments to develop a model for addressing diabetes prevention, ACASE framework—Awareness, Coverage, Availability, Screening/Referral and Enrollment. The AMA connects clinical teams with evidence-based lifestyle change programs and creates an ongoing collaboration between patients, physicians, and community-based program providers. The AMA's method for implementing diabetes prevention strategies at health care organizations (that include interventions in Bucket 2) is available at

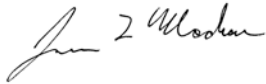
The Honorable Alex Azar  
December 20, 2019  
Page 7

the [AMA Prevent Diabetes](#). The [AMA Prevent Diabetes](#) digital tool guides clinical champions and program leads through the necessary steps to build infrastructure to support systematic screening of patients with prediabetes and enrollment in CDC-recognized lifestyle change programs.

Recognizing the role that media plays in promoting health and generating engagement, the AMA, CDC, and the American Diabetes Association partnered with the Ad Council to create the first national public awareness campaign on prediabetes. Now in its fourth year, the campaign has been successful in raising awareness but also in viewers completing a risk assessment that provides them with information to share with their physician. In 2019 alone, more than 600,000 people completed the risk assessment.

The AMA appreciates the opportunity to submit comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim L Madara".

James L. Madara, MD