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Center for Medicare and Medicaid Innovation

DATE: March 14, 2016

TO: Andrew M. Slavitt

Acting Administrator

Centers for Medicare & Medicaid Services

FROM: Rahul Rajkumar

Deputy Director

Center for Medicare & Medicaid Innovation

SUBJECT: Request for Determination of Eligibility for Expansion of Diabetes Prevention

Program (DPP) Health Care Innovation Award (HCIA) -- DECISION

ISSUE

The Centers for Medicare & Medicaid Services (CMS) is requesting your determination, under delegation of authority by the Secretary, that the Diabetes Prevention Program tested through a Round 1 Health Center Innovation Award meets the statutory criteria under section 1115A(c) of the Social Security Act for expanding the duration and/or scope of a model.

BACKGROUND

Currently, Medicare covers treatment of type 2 diabetes and diabetes self-management training, for beneficiaries who already have the condition, and diabetes screening tests for beneficiaries at risk for diabetes. No current Medicare benefit specifically addresses primary prevention for diabetes. Medicare does currently cover obesity counseling for obese beneficiaries, but it is limited to primary care clinical settings and does not specifically target diabetes prevention.

Under Innovation Center authority, CMS has tested a model for the primary prevention of type 2 diabetes in Medicare beneficiaries known as the Diabetes Prevention Program. This model was tested through an award made to the National Council of YMCAs of the United States of America (Y-USA) under Round 1 of the Health Care Innovation Awards (HCIAs).

The CDC Diabetes Prevention Recognition Program is responsible for recognizing local and national organizations that wish to be included in a registry of recognized Diabetes Prevention Programs, which was used to identify entities eligible to participate in the Y-USA HCIA project. Recognition status requires curriculum, duration, and intensity commitments. Additionally, full recognition is contingent on a program achieving specific attendance levels and an average participant weight loss of at least 5 percent. To date, over 650 organizations overall have been

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recognized by the CDC to be able to provide Diabetes Prevention Program interventions, including virtual programs, and these organizations have served over 30,000 participants, with more than 20 health plans providing some sort of coverage. According to CDC, analyses of data collected by the CDC Diabetes Prevention Recognition Program demonstrated an average weight loss of 5 percent in participants who were age 60 and older.

Building on the CDC's experience, the Y-USA HCIA initiative was specifically focused on the evaluation of the Diabetes Prevention Program in a community-based setting for Medicare FFS beneficiaries and beneficiaries enrolled in Medicare Advantage plans.

The Innovation Center's statutory authority provides that "the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested" by the Center [SSA 1115A(c)]. Section 1115A requires that in expanding a model, the Secretary take into account the model's impact on spending (supported by certification of the Chief Actuary) and quality—and that expansion not limit coverage or provision of benefits.

As a result of the certification by OACT that expansion of the Diabetes Prevention Program will not result in an increase in program spending, the independent evaluation, and the CMS Chief Medical Officer's recommendation that the Secretary determine that this model improves quality of care for Medicare beneficiaries—and because the expansion of the Diabetes Prevention Program would provide a new benefit and therefore would not deny or limit coverage or provision of benefits under Medicare — there is now sufficient information to support the determination that this model meets the statutory criteria for expansion.

DISCUSSION

To determine that the Diabetes Prevention Program is eligible for expansion under Section 1115A(c) authority, the Secretary is required to make two prospective findings. These two prospective determinations must also be paired with a certification by the Chief Actuary of CMS that expansion of the Diabetes Prevention Program would reduce or not result in any increase in net program spending under Medicare. First, the Secretary is required to determine that expansion of the Diabetes Prevention Program is expected to reduce Medicare spending without reducing the quality of care, or would improve the quality of patient care without increasing Medicare spending. Second, the Secretary is required to determine that expansion of the Diabetes Prevention Program would not deny or limit the coverage or provision of benefits under Medicare for beneficiaries. These determinations will be prospective, but will take into consideration a retrospective review of the effects of the Diabetes Prevention Program, including the Diabetes Prevention Program's evaluation report, in improving the quality of care, reducing Medicare spending, and not altering coverage or provision of benefits.

Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program according to the second year independent evaluation of the Y-USA Diabetes Prevention Program HCIA project carried out by RTI International. Approximately

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83% of recruited Medicare beneficiaries attended at least 4 core sessions and approximately 64% percent completed 9 or more core sessions.

Improved Quality of Care- Weight loss is a key indicator of success among persons enrolled in the Diabetes Prevention Program. According to the second year independent evaluation of the Y-USA Diabetes Prevention Program HCIA project covering 6,874 Medicare beneficiaries, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions.

Impact on Medicare Spending- The CMS Chief Actuary has certified that, based on savings projections, expansion of the Diabetes Prevention Program would not result in an increase in Medicare spending.

No alteration in coverage or provision of benefits- The Diabetes Prevention Program would be an added benefit and, as such, beneficiaries participating in Diabetes Prevention Program services would retain all benefits covered in traditional Medicare.

RECOMMENDATION

We recommend that you, under delegation of authority by the Secretary, make a determination that expansion of the Diabetes Prevention Program meets the statutory criteria under section 1115A(c) of the Social Security Act for expanding the duration and/or scope of a model. CMS will continue to work to determine how expansion of this model can be operationalized.

<u>DECISION</u>	`	~ ~~11/1/	
Approve // 4//		Date 37/6/11	_
Disapprove		Date	