In March 2016, the Department of Health and Human Services announced that the CMS Office of the Actuary certified that expansion of the Medicare Diabetes Prevention Program model would reduce net Medicare spending. The expansion was also determined to improve the quality of patient care without limiting coverage or benefits. These are the requirements a CMS Innovation Center model must meet to be eligible for expansion. The Diabetes Prevention Program is the second CMS Innovation Center – and the first preventive – model to meet these requirements.

Proposed Changes

CMS proposes to expand the Diabetes Prevention Program within Medicare beginning January 1, 2018. The agency proposes to designate services in the Medicare Diabetes Prevention Program as "additional preventive services" under Medicare Part B, since CMS considers the services of this program to be consistent with other types of additional preventive services .Through expansion, more Medicare beneficiaries will be able to access the benefits of the program. CMS seeks public comment on how the program should:

- Allow CDC-recognized Diabetes Prevention Program organizations to enroll in Medicare beginning on January 1, 2017.
- Reimburse programs for diabetes prevention sessions attended and the achievement and maintenance of a minimum weight loss.
- Require CDC-recognized Diabetes Prevention Program entities to submit claims to Medicare using standard claims forms and procedures, submitted electronically in batches.
- Define eligible pre-diabetic beneficiaries based on body mass index (BMI) in addition to hemoglobin A1C tests, or plasma glucose levels.
- Develop program integrity policies to monitor and audit Medicare Diabetes Prevention Program entities.
- Establish site-of-service requirements.
- Provide education, training, and technical assistance on Medicare enrollment, data security, claims submission, and medical record keeping for Medicare Diabetes Prevention Program entities.
- Collect quality metrics for payment and public reporting to guide beneficiary choice of entities.
- Be expanded over time such as nationally in the first year or phased in gradually.

Reports of Payments or Other Transfers of Value to Covered Recipients

Background

In 2013, CMS published the final rule, titled "Transparency Reports and Reporting of Physician Ownership or Investment Interests." It requires manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) to submit annually information about certain payments or transfers of value made to physicians and teaching hospitals (covered recipients). The law also requires applicable manufacturers and group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on payments or other transfers of value provided to such physician owners or investors. Commonly referred to as either the CMS Open Payments program or Sunshine Act, this policy creates transparency around the nature and extent of relationships that exist between drug, device, biologicals, medical supply manufacturers, physicians, and teaching hospitals.

In 2015 CMS issued final regulations that specifically:

- Deleted the definition of "covered device";
- Removed the continuous medical education (CME) exclusion;
- Expanded the marketed name reporting requirements to biologicals and medical supplies; and
- Required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.