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Date: September 17, 2019

To: Dawn Alley, Acting Director, State Innovations Group, CMMI

From: Katie Wunderlich, Executive Director, HSCRC

Re: Request for a Waiver to Test Virtual Supplier Participation in the Medicare Diabetes Prevention Program (MDPP)

On behalf of the State of Maryland, we are submitting this request to the Center for Medicare and Medicaid Innovation (CMMI) to allow qualified virtual suppliers in Maryland to receive Medicare reimbursement under the Medicare Diabetes Prevention Program (MDPP), consistent with the State's Medicaid HealthChoice program and §1115 Waiver Demonstration. Research indicates that CDC's National Diabetes Prevention Program (National DPP) can successfully reduce the incidence of diabetes, and we want to use all available evidence-based resources such as National DPP to reduce and delay the onset of diabetes in Maryland. This would be an investment for which the State would be held accountable under Maryland's Total Cost of Care Model (TCOC Model). We believe this is an essential investment for Maryland and therefore seek a Medicare payment waiver under the TCOC Model to permit these payments.

Background

Maryland seeks a Medicare payment waiver to enable the provision of virtual DPP lifestyle change services (e.g., online, distance learning, or combination) for Medicare fee-for-service (FFS) beneficiaries in Maryland. Presently, MDPP does not reimburse suppliers who deliver programs virtually but who are included in National DPP. Allowing Maryland to test virtual supplier inclusion within the MDPP will help Maryland meet the goals of the TCOC Model while implementing a large-scale test of virtual MDPP suppliers for CMS. Maryland is eager to expand the footprint of the evidence-based National DPP program to meet the needs of Medicare beneficiaries. However, there is an ongoing challenge to scale community-based suppliers to match the anticipated uptake, access and referrals from the health system. To date, there are only three enrolled MDPP suppliers and only nine locations in the State of Maryland set to serve the approximately 200,000 Medicare FFS beneficiaries with prediabetes or at-risk for type 2

diabetes.¹

Virtual suppliers present a ready solution to increase access for beneficiaries to participate in the National DPP.^{2,3} Maryland Medicaid participated in a three-year CDC-funded demonstration project to develop and test a delivery system for National DPP in Medicaid managed care organizations (MCOs). An outcome of this demonstration project showed no discernible difference in effectiveness and program integrity among virtual and in-person lifestyle change programs. Based on this extensive experience, the Maryland Department of Health (MDH) is confident that regulatory and oversight mechanisms already in place for the Medicaid population, in addition to those in place under the TCOC Model, sufficiently support the requested waiver.

This memo provides additional detail from a previous memo from Maryland Medicaid to the HSCRC to develop a waiver for the Inclusion of Virtual Delivery of the National Diabetes Prevention Lifestyle Change Program for Medicare Beneficiaries in Maryland and Alignment with the Program Implementation Protocols under the Maryland Medicaid §1115 Demonstration.⁴ HSCRC shared this memo with CMMI staff associated with the Maryland TCOC Model for discussion and to assess the feasibility of such a request. In response to these discussions, within this memo, the HSCRC has included Legal Details, Precedent and Use Case Details, Waiver Operations Details, and Outcomes-Based Payment Integrity Details for further consideration.

Waiver Legal Details

The State has identified two potential approaches for a waiver to federal regulations that would allow for Medicare payment to virtual suppliers in Maryland under MDPP.

Option 1 - 42 CFR §424.205 - Requirements for Medicare Diabetes Prevention Program suppliers.

CMMI could implement a waiver under the TCOC Model that waives the term “In-Person” from the requirements for Medicare Diabetes Prevention Program (MDPP) suppliers. This would allow for virtual suppliers to provide MDPP services, while still abiding by the program’s supplier requirements. Specifically, the removal of the term “in-person” from sections 424.205(d)(10), and 424.205(g)(5)(iv) and (v) would accommodate those suppliers whose services are provided virtually, thereby aligning with all modes of delivery recognized by the CDC’s Diabetes Prevention Recognition Program (DPRP).

Option 2 - SSA Section 1861 (42 U.S.C. 1395x) Waiver from Secretary Determination

¹ Behavioral Risk Factor Surveillance System (BRFSS) Data pulled from State Outcomes-Based Credit Proposal to CMMI, prevalence of pre-diabetes in MD adults based on a clinician diagnosis applied to adults aged 65+ in Maryland.

² Anderson, Monica, and Perrin, Andrew. *Tech Adoption Climbs Among Older Adults*. Pew Research Center, May 17, 2017, https://www.pewinternet.org/wp-content/uploads/sites/9/2017/05/PI_2017.05.17_Older-Americans-Tech_FINAL.pdf.

³ Memo. Maryland Department of Health, Office of Health Care Financing. Re: Inclusion of Virtual Delivery of the National Diabetes Prevention Lifestyle Change Program for Medicare Beneficiaries in Maryland and Alignment with the Program Implementation Protocols under the Maryland Medicaid §1115 Demonstration. April 8, 2019.

⁴ Ibid.

Standards to Include Virtual Visits.

CMMI could implement a waiver under the TCOC Model to waive the requirement in Section 1861(ddd)(1)(B) of the Social Security Act that, with respect to DPP in Maryland, the preventive service be recommended by a grade of A or B from the United States Preventive Services Task Force (USPSTF) and the requirement of Section 1861(ddd)(2) that the Secretary make the determinations required under Section 1861(ddd)(1) using the National Coverage Determination (NCD) to cover “Virtual Visits” as defined by CDC’s DPRP regulations.⁵

Precedent and Use Case

Maryland’s TCOC Model seeks to expand provider incentives to improve population health through innovative opportunities like MDPP. The State’s flexibility under the Model and experience operating and monitoring various payment waivers (as well as fraud and abuse waivers, in collaboration with our federal partners), along with the previous All-Payer Model Agreement, make Maryland a prime opportunity to pilot a virtual National DPP waiver for MDPP.

Additionally, research indicates that creating multi-payer incentives and alignment ultimately increases the efficacy of value-based reform and population health programs such as National DPP and MDPP.^{6,7} Maryland’s Medicaid program is expanding National DPP services—including all modes of delivery—to eligible participants under its §1115 HealthChoice demonstration, beginning in September 2019.⁸ This work with Maryland Medicaid included extensive research and development with federal partners to align with MDPP standards. To enroll as a HealthChoice DPP supplier, including virtual suppliers, Maryland Medicaid used the standards set for MDPP suppliers found in 42 CFR § 424.205. The following section includes more details on how Maryland Medicaid’s program integrity experience would inform Maryland implementation of a waiver for virtual suppliers in MDPP.

Currently, virtual suppliers of National DPP are eligible for CDC recognition status under DPRP. This has created a significant market for virtual suppliers to develop lifestyle change programming for other payers, employers and health systems throughout the country, including Maryland Medicaid and Medicare Advantage plans active in the State. Provision of virtual lifestyle change programs has been shown to be effective in senior populations,⁹ produce savings to suppliers (e.g., ACOs) and payers,¹⁰ and achieve comparable levels of clinical and economic

⁵ CDC. *Centers for Disease Control and Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures*. CDC, March 1, 2018, <https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf>.

⁶ Kissam, S. M., Beil, H., Cousart, C., Greenwald, L. M., & Lloyd, J. T. (2019). States Encouraging Value-Based Payment: Lessons From CMS’s State Innovation Models Initiative. *The Milbank Quarterly*.

⁷ Conrad, D. A. (2015). The Theory of Value-Based Payment Incentives and Their Application to Health Care. *Health Services Research*, 50, 2057-2089.

⁸ Memo. Maryland Department of Health, Office of Health Care Financing. Re: Inclusion of Virtual Delivery of the National Diabetes Prevention Lifestyle Change Program for Medicare Beneficiaries in Maryland and Alignment with the Program Implementation Protocols under the Maryland Medicaid §1115 Demonstration. April 8, 2019.

⁹ Castro Sweet, C. M., Chiguluri, V., Gumpina, R., Abbott, P., Madero, E. N., Payne, M., ... & Prewitt, T. (2018). Outcomes of a digital health program with human coaching for diabetes risk reduction in a Medicare population. *Journal of aging and health*, 30(5), 692-710.

¹⁰ Chen, F., Su, W., Becker, S. H., Payne, M., Sweet, C. M. C., Peters, A. L., & Dall, T. M. (2016). Clinical and economic impact of a digital, remotely-delivered intensive behavioral counseling program on Medicare beneficiaries at risk for diabetes and cardiovascular disease. *PLoS One*,

effectiveness and weight loss to in-person CDC-recognized lifestyle change programs.¹¹

As part of a broader diabetes prevention strategy, Maryland is exploring virtual suppliers for MDPP in context of a broader plans to increase National DPP uptake. The State is planning to provide investments that will engage hospitals and health systems with lifestyle change program provision, engage all payers to cover the program, provide referral and billing support for community-based organizations, and rapidly scale and develop a more robust supplier network. Maryland has also developed policies and goals under the TCOC Model, such as Maryland Primary Care Program (MDPCP) screening and referral protocols and an outcomes-based credit methodology, to specifically focus statewide efforts on improving the health of persons with prediabetes. All of these efforts coincide to reinforce an ultimate goal within Maryland to reduce the incidence and burden of diabetes over the course of the TCOC Model.

To reap the full benefit of DPP and all of the research and development from CDC to create and implement the program, it is imperative that Maryland expand National DPP access. Currently, the State has 54 CDC-recognized organizations, three of whom are enrolled MDPP suppliers.¹² In order to reduce Medicare beneficiary prediabetes prevalence by just 1.8 percent without the proposed waiver, the State estimates it would need approximately 227 in-person MDPP suppliers with an estimated capacity of 200 beneficiaries per year.¹³ MDPP virtual suppliers would provide an important asset to Maryland's overall plan and impact, and would be developed in conjunction with a larger effort and support network. The State has also received a letter of support from the CDC's Division of Diabetes Translation, the division responsible for DPRP certification and National DPP development (attached).

Lastly, Maryland's access issues become exacerbated by geographic and sociodemographic differences throughout the State. Currently, two of the three MDPP suppliers in Maryland are located in an urban area.¹⁴ Beneficiaries in rural areas are often farther from an in-person National DPP supplier, but in Maryland may have the highest burden of prediabetes.¹⁵ Barriers to receiving in-person care, such as transportation, safety, mobility, and resources, could exacerbate sociodemographic disparities in diabetes prevalence within Maryland.¹⁶ Virtual DPP services for Maryland Medicare beneficiaries will help to alleviate some of these access issues and ensure effectiveness and equity of the program statewide.

11(10), e0163627.

¹¹ Tice, J.A., Chapman, R., Shore, K.K., Seidner, M., Ollendorf, D.A., Weissberg, J., Pearson, S.D. *Diabetes Prevention Programs: Effectiveness and Value: Final Evidence Report and Meeting Summary*. Institute for Clinical and Economic Review, July 25, 2016, <https://icer-review.org/material/final-report-dpp/>.

¹² "Map of MDPP Suppliers furnishing MDPP Services." CMS, 2019. <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/mdpp-map.html?dist=100>; "Registry of All Recognized Organizations." CDC, 2019, https://nccd.cdc.gov/DDT_DPRP/Registry.aspx.

¹³ Based on HSCRC Analysis. July 2019. Evidence-based studies were used to model DPP outcomes, savings and supplier need based on referral, enrollment and completion evidence of DPP demonstrations and national experience.

¹⁴ "Map of MDPP Suppliers furnishing MDPP Services." CMS, 2019. <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/mdpp-map.html?dist=100>.

¹⁵ Robert Wood Johnson Foundation. "Maryland: Diabetes prevalence." *County Health Rankings & Roadmaps*, 2018, <http://www.countyhealthrankings.org/app/maryland/2018/measure/outcomes/60/data>; "Maryland." *DATAUSA*, 2017, <https://datausa.io/profile/geo/maryland/>.

¹⁶ CDC. "Trend: Diabetes, Maryland, United States." *America's Health Rankings analysis of CDC, Behavioral Risk Factor Surveillance System United Health Foundation*, 2017, <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/MD>.

Waiver Operations Details

Virtual suppliers would be subject to all existing Medicare program integrity rules for an MDPP supplier listed in §424.205(b): Requirements for Medicare Diabetes Prevention Program suppliers.¹⁷ These include:

1. MDPP preliminary recognition as defined in §424.205(c)(1) or full CDC DPRP recognition.
2. Maintain an active and valid TIN and NPI for National DPP at the organizational level.
3. Pass screening requirements as follows: Upon initial enrollment, at a “high” categorical risk in accordance with §424.518(c)(2); and upon revalidation, at a “moderate” categorical risk in accordance with §424.518(b)(2).
4. Maintain and submit to CMS a roster of all coaches furnishing MDPP services on the entity’s behalf. This includes each coach’s first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). The roster must also be updated in accordance with §424.205(d)(5).
5. Meet and certify in its CMS-approved enrollment application that they continue to meet the supplier enrollment standards described in §424.205(d).
6. Revalidate its Medicare enrollment every 5 years after the effective date of enrollment.

These requirements include a provision that the National DPP supplier’s virtual curriculum be approved by the CDC and appear on the list of DPRP recognized organizations.¹⁸

In addition to obtaining CDC recognition status, which includes approval of the virtual curriculum to ensure fidelity to the model and prevent fraudulent suppliers from entering MDPP, virtual DPP suppliers will only be able to offer MDPP services in Maryland if they have successfully enrolled with Maryland Medicaid through the online supplier enrollment portal in addition to meeting the MDPP standards listed above. Stemming from its successful performance under the CDC-funded Medicaid and National DPP demonstration, Maryland Medicaid has amended its §1115 HealthChoice demonstration waiver to extend DPP services to eligible HealthChoice managed care participants. HealthChoice DPP will cover all modes of DPP provision, with all suppliers—including virtual—held to DPRP standards and enrolled in Maryland Medicaid through electronic validation standards as “high-risk” suppliers. Maryland Medicaid has aligned nearly all supplier vetting and enrollment standards with the MDPP regulations to allow for multi-payer alignment and oversight of this virtual supplier waiver

¹⁷ 42 CFR §424.205(b): Requirements for Medicare Diabetes Prevention Program suppliers.

¹⁸ “Registry of All Recognized Organizations.” CDC, 2019, https://nccd.cdc.gov/DDT_DPRP/Registry.aspx.

request.¹⁹

Under the State’s proposed approach, we would submit a list of virtual suppliers, vetted by both MDPP Supplier and Maryland HealthChoice DPP requirements outlined above, to CMMI on an annual basis to operationalize the virtual supplier waiver.

Lastly, any virtual suppliers included in MDPP via this waiver would have to abide by the Outcomes-Based Payment Integrity Standards outlined in the following section.

Outcomes-Based Payment Integrity Standards

The State recognizes that MDPP’s outcomes-based payment structure presents an amplified need for program integrity and monitoring standards. Of significant note for program integrity is beneficiary weight reporting, which is integral to awarding or denying Medicare payment at various stages of MDPP. To address this, technological advances make it possible to provide Medicare beneficiaries with digital scales equipped with cellular chips to report weight and verify this data for outcomes, with lower risk of fraud than with in-person provision. MDPP already includes a “Waiver for Beneficiary Engagement Incentives Provided to MDPP Beneficiaries” so that these scales and services could be provided by virtual suppliers.²⁰

Virtual suppliers enrolled in the Medicaid §1115 HealthChoice demonstration already abide by a number of program integrity standards through their participation in National DPP programs for commercial plans, Maryland Medicaid, and Medicare Advantage plans. Maryland has spoken with a number of virtual suppliers to ensure that the integrity of an outcomes-based payment is possible with virtual National DPP services. Following is a list of common activities that virtual suppliers undertake to ensure the integrity of their programs and that they continue to meet the supplier requirements of the DPRP and MDPP programs. In many cases, virtual National DPP suppliers maintain more stringent monitoring for program integrity than in-person DPP suppliers.

- *Audits:* Current Medicaid and commercial plan customers require substantial audit rights and detailed data (subject to HIPAA) to ensure correct billing. Electronic audit trails are available with virtual DPP provision, similar to EHR audit trails included in 42 CFR 170.315(d)(10). Such records and audits provide optimal documentation to paper records due to time-stamp edits and software checks on data completion, validity, and edits.
- *Weight Recording:* Identical to CMS in-person suppliers, virtual suppliers do not accept self-reported weights, as they are unverifiable. With an outcomes-based payment, it is integral to the provision of DPP services that virtual suppliers invest in technology to prevent fraud and maintain program integrity. Digital scales with cellular chips send weight recordings to each National DPP participants’ unique National DPP profile. Virtual suppliers employ data scientists and programmers to monitor data for discrepancies and inaccuracies upon receipt, while also screening for quality with statistically reliable methods and programming.

¹⁹ Memo. Maryland Department of Health, Office of Health Care Financing. Re: Inclusion of Virtual Delivery of the National Diabetes Prevention Lifestyle Change Program for Medicare Beneficiaries in Maryland and Alignment with the Program Implementation Protocols under the Maryland Medicaid §1115 Demonstration. April 8, 2019.

²⁰ “Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Medicare Diabetes Prevention Program Expanded Model.” CMS, March 1, 2018, <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/MDPP-Waiver.pdf>.

- *Equipment:* A digital scale can be provided under the limits outlined in “Waiver for Beneficiary Engagement Incentives Provided to MDPP Beneficiaries.” Additionally, virtual suppliers do not furnish services to beneficiaries who indicate they do not have access to a computer, tablet or smartphone capable of accessing the programming.
- *Lesson Completion Certification:* Virtual suppliers verify lesson completion in a number of ways, such as quiz timers, mid-point checks, and other methods developed by behavioral curriculum scientists and commonly used in educational settings.
- *Data Integrity:* Virtual suppliers collect, transfer, bill and store data under a series of systematic controls during program provision. Systematic controls continuously check for inaccuracies and potential inconsistencies throughout the enrollment, engagement, outcome assessment, and billing process to ensure that a program audit could occur seamlessly, at any time necessary, and that program integrity is maintained. Any suppliers included in Maryland’s Medicare Virtual DPP waiver would meet Medicare supplier standards and therefore implement data integrity standards similar to those already in place at virtual suppliers.

At the various levels of program provision, some examples of integrity controls include:

<p><i>Enrollment Integrity</i></p> <ul style="list-style-type: none"> ● Screen for duplicate enrollments and referrals ● Record referral source ● Confirm and log participation ● Ship digital scale and instructions to enrolled beneficiary ● Establish enrollees’ files to record qualifications of eligibility criteria 	<p><i>Beneficiary Engagement</i></p> <ul style="list-style-type: none"> ● Build a comprehensive participant profile through continuous logging ● Time-stamped lesson initiation, progression, and completion checks ● Time-stamped log-ins, weigh-ins, meal reporting, and messaging with program staff ● Controlled app access and beneficiary identification through login and password authentication
<p><i>Outcomes Determination</i></p> <ul style="list-style-type: none"> ● Issue calibrated scales with cellular microchips ● Continuously monitor data through the use of cellular microchips to prevent error and/or bias in reporting and participant weight entry ● Log frequent weight data from home scale to monitor for accuracy ● Require participant confirmation and identity verification at all points of beneficiary input 	<p><i>Billing</i></p> <ul style="list-style-type: none"> ● Auto-verify claim submissions ● Auto-transfer data from participant to claims system; no manual entry allowed ● Reconciliation checks between claims and program data ● Maintain federal standards of claims system access ● Utilize claims modifiers to indicate program milestone when necessary

As Maryland develops this particular waiver with CMMI, more integrity standards and detail could be included, as needed, and outlined in the waiver amendment to the TCOC Model.



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

To Whom it May Concern:

I am writing to express my enthusiastic support for the State of Maryland's Request for a Waiver to Test Virtual Supplier Participation in the Medicare Diabetes Prevention Program (MDPP). In my capacity as Deputy Secretary for Public Health Services, I recognize what an invaluable opportunity the State and CMMI have to partner together and expand access to an evidence-based program that will greatly compliment the State's ongoing work to curb the burden of diabetes.

Maryland provides an ample opportunity to pilot an innovation to the current MDPP structure for a number of reasons. Since 2016, the State's Medicaid program has been piloting virtual suppliers under its HealthChoice §1115 Waiver Demonstration and the results have proven so positive we further expanded the program to nearly all Medicaid beneficiaries on September 1st of this year. This work has further informed how we as a State approach expanding access to the National Diabetes Prevention Program (National DPP). Nearly 85% of our participants in the HealthChoice §1115 Waiver Demonstration accessed National DPP through a virtual supplier and an independent evaluation found that the results were comparable to that of in-person delivery. I can say with certainty that our demonstration's success was due in part to the widespread access that virtual suppliers afforded.

Additionally, I am currently convening a statewide initiative to develop a robust diabetes action plan which will engage stakeholders across State agencies and healthcare stakeholders to help improve diabetes prevention and management statewide over the next 5-10 years. We recognize what an important addition MDPP will make to a comprehensive statewide plan. However, understanding the network of suppliers as it currently stands, without allowing virtual providers in the State, Maryland will not be able to fully leverage the work that the federal government has devoted to creating this important public health tool. Simply put, we would like to devote a significant effort of resources across the State to ensuring Marylanders access National DPP, but are worried there is not enough supply in the State to match the timing of our efforts. With statewide attention and support of National DPP we know that impact is possible should Maryland have the tools it necessitates.

Maryland is working hard to develop healthcare innovation under the Total Cost of Care Model that prioritizes population health improvements. The MDPP is a wonderful example of such a program and the State is ready to implement a full-force effort to disseminate its effects. Piloting innovative waivers and programs is not foreign to the State and I am sure that our experiences with making other Models a success will carry over and help CMMI to understand the positive impact of virtual providers in MDPP.

Sincerely,

Frances Phillips, RN, MHA
Deputy Secretary
Public Health Administration



Frances B. Phillips RN, MHA
Deputy Secretary for Public Health Services
Maryland Department of Health
201 W. Preston Street
Baltimore, Maryland 21201

Ms. Phillips,

We support your proposal to allow Medicare beneficiaries in Maryland to participate in the MDPP through virtual providers recognized by CDC. We understand that this is consistent with your proposal for Medicaid coverage. CDC's Statement of Support for the inclusion of virtual delivery of the National Diabetes Prevention Program (National DPP) lifestyle change program for Medicare beneficiaries in Maryland.

- CDC is on record supporting the provision of the Medicare Diabetes Prevention Program (MDPP) in virtual form as critical to expand MDPP access to all eligible Medicare beneficiaries with prediabetes.
- A growing body of evidence demonstrates that the National DPP lifestyle change program can be effectively furnished virtually.
- The market for virtual delivery of the National DPP lifestyle change program is growing rapidly in response to consumer demand and enhancements in technology that make virtual programs highly scalable and convenient for participants to access.
- Many private payers (including Medicare Advantage plans) have contracts with virtual organizations to offer the National DPP lifestyle change program to their members.
- More than 100 organizations with recognition from the CDC currently deliver the National DPP lifestyle change program virtually, and over 190,000 individuals (63%) have participated in the program through these organizations.
- From 2016-2019, CDC worked with the Maryland Department of Health on a Medicaid Demonstration Project to scale the National DPP lifestyle change program for Medicaid beneficiaries. Evaluation results showed that virtual delivery of the program was feasible, with about half of all participants choosing to enroll in virtual options and achieving attendance and weight loss results comparable to in-person delivery.

Please let us know if there is anything else we can do to help with this.

Ann Albright, Ph.D., R.D.

Ann Albright, PhD, RD
Division Director
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