National Clinical Care Commission
Meeting #6 (virtual)
Wednesday, February 19, 2020
1:00 pm — 5:14 pm EST

Meeting Summary

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Welcome, Roll Call, and Review of the Agenda

Linda Harris, PhD, Designated Federal Officer for the National Clinical Care Commission (NCCC), welcomed everyone and conducted roll call (see Appendix for Commission member attendance). The meeting started with a quorum.

Clydette Powell, MD, MPH, Technical Lead for the Commission, briefly explained the purpose of the meeting and reviewed the meeting agenda. She thanked the Commission members for developing questions, the Centers for Medicare and Medicaid Services (CMS) representative and alternate for their assistance in identifying specific speakers from CMS, and the speakers from CMS for presenting at the meeting.

Vote on the Diabetes Prevention and Care Model

Dr. Powell provided context and background on the Diabetes Prevention and Care Model, a product of many weeks of discussion that began in November 2019 when the model was first presented publicly. Dr Herman made a motion for the Commission to vote on the Model. Dr. Harris conducted a roll call vote. All Commission members who were present at the time voted yes to approve the model.

Achieving Health Equity and Reducing Disparities in Diabetes

Cara James, Director, CMS Office of Minority Health (OMH), provided an overview of diabetes-related disparities among Medicare beneficiaries. She noted that CMS strives to achieve equity by

- Increasing understanding and awareness of disparities,
- Developing and disseminating solutions, and
- Implementing sustainable actions.

Dr. James noted that while diabetes is not a leading cause of death for the general population in the U.S., it is one of the top five leading causes of death in certain populations, including American Indians, African Americans, Hispanics, Asian and Pacific Islanders. She pointed out that the prevalence of diabetes among Medicare fee-for-service beneficiaries is especially high in certain areas of California, Florida, and Texas--more than half of U.S. Hispanics live in those three states, and that prevalence of diabetes and prediabetes is higher in black and Hispanic populations than other populations.

Dr. James also noted that the prevalence of diabetes is higher among Medicare fee-for-service beneficiaries with intellectual or developmental disabilities, compared with beneficiaries who have no intellectual or developmental disabilities.

Dr. James explained that Medicare helps pay for diabetes testing supplies and self-management education; however, awareness of the benefit is lower among black and Hispanic Medicare

beneficiaries with early diagnosed diabetes than their White counterparts. Dr. James highlighted the need to address the disparity in awareness.

Dr. James referenced the Executive Order on Advancing American Kidney Health and highlighted a few of CMS's efforts and focuses. She provided an overview of the Medicare Diabetes Prevention Program (MDPP). Under the program, she noted, Medicare pays organizations (MDPP suppliers) to provide at-risk beneficiaries with a group-based intervention that uses a Centers for Disease Control and Prevention (CDC)-approved National Diabetes Prevention Program curriculum. The curriculum covers diet, physical activity, and weight loss. Eligible beneficiaries may receive up to 2 years of sessions.

Dr. James encouraged diabetes prevention stakeholders to help enhance MDPP's success by:

- Encouraging organizations to work toward CDC recognition,
- Helping educate organizations on CMS enrollment and billing processes using MDPP resources, and
- Working with providers to increase awareness and referrals.

Dr. James also stressed the importance of offering culturally and linguistically appropriate programs. To help in that regard, CMS has published a catalog of evidence-based approaches to diabetes prevention that are tailored for vulnerable populations (PDF, 13 MB, 38 p), she noted.

Additionally, Dr. James emphasized the need to increase utilization of ICD-10 Z-codes on Medicare fee-for-service claims in order to capture factors such as social determinants of health (SDOH) that affect beneficiaries' health status. She noted that CMS is engaged in ongoing efforts to collect more standardized data regarding SDOH in rehabilitation facilities, skilled nursing facilities, long-term care facilities, hospitals, and home health settings.

At the end of her presentation, Dr. James highlighted CMS's new initiative to assist patients and pointed out new resources related to diabetes.

Discussion

After the presentation, Dr. James responded a number of questions and comments from the Commission members. Key discussion points are summarized as follows.

Dr. Dean Schillinger asked what proportion of CMS's budget is devoted to OMH, and what proportion of OMH's budget is devoted to diabetes or prediabetes.

Dr. James responded that she would have to do a bit of research to find out the proportion. She explained that OMH does not focus on specific diseases such as diabetes because that is not how the budget is aligned.

Dr. Carol Greenlee asked Dr. James what the Commission could recommend to CMS to reduce disparity for people with diabetes and prediabetes.

Dr. James responded that the ability to address SDOH is critical, and that at CMS they are trying to address the issue within their ability. However, she also acknowledged the challenges they face (e.g., lack of awareness of the resources, and addressing a lifetime of challenges). To that end, she noted, the Commission could recommend actions to help

- Increase beneficiaries' awareness of available resources;
- Make sure providers communicate information about the resources in a way that beneficiaries can understand; and
- Reduce out-of-pocket costs, which can adversely affect treatment adherence.

Dr. William Herman asked if OMH and other federal agencies are doing anything to address affordability and beneficiaries' lack of awareness of available resources.

Dr. James replied all agencies have a role to play in that regard. She specifically mentioned the outreach and awareness efforts of CDC, the Health Resources and Services Administration's (HRSA's) community health centers, and efforts of the Indian Health Service (IHS). And she pointed out the importance of multiple agencies working together through different channels to magnify the impact.

Medicare Coverage, Durable Medical Equipment, and Program Integrity

Joel Kaiser, Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Policy, briefly reviewed the statute and coverage requirements related to durable medical equipment. He noted that durable medical equipment must be appropriate for use at home in order to be covered by CMS. He said insulin infusion pumps have been covered for 25 years under the CMS benefit, and coverage for continuous glucose monitors was added more recently.

Mr. Kaiser noted that the statutory requirements limit payments for expensive items such as insulin infusion pumps. Ownership of a pump officially begins after a 13-month rental period. CMS will pay for insulin infusion pump replacements after 5 years.

Beth Koller, MD, FACE, from the Coverage and Analysis Group explained the Medicare authority and requirements for different equipment. She noted that coverage determinations are based on whether a patient has experienced diabetes complications or other comorbidities. Diabetes alone may not be not a qualifying condition.

Dr. Koller noted that patients who are new to Medicare must meet specific evidence and documentation requirements to establish eligibility for coverage of insulin infusion pumps, continuous glucose monitors, glucose meters, glucose test strips, and an artificial pancreas. For example, in order for glucose meters and glucose test strips to be covered, physicians and other health care providers must submit documentation every 6 months, verifying glycemic control and demonstrating that the patient has been trained to use the meter and test strips. Dr. Koller

encouraged the Commission to use the various URLs included in her presentation slides for more information about the requirements.

Jill Nicolaisen, Senior Technical Advisor, Center for Program Integrity, provided an overview of her team's activities and efforts to reduce administrative burden while ensuring legitimate payments are made to both providers and eligible beneficiaries. She shared that CMS uses contractors to help with medical review and audit for those payments.

Ms. Nicolaisen pointed out that some providers do not adequately understand coverage requirements. She noted that education is key to addressing that problem. To that end, CMS provides educational materials on its website, conducts webinars, and meets with provider focus groups. Additionally, CMS offers one-on-one education to help providers correct claim errors uncovered during medical review.

Ms. Nicolaisen clarified that CMS does not make policies, and that documentation is driven by billing rules and coding.

Discussion

Dr. Herman asked Dr. Koller if a committee makes decisions related to coverage policies and what the process is for making the decisions.

Dr. Koller referred Dr. Herman to the following electronic sources for more information.

- Federal Register/Vol. 78, No. 152/Wednesday, August 7, 2013 (PDF, 205 KB, 6 p)
- Medicare Coverage Determination Process

Dr. Herman then asked how easy it would be to get the policies changed. Dr. Koller responded that decisions are based on evidence and that new evidence is required to effect a change in policy.

Dr. Herman pointed out that manufacturers' warranties on insulin infusion pumps usually last 4 years; however, CMS will pay for pump replacement only after 5 years. He commented that the coverage requirements for continuous glucose monitors (4 times daily) appears to be counterintuitive. He asked Dr. Koller for her thoughts.

Dr. Koller responded that Dr. Herman's comment about insulin infusion pumps is not a matter of coverage. Mr. Kaiser added that durable medical equipment must withstand repeated use. He also said the 5-year requirement regarding insulin pump replacement is in the statute. Additionally, Mr. Kaiser noted that in order to change the requirement for replacement frequency, CMS would need to have evidence to show the lifetime of the equipment.

Dr. Greenlee referenced the CMS requirement that providers submit the same documentation every 6 months in order for glucose test strips to be covered. She said that 6-month window seems very narrow, as diabetes is incurable and lifelong in most cases (the exception being

patients who receive an artificial pancreas). Dr. Greenlee asked if the 6-month requirement is the result of CMS rulemaking or a law, how can it be changed, and if CMS provides guidance for local contractors.

Dr. Koller responded that local contractors would be able to state the evidence behind the CMS policy on documentation for glucose test strips, that the links included in the slides provide details regarding how decisions are made. Ms. Nicolaisen added that the 6-month requirement applies to high-utilization patients and may not be in effect once a patient has been stabilized.

Dr. Herman asked whether studies have been conducted to determine whether the current requirements reduce inappropriate utilization.

Ms. Nicolaisen said no. She explained that the Center for Program Integrity enforces requirements that are already in place. She noted that they would take the question/recommendation back to the agency.

Dr. J. William Cook commented on the burden of documentation. He pointed out that the documentation required every 6 months for coverage of glucose test strips can be found in a patient's medical record. He asked if CMS has attempted to set up a portal that can be used to extract information from medical records, rather than requiring providers to redundantly copy information into forms. He stated that reducing redundant requirements would enhance providers' ability to care for patients.

Ms. Nicolaisen replied there are ongoing efforts to address the issue.

Diabetes Self-Management Education & Training, Virtual Care, and Other Provider Types Delivering Diabetes Care

Jennifer Lloyd, PhD, MA, who works in the Centers for Medicare and Medicaid Innovation (CMMI), first briefly explained the Diabetes Self-Management Education and Training (DSMT) program, which uses an evidence-based curriculum that covers topics such as nutrition and foot care. Beneficiaries, she noted, are eligible to receive DSMT if they have been diagnosed with diabetes in the past year.

Dr. LIoyd then highlighted results of two publications that she shared with the Commission members prior to the meeting. The first publication described characteristics associated with the utilization of DSMT, and reported that only 5% of patients with newly diagnosed diabetes utilized the program. Minority groups, she noted, tended to have lower utilization rate, which is in line with broader health disparities. Dr. LIoyd pointed out low awareness is a reason for the low utilization rate, and she acknowledged that factors (e.g., health literacy) that were not captured might have biased the results.

Dr. LIoyd explained that the second publication captured the benefit of DSMT. The analyses of claims data for random samples of individuals newly diagnosed with diabetes suggested that

DSMT results in lower rates of hospitalization and fewer visits to the emergency department. Given the relatively low cost of DSMT, the study suggested there might be room for a substantial return on investment. Dr. LIoyd acknowledged the limitations of the publication and noted that the results may not be applicable to larger populations and other beneficiaries.

Dr. Koller discussed the requirements regarding DSMT and medical nutrition therapy (MNT). Notably, patients in hospitals and skilled nursing facilities are not eligible for coverage of MNT. For both DSMT and MNT, face-to-face service is required, except under special circumstances.

Gift Tee, Director of the Division of Practitioner Services, touched on payments for MNT. Regardless of whether it occurs in an individual or group setting, MNT must be provided by a certified provider or a pharmacist in order to be covered.

Emily Yoder, from the Hospital and Ambulatory Policy Group, provided an overview of virtual care. She explained that Medicare telehealth is about incentivizing care for patients in rural areas. Nutritionists, physician assistants, and nurse practitioners can provide telehealth services, which are statutory benefits. However, she noted, the utilization is low due to the restrictions and CMS has no leeway to change the restrictions.

Ms. Yoder explained that in an effort to modernize care, CMS begins covering patient-initiated communication technology-based services ("virtual check-in"). One example would be a remote asynchronous service whereby patients send their provider a photo of a rash.

Ms. Yoder noted that CMS recognizes the value of virtual care and they are looking forward to continuing and expanding the services. She pointed out the need for continued stakeholder engagement, input from the public, as well as resources in order to develop codes.

Discussion

Dr. Herman commented on the two publications which Dr. LIoyd shared, and he pointed out the low uptake of DSMT. He asked Dr. Lloyd to elaborate the varied rates she mentioned (5-8%, and 13%). He also commented that the total cost of care provided is low, and he wanted to know if CMS would increase the reimbursement.

Dr. Lloyd clarified that the 5-8% uptake rate is among those patients who were newly diagnosed with diabetes; however many qualified individuals were not captured in the study. She shared that almost a third of Medicare beneficiaries were receiving some type of disease management services (e.g., attending a class). Regarding Dr. Herman's question on increasing reimbursement, Dr. LIoyd and other speakers responded that they would take it back to the agency.

Dr. Schillinger asked if the content of the presentation on virtual care could be provided to the Commission. Ms. Yoder responded yes. She clarified that payment-related polices and guidance are all available on CMS's website.

Dr. Schillinger and other Commission members then requested clarification regarding the differences between telehealth services and communication technology-based services and the implications of those differences for providers. Ms. Yoder highlighted the following.

- Medicare telehealth is a statutory benefit allowing for certain covered services to be provided at the in-person facility in rural areas (with restrictions). In comparison, communication technology-based services are newer, take into account resource costs, and are valued lower than telehealth.
- Telehealth requires 2-way audio or video communication. It must be synchronous and can be conducted via phone call, Skype, or any sort of chat.
- Communication technology-based services involve patient-initiated, asynchronous interactions.
    - The "virtual check-in" is not meant to substitute for in-person visits.
    - It can be billed separately only if no in-person visit occurred. Otherwise, payment for the virtual check-in would be bundled into payment for an in-person visit.
    - It does not cover a phone call regarding blood sugar.
    - Outbound communications from providers to patients are not covered.

Dr. Schillinger and Dr. Bolen noted that the Commission would need to follow up to better understand the differences between telehealth services and communication technology-based services.

Dr. Bolen noted that lay-led diabetes management training and empowerment training are not covered DSMT benefits. She asked if CMS would consider covering such programs and, if not, what would be the best way to pursue a rule change to enable such coverage.

Dr. Koller replied that DSMT is covered only if it is provided by people who meet statutory credentialing requirements. Lay-led diabetes programs are outside the scope of DSMT Act.

Dr. Herman asked Dr. Koller how statutes are changed. Dr. Koller replied that statutes come from public law. She suggested the Commission consulting the links listed on slide 13 of her presentation, starting with public law (which applies to Medicare, not Medicaid) and then looking at how regulations are implemented. The links from the slide are listed below:

- https://www.govinfo.gov/content/pkg/PLAW-105publ33/pdf/PLAW-105publ33.pdf (PDF, 1.9 MB, 537 p)
- https://www.govinfo.gov/app/details/FR-2000-12-29/00-32703
- https://www.govinfo.gov/content/pkg/FR-2000-12-29/pdf/FR-2000-12-29.pdf (PDF, 5.7 MB, 426 p)
- https://www.cms.gov//Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/DSMT-Accreditation-Program
- https://www.govregs.com/regulations/expand/title42_chapterIV_part410_subpartG_section410.132

- https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-132.pdf (PDF, 145 KB, 1 p)

Dr. Bolen asked if the CMS limit on hours for DSMT is a lifetime limit. Dr. Koller clarified that people with diabetes may receive up to 10 hours of DSMT during the first year. They may be eligible to receive additional hours of DSMT in subsequent years. The requirements are all laid out in statute or regulation.

Action Items

- CMS speakers will provide content of the presentation on virtual care to the Commission.
- The Commission will follow up with the CMS speakers to better understand the differences between telehealth services and communication technology-based services.

Access to Part D Drugs and Formulary Review

After a short break, Dr. Harris conducted roll call and the meeting resumed with a quorum.

Stephanie Hammonds, PharmD, RPh, provided a brief history of Medicare Part D and explained how the benefit is administered. She explained that private health insurers, known as "sponsors," contract with CMS to provide the Part D benefit through market-based plans, and beneficiaries can use a tool called Plan Finder to find a prescription drug plan that best meets their needs.

Dr. Hammonds also reviewed the regulatory definition of a Part D drug. Insulin, medical supplies associated with insulin injection, and supplies directly associated with insulin delivery (e.g., an inhalation chamber used to deliver insulin via inhalation) are all included under that regulatory definition, if they are used for a medically accepted indication.

Dr. Hammonds highlighted some of the limits of CMS' statutory authority. For example, CMS cannot interfere with the negotiations involving drug manufacturers, pharmacies, and prescription drug plan sponsors. Nor can CMS require a particular formulary or price structure for reimbursement. In addition, CMS cannot approve plans that are likely to substantially discourage the enrollment by certain beneficiaries.

Robert Dombrowski, Deputy Director of the Division of Formulary and Benefits Operations, explained CMS's process of reviewing formularies submitted by Part D sponsors. Notably, sponsors must use a formulary that has been developed and reviewed by a pharmacy and therapeutics (P&T) committee. The committee's decisions must be based on:

- Scientific evidence/standards of practice,
- Peer-reviewed literature,
- Pharmacoeconomic studies, and
- Outcomes research data.

Dr. Dombrowski explained that in early June, before a contract year begins, plan sponsors submit initial formularies, utilization management tools, and tier information to CMS. Given the volume of submissions and the time frames for review, a standardized format is essential. To that end, CMS introduced the Formulary Reference File, which lists drugs for formulary inclusion and streamlines the submission and review process.

Dr. Dombrowski noted that the purpose of the three-stage formulary review process is to identify and resolve any deficiencies or concerns. Part D sponsors are directed to either revise their formulary file or provide clinical detail to explain why their formulary is not deficient in the area identified.

Discussion

Dr. Herman asked why some beneficiaries do not opt for the Part D benefit. Dr. Dombrowski responded that some beneficiaries may have other coverage (e.g., through the Veterans Health Administration).

Dr. Bolen followed up by asking if cost prevents people from opting for Part D. Dr. Hammonds replied that Part D does provide subsidy to low-income people.

Dr. Cook commented that a small number of people in their late 60s who take only one medication or no medications may not feel Part D is worth the cost.

Dr. Herman asked if formulary reviewers are sensitive to cost for a new class of drugs that are included in treatment guidelines and if reviewers ask plan sponsors to either put those drugs in a lower tier or lower the co-pay for them.

Dr. Dombrowski explained that plan sponsors are not limited to what is listed in the Formulary Reference File. He noted that cost is not the only consideration. Other considerations include clinical requirements or restrictions that protect beneficiaries—e.g., certain routine monitoring parameters. P&T committees, Dr. Dombrowski added, read widely accepted treatment guidelines and make their own determinations based on the standpoint of pharmaco-economics and efficacy.

Dr. Cook shared that his office receives a barrage of calls each January, when insurance companies switch drugs, many of which require pre-authorization and treat lifelong conditions. He asked if CMS is doing anything to streamline the process and save time for providers and their staff.

Craig Miner responded that CMS is looking into the issue. He acknowledged that it can be challenging for plans in a competitive marketplace to offer decent premiums while ensuring continuity of care. Currently, Medicare's transition policy allows patients to have their prescription refilled during the first 90 days if coverage has changed or the patient is newly enrolled. Going forward, he added, electronic prescribing at the point of care could help. In the

meantime, CMS is looking into other ways to reduce the burden while remaining a good steward of resources.

Dr. Herman asked if CMS has thought of doing anything to direct physicians or patients to good generic alternatives within classes. According to Dr. Miner and Dr. Dombrowski, that tends to happen at the plan level, not at the level of CMS.

Dr. Herman acknowledged that Part D legislation prevents CMS from negotiating on price. He asked if CMS sees any way around that issue. Dr. Miner noted that he is not in the position to address the question.

Dr. Herman followed up by asking if negotiating on price would be useful under Part D. If so, who would address it and how would it be addressed? Dr. Miner again replied that he is not able to provide answers.

Dr. Meredith Hawkins referenced the Canadian government's authority to negotiate on price. She expressed her interest to know how much the U.S. government could save if negotiating were to enter the picture. Dr. Miner stated that in his position, he was unable to give her a good answer.

Section 1115 Demonstrations, Non-Emergency Medical Transportation, Medicaid Core Set

Judith Cash, Director of the State Demonstrations Group, provided an overview of Section 1115 Demonstrations. Under Section 1115(a) of the Social Security Act, the Secretary of Health and Human Services (HHS) is authorized to approve demonstration projects that are likely to promote Medicaid's objectives. A state that can provide its own funding portion may receive matching federal funds for the demonstration. As of February 1, 2020, there were 67 approved demonstration projects across 46 states and Washington, DC.

Ms. Cash said Section 1115 demonstrations allow states to implement innovative programs. Accordingly, the demonstrations are considered policy experiments that require careful monitoring and robust, independent evaluation.

Ms. Cash noted that community engagement is a priority of the current administration. She shared that Michigan has an ongoing community engagement demonstration project, and a number of community engagement demonstrations in other states have been challenged in court.

Alissa DeBoy, Director of the Disabled and Elderly Health Programs Group, then discussed non-emergency medical transportation, which states were previously required to provide for all Medicaid beneficiaries. However, states now have the flexibility to decide whether or not to offer transportation to their beneficiaries. Ms. DeBoy noted that CMS will issue a request for

information (RFI), and she encouraged the public to review and respond to the RFI, which will help CMS write a proposed rule on the matter.

Karen Matsuoka, PhD, Director of the Division of Quality and Health Outcomes, talked briefly about quality measurement. She acknowledged that CMS does not measure SDOH explicitly; however, the measures are sensitive to SDOH. She provided examples of how states use innovative ways to address SDOH-related issues.

Discussion

Dr. Herman asked Ms. Cash whether funds for external evaluation of 1115 Demonstration Projects are rolled into the budget. Ms. Cash said yes. She further explained that states can claim a federal match for evaluation.

Dr. Herman then asked Dr. Matsuoka if there is a reference for Medicaid's core set of quality measures, and if diabetes is included in that core set.

Dr. Matsuoka replied yes. She added that all core set of measures are available on Medicaid.gov, and diabetes is included in the core set.

Model Testing and the Medicare Diabetes Prevention Program

Nina Brown-Ashford, Deputy Director of the Prevention and Population Health Group, provided background information on the history and goals of the CMS Innovation Center, which was created by the Affordable Care Act to develop, test, and implement new payment and delivery models. The statute allows for expansion (through rulemaking) of a model's duration and scope if the model meets statutory prerequisites and one of the three following criteria.

- Improves quality without affecting cost
- Reduces cost without affecting quality
- Improves quality and reduces cost

Elizabeth Mathews, Director of the Division of Health Care Delivery, then discussed MDPP, the first prevention model established through the CMS Innovation Center. She explained MDPP is a group-based intervention that builds on the success of CDC's National Diabetes Prevention Program (NDPP), and it is a structured lifestyle intervention that was tested in the Medicare population.

MDPP pays organizations (known as MDPP suppliers) to deliver up to 2 years of sessions to groups of eligible, at-risk Medicare beneficiaries, who pay no out-of-pocket costs for the service. To receive the service, beneficiaries must

- Be enrolled in Medicare Part B or Part C;
- Present one of three blood test results indicating prediabetes;
- Have a body mass index of at least

- 23 if Asian American, or
- 25 if not Asian American;

- Not have a previous diagnosis of diabetes or end-stage renal disease; and
- Be new to MDPP.

MDPP suppliers bill Medicare directly for providing the MDPP service to Medicare beneficiaries. Examples of MDPP suppliers include the following.

- Hospitals
- Community organizations
- Churches
- Clinics

MDPP suppliers can expect to receive up to $689 per eligible beneficiary, provided that attendance and weight loss milestones are reached.

Before enrolling in MDPP, suppliers must achieve full or preliminary recognition from the CDC and meet other program eligibility requirements. Notably, existing NDPP providers must re-enroll in MDPP in order to deliver MDPP services. Ms. Mathews shared that a webinar on enrollment in MDPP will be held later this month.

MDPP suppliers arrange for clinical or non-clinical professionals trained in the CDC-approved curriculum to serve as MDPP coaches, who may be employees, contractors, or volunteers of an MDPP supplier. Each coach must have a valid National Provider Identifier and meet other requirements.

Presenters' Answers to Questions Submitted Ahead of Time

After the presentation, the presenters answered a list of questions from the Commission members that were submitted to CMS prior to the meeting. Key topics of the questions and answers are summarized as follows.

Lack of coverage for virtual MDPP services
Commission members wanted to know the following.

- Why CMS does not cover virtual MDPP services?
- Is CMS looking at different data sources to reinforce the efficacy of virtual DPP?
- Does CMS anticipate extending coverage to virtual MDPP services?

Ms. Brown-Ashford noted that currently, Medicare-enrolled MDPP suppliers must provide services in person, although a limited number of virtual make-up sessions are allowed. The decision not to cover virtual MDPP services is based on the authority given by the Secretary of HHS to expand model tests. Original tests of the MDPP program included only in-person

services. CMS agrees that virtual availability would support consumer choice and access, especially in rural area, and it is actively exploring options for a viable path to tests of virtual MDPP services.

Lifetime limit on receipt of MDPP services

The Commission asked why beneficiaries are allowed to enroll in MDPP only if they have not previously received MDPP services. Ms. Mathews replied that the lifetime requirement allows CMS to capture data needed to test the MDPP model and evaluate the program. She also said the requirement applies only to participation in the expanded MDPP, not to participation in CDC's National Diabetes Prevention Program.

Enrollment and reimbursement challenges

Many providers find the MDPP paperwork onerous and the reimbursement low. The Commission wanted to know if CMS had any thoughts on these issues and on how low current uptake might be addressed.

Ms. Mathews acknowledged that initially, CMS had a number of challenges with enrollment. She said CMS has convened focus groups and conducted other outreach activities in areas with higher numbers of eligible organizations that are not enrolled in MDPP to explore why those organizations have not enrolled. Such efforts have helped increase the pipeline for MDPP suppliers.

CMS also targets outreach at areas where the number of beneficiaries enrolled in MDPP is low. Additionally, CMS works with Medicare Administrative Contractors to facilitate the enrollment process and holds webinars on the billing process.

Ms. Mathews reminded everyone that MDPP is an expanded model test, so changing the amount and structure of MDPP payments would require a legislative change and is not an option at this time. CMS will address reimbursement issues when it is able to do so, she said.

Medicaid coverage of diabetes prevention programs

A Commission member asked: As it works with states on Medicaid DPP coverage, what is CMS doing to ensure states understand the value of covering all CDC-recognized modalities?

Ms. Mathews responded that states have the flexibility to design their own programs, as long as the programs meet the CDC's Diabetes Prevention Recognition Program standards. CDC is working directly with states on DPP coverage. States are not required to design programs that align with MDPP, but CMS understands that some states (e.g., Maryland) are doing so.

Ms. Mathews confirmed that states can cover virtual MDPP services for the Medicaid population.

CMS and CDC requirements
The Commission wanted to know if there could be better alignment between CMS and CDC requirements for prediabetes treatment in terms of payment and quality assurance.

Ms. Mathews acknowledged that differences in requirements may cause confusion for providers who participate in MDPP and CDC's National Diabetes Prevention Program. She said CMS works closely with its CDC counterparts to minimize issues and increase the efficiency of the process.

Discussion
Dr. Herman asked what proportion of CDC National Diabetes Prevention Program providers also provide MDPP. Ms. Mathews replied that approximately 800 organizations eligible to participate in MDPP, of which only 192 are currently enrolled in MDPP.

Dr. Herman then asked what the primary barriers to enrollment in MDPP are. Ms. Mathews cited the following barriers.

- Enrollment process
- Billing and claims infrastructure (e.g., software)
- Cost of administering the program
- Lack of coverage for virtual MDPP services

Additionally, Dr. Herman asked if it is difficult for a lay provider to get a National Provider Identifier number. Ms. Mathews replied no. All details, she added, can be found on CMS's website

Oral Public Comments
The Commission heard oral comments from four members of the public.

Larry McNeely
Larry McNeely, Director of Public Policy at the American Diabetes Association, expressed his appreciation for the Commission's attention to health equity and its focus on SDOH for all. As one example, food insecurity is associated with type 2 diabetes and poor glycemic control, and it tends to be more prevalent in African American and Latino populations and in single-parent households. Leveraging effective USDA programs, such as SNAP, school meals, and WIC, are key to any diabetes control and prevention strategy, in addition to clinical work.

Mr. McNeely emphasized that progress on MDPP, particularly with respect to virtual access, is urgently needed to realize the program's promise. He noted that his association's letter to the Commission outlines steps that must be taken with respect to Diabetes Self-Management Education and Support. Additionally, he urged the Commission to consider broader access to Medicaid and lower cost sharing for services that it recommends. In terms of screening for type

2 diabetes and prediabetes, he stressed that we must close the gap between recommendations and real-world practices.

Charlene Dorcey

Charlene Dorcey, a registered dietitian and certified diabetes educator, spoke on behalf of the Academy of Nutrition and Dietetics, which recently submitted comments on policies, promising practices, limitations, and gaps for the Commission's consideration. She noted that the Academy of Nutrition and Dietetics requests that the Commission consider two promising practices.

- Access to MNT services for Medicare beneficiaries with prediabetes
    - Currently, MNT is covered only for patients with diabetes and renal disease, hampering the health care system's ability to intervene early.
- Need for HHS to recognize intensive behavioral therapy for obesity (IBT) as within the scope of practice for registered dietitians
    - Currently, only primary care providers can bill Medicare directly for IBT.

The Academy of Nutrition and Dietetics, Ms. Dorcey added, also identified many limitations and gaps in coverage for DSMT, MNT, IBT, and telehealth. For example, coverage is not available for DSMT and MNT if both services are offered on the same day. In addition, access to services is also constrained by 1) diagnostic lab criteria that are not aligned with guidelines (FBS >100 or 110 mg/dl, and 2) limitations on referral sources that do not reflect how coverage is provided.

Ms. Dorcey then referenced CMS's current policy on telehealth. She noted that expanding availability of telehealth would help patients in rural and suburban areas who have mobility issues. The Academy of Nutrition and Dietetics is available as a resource should the Commission need it, she said.

Frank Harrington

Frank Harrington, Director of Reimbursement and Regulatory Affairs for the American Association of Nurse Practitioners, noted that nurse practitioners (NPs) are the largest and fastest growing specialty providing Medicare-reimbursed services. He pointed out that 36% of Medicare patients receive a billable service from an NP; however, he noted, NPs' ability to provide high-quality care is constrained by outdated Medicare regulations.

Mr. Harrington asked the Commission to recommend removal of the constraints, which require NPs to locate a physician for certification and documentation of the need for foot care, therapeutic shoes, and other interventions that improve quality of life and reduce health care spending. NPs also must obtain a physician's signature before adjusting medication or ordering MNT, cardiac rehabilitation, or pulmonary rehabilitation.

Hannah Martin

Hannah Martin, Director of Legislative and Government Affairs at the Academy of Nutrition and Dietetics, reiterated the Academy's availability to assist the Commission. She thanked the Commission for all of its studious work.

Adjournment

The meeting was adjourned at 5:14 p.m. eastern.

Appendix: Commission Members and HHS Support Staff

Commission Members Present for NCCC Meeting 6

Commission Chair
William H. Herman, MD, MPH, Stefan S. Fajans/GlaxoSmithKline Professor of Diabetes, Division of Metabolism, Endocrinology, and Diabetes, Department of Internal Medicine, University of Michigan, Ann Arbor, MI

Public Members (Special Government Employees)
Shari Bolen, MD, MPH, Associate Division Director of Internal Medicine, Center for Health Care Research and Policy, Case Western Reserve University, Cleveland, OH

John Boltri, MD, FAAFP, Chair and Professor, Department of Family and Community Medicine, Northeast Ohio Medical University College of Medicine, Rootstown, OH

J. William (Bill) Cook, MD, Chair, Board of Directors, Ascension Medical Group, Baltimore, MD

Ayotunde Dokun, MD, PhD, FACE, Director, Division of Endocrinology and Metabolism, Department of Internal Medicine, University of Iowa Health Care, Iowa City, IA

Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE, Clinical Pharmacy Specialist, Primary Care, Midtown Medical, Eskenazi Health, Indianapolis, IN

Carol Greenlee, MD, FACP, FACE, Faculty Co-Chair, Center for Medicare and Medicaid Innovation Transforming Clinical Practice Initiative, Grand Junction, CO

Meredith Hawkins, MD, MS, Director, Global Diabetes Institute, Albert Einstein College of Medicine, Bronx, NY

Shannon Idzik, DNP, ANP-BC, FAAN, FAANP, Associate Dean and Professor, Doctor of Nursing Practice Program, University of Maryland Baltimore School of Nursing, Baltimore, MD

Dean Schillinger, MD, Chief, UCSF Division of General Internal Medicine, San Francisco General Hospital, San Francisco, CA (joined after the roll call)

David Strogatz, PhD, MSPH, Director, Center for Rural Community Health, Bassett Research Institute, Bassett Health Care Network, Cooperstown, NY

Federal Members (Regular Government Employees)
Ann Albright, PhD, RDN, Division Director, Division of Diabetes Translation, Centers for Disease Control and Prevention, Department of Health and Human Services

Ann Bullock, MD, Director, Division of Diabetes Treatment and Prevention, Office of Clinical and Preventive Services, Indian Health Service, Department of Health and Human Services (joined after the roll call)

William Chong, MD, Acting Deputy Director, Division of Metabolism and Endocrinology Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services

Paul Conlin, MD, Chief, Medical Service, Veterans Affairs Boston Healthcare System, Department of Veterans Affairs

Naomi Fukagawa, MD, PhD, Director, Beltsville Human Nutrition Research Center, Department of Agriculture

Barbara Linder, MD, PhD, Program Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services

Aaron Lopata, MD, Senior Medical Advisor, Maternal and Child Health Bureau, Office of the Associate Administrator, Health Resources and Services Administration, Department of Health and Human Services

Barry Marx, MD, Director, Office of Clinician Engagement, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services, Department of Health and Human Services

Donald Shell, MD, MA, Director, Disease Prevention, Disease Management and Population Health Policy and Oversight, Office of the Assistant Secretary of Defense for Health Affairs Health Services Policy and Oversight, Department of Defense

Howard Tracer, MD, Medical Officer, U.S. Preventive Services Task Force Program, Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, Department of Health and Human Services

CAPT David Wong, MD, FAAP, Medical Officer, Office of Minority Health, Office of the Assistant Secretary for Health, Department of Health and Human Services

Commission Members Absent from NCCC Meeting 6

Ellen Leake, Chair, Juvenile Diabetes Research Foundation, International Board of Directors, Jackson, MS

HHS Support Staff in Attendance

Linda Harris, PhD, Designated Federal Officer, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Clydette Powell, MD, MPH, FAAP, Medical Officer and Technical Lead, Division of Health Care Quality, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Erika Kim, **PharmD,** ORISE Fellow, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services