



April 10, 2014

RFI: Specialty Care Complex/Chronic Disease Model

To Whom It May Concern:

The Healthcare Leadership Council (HLC) is pleased to respond to the Center for Medicare and Medicaid Innovation (CMMI) request for information on Specialty Practitioner Payment Model Opportunities. The below HLC comments address CMMI's interest in pursuing new models of care that focus on specific diseases and patient populations to incentivize improved care, better health, and lower costs with a focus on the development of innovative payment and service delivery models for patients either with or at high risk for diabetes or prediabetes.

HLC, a coalition of chief executives from all disciplines within American healthcare, is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. HLC members advocate measures to increase the cost-effectiveness of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to elevate value.

Episode-based Payments for Diabetes

HLC members have chosen to focus on diabetes as a lens through which to understand complex chronic disease treatment and payment models. We decided to begin with diabetes because the disease has a significant impact on patients and families, as well as every sector of the healthcare industry, and carries extensive costs for payers. When diabetes is treated appropriately, healthcare system operations are integrated, efficient, and patient-centric.

Effective treatment of diabetes represents a major opportunity for healthcare savings because it is prevalent, well-understood, and its comorbidities are preventable and costly to treat. There is extensive evidence showing that care coordination, prevention, and disease management dramatically curb the health and cost effects of the disease. According to the American Diabetes Association, the estimated total cost of the disease reached \$247 billion in 2012, a 41 percent increase over the past five years. These costs are driven primarily by an increase in the number of people living with the disease – nearly 26 million adults and children. Medical expenditures for these individuals with

diabetes are 2.3 times higher than for those without the disease. Often, the programs with the best proven outcomes for diabetes prevention and management are not supported by existing payment structures. HLC members have experienced these challenges firsthand.

As noted in the request for information (RFI), in order to make episode-based payments, an episode of care must be defined for reimbursement. Since HLC's multisector membership interacts with diabetes at all points along the continuum of the disease, we identified the progression of care and payment from screening and pre-diabetes to diabetes diagnosis and management to the final complications and comorbidities associated with diabetes (see attached chart). Within each "stage," different treatments and payments comprise evidence-based best practices. **We suggest that CMMI support and promote best practices in diabetes management by building a reimbursement model or models that establish an episode payment for each "stage" of diabetes. This would allow the beneficiary to progress to each stage of care without experiencing a gap in care and provide reimbursement for the right set of services associated with each stage.**

We encourage this method because defining an episode of diabetes care by a period of time is problematic. Each diabetes beneficiary requires different treatment plans and care depending on their health status. Furthermore, the time horizon of disease progression varies widely among patients. A patient could remain in one "stage" for years while another may progress more quickly. Given the different etiologies, available treatments, and disease management approaches for patients with Type 1 and Type 2 diabetes, different approaches may be necessary within these stages to create specialty practitioner models that appropriately account for the complexity and resources associated with providing the highest quality care to these distinct populations. For a chronic disease like diabetes, optimal treatment may include prevention of the disease, management of the condition (e.g., control/reduction of A1c) or treatment of disease comorbidities. For some diabetes patients, the ultimate goal (quality measure) is to stay at the management "stage" and avoid progression to worse health or comorbidities. The continued management and monitoring required for improved outcomes does not lend itself to a time limited episode-based payment. Therefore, rather than focus on a time-based approach for chronic diseases like diabetes, we suggest that CMMI consider supporting care models employed by HLC members, defining an episode as a stage of the disease that focuses on the type and progression of the disease. These models should incorporate complications and comorbidities to best meet the needs of the patient.

A disease stage payment for diabetes would address inappropriate variation in utilization (services are often not used because they are not covered). As disease progression varies (and may be outside a practitioner's control), it is important that CMMI develop and test payment policies and tools needed for patients and providers to administer appropriate, best practice, patient-centered care – recognizing that timely, proactive care can often prevent future complications and costs. As part of this, any payment needs to have clear process and outcome evaluation measures. Finally, it is

crucial that a diabetes “episode” or “stage” of disease payment permit change of the responsible practitioner over the course of the disease as progression leads to different needs and treatments. The wide variation in chronic disease progression and management make episode-based treatment focused on a single practitioner challenging.

Other Considerations and Payment Challenges

In some cases, the Medicare payment structure lags far behind current recommendations for diabetes care or even hinders it. In addition to collecting evidence on the savings associated with evidence-based management of diabetes, HLC members have compiled a comprehensive review of payment gaps in diabetes care. These gaps occur along the entire progression of the disease, from detection to prevention and to management of the disease and its comorbidities. **We urge you to consider these important themes as you look at new models of care that focus on specific diseases to incentivize improved care, better health, and lower costs.**

Detection Challenges

The first “episode” relating to diabetes is detection of diabetes or prediabetes. Targeted screening of people at high risk for Type 2 diabetes is an essential first step to identify those with prediabetes (detection is likely less of an issue for individuals with Type 1 diabetes). These individuals can be referred to evidence-based, community-based diabetes prevention programs that focus on diet, exercise, and weight loss measures to prevent or delay the onset of Type 2 diabetes and those with undiagnosed diabetes who can begin treatment as early as possible in the course of their disease to prevent or delay the onset of complications. Early detection and treatment leads to better patient outcomes and may lead to lower overall costs to payers.

Unfortunately, several factors hinder this first, important step from taking place. Within the Medicare program, diabetes testing is covered—but is underutilized—and Medicare beneficiaries have limited awareness of the benefit. Medicare’s Annual Wellness and Welcome to Medicare visits include screening, but low utilization of these benefits prevents many at-risk, prediabetic, and diabetic patients from being identified. In at-risk adults, Medicare will cover without cost sharing two diabetes screening tests in a 12 month period. With guidelines recommending patients not at the A1c goal after three months on Metformin have additional therapy added, two tests per year may not be sufficient for a newly diagnosed patient. One test is needed to form a baseline, and a second test (at three months to determine if additional therapy is needed) would bring the patient to their yearly limit.

Medicare does not accept diagnosis of diabetes or prediabetes using the A1c test (only the fasting blood glucose tests, which also can check for prediabetes). A fasting blood glucose test cannot be performed in settings like a mobile clinic or health fair because it requires advance preparation (fasting). This hinders the vast majority of the

population—many who have diabetes or prediabetes and are unaware of it¹—from getting screened, learning they have diabetes, and being referred to a physician to begin treatment. Even patients who are screened or complete a health risk assessment (HRA) sometimes experience barriers between learning they have diabetes and actually beginning treatment.

Given the amount of low-cost screening that could be accomplished in the community setting, CMMI should strongly consider reimbursement of community-based screening for prediabetes and diabetes. Additionally, there is currently no reimbursement for patient education on the importance of screening. Other missed opportunities lie in the fact that Medicare does not reimburse physical health providers for the management of mental health co-morbidities, which results in under screening, under-reporting, under-treatment, and higher healthcare costs for diabetes.

Screening is the first step toward treatment, and without appropriate screening, the disease progresses further before the patient is aware and tries to manage it—resulting in additional health complications and costs. Diabetes typically has few or no recognizable symptoms in its early stages. As a result, when people are first diagnosed with the disease, they may already have complications. There is also evidence to show that early identification through screening of people with undiagnosed diabetes could be vital to helping them prevent the long-term complications of the disease.² HLC strongly urges CMMI to consider barriers to screening in any chronic disease payment model, but especially those relating to diabetes.

Prevention Challenges

Diabetes is a well-understood disease and studies have shown that Type 2 diabetes can be delayed or prevented through diet and exercise.³ However, significant barriers remain in prevention.

There is broad agreement that prediabetic patients should be counseled to make lifestyle changes—but this education is not reimbursed. Physicians rarely refer patients for education, and when they do refer patients, the cost of the educational visit is sometimes placed on the patient—many of whom have limited resources with which to afford additional visits. We recommend support for the National Diabetes Prevention Program (N-DPP), a low-cost, evidence-based lifestyle counseling program administered by community organizations. It is currently not a covered Medicare benefit, lacks a reimbursement pathway, and faces significant recruitment and provider awareness obstacles. We strongly recommend that Medicare incorporate coverage of N-DPP certified programs into any chronic disease care models aimed at individuals with diabetes.

¹ 7 million Americans have diabetes but are undiagnosed. About 90 percent of the 79 million Americans with prediabetes are unaware of their condition.

² American Diabetes Association. Standards of medical care in diabetes – 2013. *Diabetes Care*. 2013; Vol. 36, Supplement 1, page S14.

³ National Diabetes Information Clearinghouse. Diabetes Prevention Program: DPP results. National Institute of Diabetes and Digestive and Kidney Diseases. <http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/>. Published November 6, 2012. Accessed June 25, 2013.

We also encourage CMS to cover appointments for medical nutrition therapy (MNT) and self-management education for prediabetes patients—as well as education and healthy lifestyle programs that show evidence supporting prevention of diabetes. Medicare pays for medical nutrition therapy (MNT) provided by a registered dietician only for beneficiaries with diabetes and renal diseases but not for beneficiaries diagnosed with prediabetes. Since patients with prediabetes can slow or reverse their progress toward developing diabetes through diet and exercise, this type of coverage would be valuable to preventing diabetes in millions. Some HLC member organizations have educators that spend time providing education and medication in person and by phone and email to help patients with self-management and support their change in lifestyle goals. None of this time is reimbursed, yet they have seen a positive improvement in patient outcomes with patients who received education and follow-up by phone. Patient-supporting initiatives such as this and community-based counseling would lead to their far greater adoption by providers and better health outcomes.

Finally, some HLC members located in rural areas rely on telemedicine to treat prediabetic patients, but have found that telehealth guidelines for diabetic treatment are too narrow to be effectively utilized. Current guidelines do not provide reimbursement for prediabetic education, remote care, care coordination, or coaching (e.g., phone, follow-up text messages, online) for the prevention of diabetes. Finally, there is no recommendation for the use of telehealth for patients with a diagnosis of prediabetes, hyperglycemia, or glucose intolerance.

Care/Management Challenges

The Diabetes Working Group (DWG) commissioned a comprehensive provider survey of over 1,000 diabetes care providers, which found the three most frequent barriers to care were time with patients, inadequate reimbursement, and patient adherence. This was true for individuals with Type 1 or Type 2 diabetes. Greater alignment between best practices in diabetes management and care and reimbursement for this care could lead to better outcomes for both patients and payers.

Successful diabetes management requires lifestyle support such as diabetes self management training (DSMT) and diabetes self management education (DSME). For individuals with Type 1 diabetes, or Type 2 diabetics who require insulin, comprehensive management and monitoring is necessary to assure that patients maintain appropriate glucose control—either through multiple daily injections of insulin or technologies such as insulin pumps, combined with frequent blood glucose testing and continuous glucose monitoring (CGM).

Currently, CMS provides no reimbursement for remote care, care coordination, or coaching (e.g., phone visits, follow-up text messages, online) for the care and management of diabetes. Certified diabetes educators are not authorized to provide DSMT services, including telehealth services, under Medicare Part B, and Medicare reimburses for DSMT but not DSME. Medical nutrition therapy and DSMT are not

reimbursable on the same day. Diabetes case managers and educators receive differential reimbursement. The new care coordination HCPCS G-code has not been interpreted to include remote care coordination or coaching. Beyond basic evaluation and management services, few other avenues exist to compensate diabetes care providers for the intensive time and effort necessary to provide comprehensive management and support to patients with Type 1 diabetes. This patchwork of regulation and reimbursement for DSMT and DSME creates unnecessary gaps in care and makes healthcare more expensive overall.

In addition to undermining provider support, the current reimbursement structure makes it difficult for diabetes patients to monitor the disease themselves. Medicare does not cover the tools and devices that some patients need to most effectively monitor their diabetes.

- Medicare does not recognize CGM as a covered benefit. In numerous clinical trials, CGM systems have demonstrated improvement in overall glucose control and reductions in dangerous episodes of hypoglycemia when compared to self-monitoring of blood glucose (SMBG). Since CGM technology is covered widely outside of Medicare, beneficiaries entering Medicare may be forced to give up the diabetes monitoring system that they had become accustomed to using with another payer.
- The 2013 competitive bidding program limits choices and access to certain types of diabetes testing supplies, such as blood glucose testing strips, purchased through mail order. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch test systems. Product switching can have negative health and economic consequences.

Additional challenges CMMI might consider include patient adherence for individuals with hypoglycemia. Hypoglycemia is a significant cause of emergency room visits and hospitalizations, which increases the cost of treatment. Consideration of education and alternate therapies for patients who experience hypoglycemia may help to alleviate the incidence of hypoglycemia.

Another care management challenge to consider in effective diabetes management are cases of clinical inertia – inadequate intensification of therapy by the provider. For example, newly diagnosed patients often stay on Metformin alone for about 14 months without additional agents being added, even though they have not met their A1c goal. Greater alignment between reimbursement structures and appropriate care steps could also lead to better outcomes for both patients and payers.

At the healthcare system level, physicians of patients with multiple physicians are not incentivized to work in care teams, which prevent diabetes patients from receiving coordinated, consistent care across numerous encounters. A 2014 RAND study of nearly 300,000 Medicare recipients found that patients with better continuity of care were less likely to be hospitalized, less likely to visit hospital emergency departments, had lower rates of complications, and had lower overall costs for their episodes of care.

It also found that improving the coordination of care for patients could generate significant savings for Medicare.⁴

Finally, diabetes management also faces hurdles in the area of reporting and quality. There is a lack of uniform quality metrics across government programs, coupled with limited diabetes quality measures and alignment across Medicare programs. Payment is not currently tied to meeting appropriate standards of care for all services delivered. These gaps disincentivize comprehensive diabetes care and make it harder for quality to be assessed and for providers and payers to monitor and respond to data.

These care management challenges must be addressed for Type 1 and Type 2 diabetes to assure that models under the CMMI Specialty Practitioner Payment Models Opportunities initiative achieve the goals of effective, efficient, high quality care for individuals with diabetes.

Thank you for providing us with this opportunity to comment. We look forward to a continued dialogue through which we can identify the care structures that will best meet patient needs and control disease progression. If you have any questions, please do not hesitate to contact me or Tina Olson Grande, VP of Policy, at tgrande@hlc.org or 202-449-3433.

Sincerely,



Mary R. Grealy
President

⁴ "Continuity and the Costs of Care for Chronic Disease" *JAMA Intern Med.* Peter S. Hussey, PhD; Eric C. Schneider, MD; Robert S. Rudin, PhD; D. Steven Fox, MD1; Julie Lai, MPH1; Craig Evan Pollack, MD. March 17, 2014.

THE DIABETES CHALLENGE

SCREENING

At-risk population

PREVENTION

Prediabetes

79 million Americans with prediabetes

Undiagnosed

7 million Americans with undiagnosed diabetes

MANAGEMENT

Diabetes

19 million Americans with diabetes

- Healthy lifestyle support (diabetes self-management training (DSMT) and diabetes self-management education (DSME))
- Care coordination/management
- Medical nutrition therapy (MNT)
- Specialists (kidney, foot, eye)
- Insulin and drug therapy
- Artificial pancreas technology
- Endocrinologists

Complications

- End stage renal disease
- Amputations
- Blindness
- Heart disease
- Stroke
- Other comorbidities

THE DIABETES CHALLENGE: PAYMENT GAPS

SCREENING

At-risk population

Detection Challenges

Medicare

- Medicare does not reimburse for A1c screening tests needed for referral.
- Medicare beneficiaries have limited awareness of Medicare screening benefit.
- Low utilization of Medicare's Annual Wellness and Welcome to Medicare visits that include screening.

General

- No reimbursement for screening programs located in a community setting.
- No reimbursement for patient education on the importance of screening.
- Gap between health screenings (including health risk assessments (HRA)) and entry into diabetes treatment.
- According to research submitted by McKesson, CMS has not reimbursed nonmental health providers for management of mental health comorbidities, which results in underscreening, underreporting and undertreatment.

Other

- USPSTF-recommended screening guidelines are limited to only screening asymptomatic adults with high BP.
- There is no USPSTF recommendation on diabetes prevention.

PREVENTION

Prediabetes

Undiagnosed

Prevention Challenges

- National Diabetes Prevention Program (National DPP):

- Not a covered Medicare benefit
- Lacks a reimbursement pathway
- Recruitment and provider-awareness obstacles

- Medicare pays for medical nutrition therapy (MNT) provided by a Registered Dietician only for beneficiaries with diabetes and renal diseases but not for beneficiaries diagnosed with prediabetes. No telehealth recommendation for prediabetes, hyperglycemia, or glucose intolerance.

- No reimbursement for prediabetic education, remote care, care coordination, or coaching (e.g., phone, follow-up text messages, online) for the prevention of diabetes.

MANAGEMENT

Diabetes

Care/Management Challenges

Healthy lifestyle support/DSMT/DSME

- No reimbursement for remote care, care coordination, or coaching (e.g., phone visits, follow-up text messages, online) for the care and management of diabetes.
- Certified Diabetes Educators are not authorized to provide DSMT services, including telehealth services, under Medicare Part B.
- Medicare reimburses for DSMT but not DSME. MNT and DSMT are not reimbursable on the same day.
- Differential reimbursement for diabetes case managers and educators.

Care coordination

- New care coordination HCPCS G-code has not been interpreted to include remote care coordination or coaching.

System

- Physicians not incentivized to work in teams.
- Lack of uniform quality metrics across government channels.
- Limited diabetes quality measures and alignment across Medicare programs.
- Payment is not tied to meeting appropriate standards of care for all services delivered.
- Diabetes Working Group commissioned a comprehensive provider survey of over 1,000 diabetes care providers, which found the three most frequent barriers to care were time with patients, inadequate reimbursement, and patient adherence.
- Medicare does not cover continuous glucose monitoring.