Personal Connected Health Alliance
A HIMSS Innovation Company

December 19, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC

RE: Request for Information - PreventionX

Submitted by Email to: preventionx@hhs.gov

Dear Secretary Azar:

The Personal Connected Health Alliance (PCHAlliance) is pleased to have the opportunity to provide comments on the "Request for Information – PreventionX." PCHAlliance appreciates the agency's leadership and work to modernize prevention, improve the health of our nation, and advance evidence based connected wellness. We offer our comments and recommendations to enable the use of evidence based connected health and wellness.

PCHAlliance and its members aim to make health and wellness an effortless part of daily life. Providing evidence-based education, self-management tools, and communication with health providers as needed through digital connectivity, PCHAlliance members provide the clinical prevention tools and, hold much insight and capabilities for community and home-based innovative health and wellness.

The PCHAlliance, a non-profit organization formed by HIMSS, believes that health is personal, extends beyond healthcare, and digital connectivity has the potential to transform delivery of chronic condition care and population health. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

Among the questions posed by the Department, all of which are thoughtful, PCHAlliance and its members have first-hand experience with the barriers to more effective prevention and delayed progression of chronic disease. We note that these barriers limit innovation and development of new approaches and delivery mechanisms for health and wellness. Hence most of our response focus' on the first question of the PreventionX RFI.

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

Digital technologies and online app-based services provide a clear pathway for important innovation that provides support and tools consumers need to achieve health and wellness where they live and work. For example, there are several virtual or online based diabetes prevention, weight management, blood pressure control, and diabetes self-management programs in the market. These are generally accessible, improve consumer engagement in healthy lifestyle actions, and, compared to a clinic or hospital-based service, low cost. However, coverage and reimbursement for behavior change and behavior support programs is limited. ***The disconnects between reimbursement and coverage policy, prevention policy, and evidence impedes widespread use of these programs and services.*** As a result, home and community-based prevention services are a consumer product, rather than a health service. The consumer is expected to fund and engage to improve their health (defying the biologically based cravings around food and activity that are fundamental to a healthy lifestyle) while also paying out of pocket to do so for long term promise of improved health and wellness. The well-established link between socioeconomic status and chronic disease burden in the United States[i] amplify these disconnects by limiting access to consumer-based programs for those who need them most.

The following are specific examples of public policy that establishes the most significant and immediate barriers to development and adoption of evidence based, innovative, connected care prevention services:

- Insurers cover only clinic or hospital-based screenings. For example, according to the National Conference of State and Local Legislators (NCSL), only 16 states covered nutritional counseling services (not the intensive behavior change for healthy lifestyle recommended by USPSTF) to address weight related conditions and most of those were for type 2 diabetes[ii]. Connected or virtual behavior change counseling and self-management training programs (the more accessible and lower cost approach to behavior change for healthy lifestyle) are generally not covered. The message to consumers from this odd approach to coverage of lower cost, accessible healthy lifestyle behavior change services is: 1) behavior change for healthy lifestyle is not part of health care; and, 2) such services must be paid for by discretionary funds.

The Diabetes Prevention Program, an intensive behavior change for healthy lifestyle program, using the best behavior change science is able to delivery a low cost intervention that delays onset of Type 2 diabetes. When tested in the Medicare program (via a CMMI pilot), the community based, lay coach delivery model was found to save over $2,000 per Medicare beneficiary within 15 months.

- Medicare coverage, through National Coverage Decisions (NCD), excludes evidence based connected care, community-based care, and home-based care even when those delivery modes are part of the evidence used to make United States Preventive Services Task Force (USPSTF) recommendations. The most recent example of the disconnect between

Medicare coverage policy and USPSTF recommendations is the recent Ambulatory Blood Pressure Monitoring NCD[iii] which requires several physician visits and provides coverage for ambulatory blood pressure monitoring only for suspected white coat syndrome high blood pressure. In contrast, the USPSTF recommendation for blood pressure screening to diagnose high blood pressure recommends ambulatory or **home-based blood pressure monitoring** to diagnose all suspected high blood pressure, not just in the case of white coat syndrome [iv]. NCDs on behavior change counseling, for obesity[v] and Cardiovascular Disease (CVD) risk[vi], cover only counseling delivered face to face by a provider (in the case of obesity limited to a primary care provider). This coverage is not aligned with USPSTF recommendations which documents intensive behavioral therapy delivered in person or through digital communications in the community as effective[vii]. With Medicare leading the way, private health plans limit coverage and do not provided coverage in line with USPSTF recommendations.

In yet another disconnect between reimbursement and coverage policy and evidence based care, durable medical equipment coverage in Medicare almost always requires that digital data from a device be transmitted by a dedicated receiver. Yet, a receiver for digital data to transmit from a device to patient and provider (into software monitoring platforms chosen by the provider and/or patient) can be a personal connected tablet, phone, or computer. Instead, Medicare only covers devices with digital capability with a dedicated receiver/transmitted, rather than relying on what the beneficiary is funding themselves (personal device). Instead of modern, app-based transmission and use of digital data, patient generated health data from a monitor (blood pressure monitor, weight scale, pulse oximeter, etc.) is collected and transmitted via an additional part of or with the device that is a dedicated receiver/transmitter. Digital tools covered by the DME benefit therefore are clunky and do not reflect today's technology or consumer expectations, because they must include a separate device that is used only for transmitting the data, rather than via a smart phone or computer-based app.

The University of Mississippi Medical Center leveraged its telehealth network for a pilot program to treat 100 rural residents (Medicaid beneficiaries) with type 2 diabetes. Leveraging RPM, the University of Mississippi Medical Center provided care management and patient education. The results of the pilot program included improved health and reduced health care utilization for those who received care management through remote monitoring. Additionally, this led to an estimated savings to Medicaid of $339,184 for the 100 enrolled patients.

The cost of the disconnect between coverage and reimbursement and innovative prevention and self-management tools is high. The obstacles and barriers to the evidence proven programs that support healthy lifestyle lead to:

- Higher costs for Medicaid, Medicaid and private payers which all must cover more care;
- Poorer outcomes and quality of life for consumers who continue to struggle with healthy lifestyle which no support for evidence-based behavior change services;
- Stifled innovation because reimbursement and coverage is limited to clinic and hospital based services.

Conclusion:

Scientific advancements and innovation that connects population health and community-based care with clinical preventive services would flourish if a robust marketplace existed for prevention services and preventive care developed. The science of behavior change is well developed, rather it is the lack of coverage and extremely low reimbursement rates that stifle consumer adoption. We very much hope that this PreventionX RFI will be an opportunity to move forward with better models of reimbursement and coverage for prevention. Developing bundled payment for prevention services and population health targets that allow and incent providers to have their patients use connected care behavior change; other innovative means that include evidence based connected care healthy lifestyle programs as part of a broad, robust health ecosystem will be essential to the future or our nation's health. Consumers deserve a system that promotes and embraces a health-oriented health care system, rather than a sick care system. PCHAlliance and its members stand ready to be a resource for the Department as you work to develop new and innovative coverage and reimbursement models to promote health.

Sincerely,

Robert Havasy, MS
Managing Director, Personal Connected Health Alliance

---

[i] Paula A. Braveman, Catherine Cubbin, Susan Egerter, David R. Williams, Elsie Pamuk, "Socioeconomic Disparities in Health in the United States: What the Patterns Tell Us", *American Journal of Public Health* 100, no. S1 (April 1, 2010): pp. S186-S196.

[ii] See NCSL Website for coverage of obesity and nutrition related services at: http://www.ncsl.org/research/health/aca-and-health-mandates-for-obesity.aspx

[iii] See CMS Decision Memo on Ambulatory Blood Pressure Monitoring at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=294

[iv] See USPSTF Recommendation on High Blood Pressure Screening at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/high-blood-pressure-in-adults-screening

[v] See CMS Decision Memo on Intensive Behavioral Therapy for Obesity at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=obesity&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA&

[vi] See CMS NCD on Intensive Behavioral Therapy for Cardiovascular Disease at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=348&ncdver=1&bc=AAAAQAAAAAAA&

[vii] See USPSTF Recommendation on Weight Loss to Prevent Obesity Related Disease at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-interventions1