Summary Report of Clinician Committee Meetings: Development of a Diabetes Outcome Measure for the Merit-based Incentive Payment System

March 2019

Prepared by:
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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (CORE) to develop outpatient outcome measures that can be used to assess the quality of care provided by clinicians who are eligible to participate in the Merit-based Incentive Payment System (MIPS). As part of this project, CORE is developing a measure to address short-term diabetes complications.

The MIPS short-term diabetes complications measure will be based on administrative claims data and will be risk-adjusted for patient demographic and clinical characteristics. The quality measure scores will be calculated using patient characteristics and outcomes documented on routinely submitted Medicare claims; therefore, the clinicians whose performance will be assessed by the quality measure will not need to submit any additional data directly to CMS.

As is standard with all measure development processes, CORE is obtaining stakeholder input on the measure. CORE has convened two stakeholder groups:

1) Technical Expert Panel (TEP): CORE has assembled a national TEP of clinicians, patient advocates, and other stakeholders. The TEP is providing input to help shape the measure concept and specifications.
2) Clinician Committee: In addition to the TEP, CORE has assembled a Clinician Committee to provide more detailed input during the measure development process. Specifically, CORE has convened a Clinician Committee of professional society representatives and front-line clinicians from rural and/or underserved communities. The Clinician Committee members collectively bring expertise in providing ambulatory care to people with diabetes nationally.

This report presents the measure development team and the Clinician Committee members, summarizes the issues discussed, and summarizes feedback and recommendations received from the Clinician Committee during its first and second meetings. CORE will update this report to include feedback and recommendations from future meetings as they occur.

Measure Development Team

The CORE measure development team consists of individuals with expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See Table A1 in Appendix A for the full list of members of the CORE measure development team.

Faseeha K. Altaf, MPH, and Kasia J. Lipska, MD, MHS lead the MIPS short-term diabetes complications measure development team. Ms. Altaf has over six years of experience developing and evaluating quality measures for the ambulatory and hospital settings. Dr. Lipska is an endocrinologist at the Yale School of Medicine and a Clinical Investigator at CORE. Her research seeks to better understand the balance of benefits and harms of glucose-lowering therapy in older adults with type 2 diabetes.

Elizabeth Drye, MD, SM, Senior Director of Quality Measurement at CORE and a Research Scientist at the Yale School of Medicine, oversees the work.

The remainder of the CORE measure development team provides a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology.

Vinitha Meyyur, PhD, the project's Contracting Officer Representative, and additional CMS staff overseeing the MIPS program, including Daniel Green, MD; Susan Arday, MHS, RN; Julie Johnson, MPH; and Sophia Sugumar provide ongoing input.

Clinician Committee Composition

CORE released a public call for nominations to convene the Clinician Committee. Potential Clinician Committee members were recruited via emails to individuals, professional societies, and organizations recommended by the MIPS short-term diabetes complications measure development team and stakeholder groups, email blasts sent to CMS email listservs, and through a posting on CMS's website.

The Clinician Committee is composed of 15 members (see Table 1 on pages 5-6). The Clinician Committee is comprised of front-line clinicians who provide ambulatory care to people with diabetes, including clinicians who practice in rural and/or underserved areas, as well as professional society representatives. The role of the Clinician Committee is to provide feedback to CORE on key methodological and clinical decisions for the MIPS short-term diabetes complications measure under development. The appointment term for the Clinician Committee is from October 2018 through July 2019.

Responsibilities of Clinician Committee members include:

- Reviewing background materials provided by CORE prior to each meeting;
- Participating in Clinician Committee meetings held by webinar/teleconference or in person; and
- Providing input on key clinical and methodological decisions, including measure cohort and outcome definitions, risk adjustment, and attribution of outcomes to MIPS eligible clinicians.

Table 1. Clinician Committee roster -- member name, organization, society representation if applicable, and location

Name and credentials	Title (organization)	Society Clinician Committee is representing (if applicable)	Location
Amisha Wallia, MD, MS	Endocrinologist (Northwestern Medical Group); Assistant Professor (Northwestern Feinberg School of Medicine)	Endocrine Society	Chicago, IL
Amy Mullins, MD, CPE, FAAP	Medical Director for Quality Improvement (American Academy of Family Physicians)	American Academy of Family Physicians	Leawood, KS
Andrew J. Lee, MD, FACP	Regional Medical Director, Medical Director Population Health (Medstar Medical Group)	N/A	Bowie, MD
Benjamin Prohaska, PA-C	Physician Assistant (Renown Health Medical Group)	American Academy of Physician Assistants	Reno, NV
Deidra Crews, MD, ScM	Nephrologist (Johns Hopkins Medicine); Associate Professor of Medicine/Nephrology (Johns Hopkins University School of Medicine)	N/A	Baltimore, MD
Emily Schroeder, MD, PhD	Endocrinologist (Colorado Permanente Medical Group, Kaiser Permanente Colorado); Investigator at Institute for Health Research (Kaiser Permanente Colorado); Associate Professor in Division of Endocrinology, Metabolism, and Diabetes (University of Colorado Denver School of Medicine)	American Heart Association	Aurora, CO
Lucia Novak, MSN, ANP-BC, BC-ADM, CDTC	Owner (Diabetes Consulting Services); Nurse Practitioner and Director (Riverside Diabetes Center)	N/A	Riverdale, MD
Matthew K. Pickering, PharmD	Director, Research Quality Strategies (Pharmacy Quality Alliance)	Pharmacy Quality Alliance	Alexandria, VA

Name and credentials	Title (organization)	Society Clinician Committee is representing (if applicable)	Location
Meggan Grant-Neirman, DO, MBA	Family Physician (First Street Family Health)	N/A	Poncha Springs, CO
Melissa Stroh, PA-C	Physician Assistant (Kiowa District Hospital)	N/A	Kiowa, KS
Michael Steinman, MD	Attending, Geriatrics Clinic (San Francisco Veterans Affairs Medical Center); Professor of Medicine (University of California at San Francisco School of Medicine)	American Geriatrics Society	San Francisco, CA
Nestoras Mathioudakis, MD, MHS	Attending Physician (Johns Hopkins Hospital); Core Faculty (Armstrong Institute for Patient Safety and Quality); Clinical Director, Endocrinology, Diabetes & Metabolism; Assistant Professor of Medicine (Johns Hopkins School of Medicine)	N/A	Baltimore, MD
Richard Hellman, MD	Clinical Endocrinologist (Hellman & Rosen Endocrine Association)	American Medical Association	North Kansas City, MO
Rodolfo Galindo, MD	Assistant Professor of Medicine at Emory University School of Medicine	American Association of Clinical Endocrinologists	Atlanta, GA
Vivian Fonseca, MD, FRCP	Endocrinologist (Tulane Medical Center); Past President (American Diabetes Association); Professor of Medicine and Pharmacology; Assistant Dean for Clinical Research; Tullis – Tulane Chair in Diabetes (Tulane University); Chief, Section of Endocrinology and Metabolism (Tulane University Health Sciences Center)	American Diabetes Association	New Orleans, LA

Clinician Committee Meetings

CORE held the first Clinician Committee meeting on December 10, 2018 (Clinician Committee Meeting 1), and its second meeting on February 28, 2019 in Baltimore, Maryland (see Appendix B for the Clinician Committee meeting schedule). This report contains summaries of Clinician Committee Meeting 1 and in-person Clinician Committee Meeting 2.

Clinician Committee meetings follow a structured format. CORE presents key issues identified during measure development and a proposed approach to addressing them, and Clinician Committee members review, discuss, and advise on the issues.

Key Issues Discussed During Clinician Committee Meeting 1

Prior to Clinician Committee Meeting 1, CORE provided the Clinician Committee members with materials for review. Materials prepared for the meeting included:

- The slide deck for the meeting.
    - The slide deck included CMS MIPS program policy relevant to the project, an introduction to the measure, and topics for Clinician Committee review.
- The meeting agenda.
- The environmental scan/literature review for the MIPS short-term diabetes complications measure.

During the meeting, CORE solicited feedback from the Clinician Committee about the technical challenges for the measure, including how to attribute the short-term complication outcomes to individual clinicians (or groups of clinicians).

In addition to providing input on the measure's technical challenges, Clinician Committee members also provided input on cohort exclusions, outcome definition, risk-adjustment variables, and approaches to attribution for the measure.

Following the meeting, Clinician Committee members provided additional feedback on the International Classification of Diseases, Ninth Revision (ICD-9) and International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes that define the cohort of patients with diabetes, and those that define the two outcomes (hypoglycemia and hyperglycemia).

Executive Summary of Clinician Committee Meeting 1

Overview of Information Presented by CORE

CORE reviewed:

- Goals of the meeting.
- Introduction to quality measurement.
- The development of the MIPS short-term diabetes complications measure:
    - Project overview and timeline,

    - Measure background, and
    - Measure specifications: cohort, outcome, and risk adjustment.
- Potential technical challenges in measure design.

Overview of Clinician Committee Feedback

Feedback from the Clinician Committee included the following:

- Members were generally supportive of the short-term complication outcomes as targets for quality measurement, although some preferred a focus on the long-term complications of diabetes.
- Clinicians underscored the importance of capturing outcomes with the right set of codes and ensuring that the codes have been validated. They noted regional differences in coding practices and potential for gaming the measure (for example, by coding a symptom rather than hypoglycemia).
- Several members expressed support for a broad cohort that includes all patients with diabetes. However, one member preferred exclusion of steroid-induced and gestational diabetes from the measure cohort.
- Clinician Committee members discussed the importance of adequate risk adjustment to ensure the measure is fair. Beyond usual medical comorbidities, members underscored the importance of cognitive impairment and depression, patient resources, education, income, access to technologies (such as continuous glucose monitoring systems), prescription coverage (which affects selection of specific drugs for diabetes), and access to specialty care (endocrinology) as factors that may impact measure outcomes.
- Clinician Committee members suggested several potential approaches to attribution, which included attribution based on which clinician is prescribing diabetes medications, which clinician is ordering A1C tests, which clinician is billing for services the most, as well as shared attribution between primary care providers and endocrinologists.

Detailed Summary of Clinician Committee Meeting 1

Welcoming Remarks

- The CORE team and CMS welcomed the Clinician Committee members to the meeting to discuss the development of outpatient outcome measures for MIPS. The CORE team reviewed the confidentiality agreement and the funding source for the project.
- CORE conducted roll-call of meeting participants; 11 of 15 Clinician Committee members were in attendance.

Introduction to Quality Measurement

<u>CORE Presentation to the Clinician Committee</u>

- CORE reviewed the types of quality measures including structural, process, and outcome measures.

- CORE discussed outcome measures, noting that outcome measures reflect the impact of the health service or intervention on the health status of patients.
- CORE reviewed the components of outcome measures: the cohort or the group of patients included in the measure; the outcome, which is the result of care or what happens to the patient; and risk adjustment, which is the process that helps to account for differences in patient mix so that variation in performance reflects differences in care quality and not differences in patient mix.
- CORE provided an overview of the meeting's goals.

Project Overview

CORE Presentation to the Clinician Committee

- CORE is developing an outcome measure for MIPS which will focus on patients with diabetes, measure short-term complications of care, be risk-adjusted, and evaluate quality of care provided by clinicians or groups of clinicians. It will be completed in July 2019.
- CORE noted the measure is still in early stages of development and that CORE has been focused on defining the cohort and outcomes as well as the preliminary attribution approach.
- CORE summarized approaches to getting stakeholder input during development noting the input of the TEP as well as the Clinician Committee.

Development of Diabetes Short-Term Complications Measure

CORE Presentation to the Clinician Committee

- CORE summarized its preliminary approach to the MIPS short-term diabetes complications measure.
    - The data sources for measure development include Medicare Fee-for-Service (FFS) administrative claims (Part A, Part B, Part D) from years 2013-2015.
    - The cohort is currently defined as: Medicare FFS beneficiaries aged 65+ with a diabetes diagnosis (based on Healthcare Effectiveness Data and Information Set [HEDIS] criteria using claims data from up to 2 years prior to the measurement period) who are enrolled in Part A and B during, and 1 year prior to, the measurement period.
    - The outcome is defined as:
        - A *hyperglycemic* or *hypoglycemic* event that leads to healthcare utilization (hospital admission, emergency department [ED] visit, or observation stay) and is identified as a primary/principal discharge diagnosis from the ED or hospital, based on claims.

- CORE provided preliminary thoughts about the risk-adjustment model. The goal of risk adjustment is to account for differences in case-mix across MIPS eligible clinicians so the measure score illuminates variation in performance. The two outcomes of interest are relatively rare; therefore, it may be necessary to restrict the measure to larger clinician groups to be able to reliably measure the outcome rates across providers.
- CORE asked Clinician Committee members if they had any clarifying questions about the measure concept or any of the material.
- CORE reviewed the technical challenges, which were determining whether to include a broad group of patients with diabetes in the cohort or restrict to patients using high-risk medications. In addition, CORE pointed out the challenges associated with a relatively low outcome rate and the inability to account for hypoglycemic events occurring outside of the ED or hospital, such as those treated and released by emergency medical service (EMS) providers or those treated by family or caregivers at home.
- CORE led the Clinician Committee members in a "round robin" to solicit thoughts about ways to address the measure technical challenges as well as other technical challenges they may foresee.

<u>Clinician Committee Feedback</u>

Measure Concept

- One member expressed that the focus of this measure is too much on short-term complications. While short-term complications are vital to the health of the patient, long-term complications tend to be of greater priority. The member noted clinicians are seeing fewer admissions for short-term complications (aside from diabetic ketoacidosis). In contrast, the member noted gaps in diabetes management to reduce the risk of long-term complications and recommended the use of appropriate surrogates to focus in on these longer-term outcomes.
- One member agreed long-term complications are important as they comprise two-thirds of the costs and much of the misery for the patients. The member highlighted that validity of hyperglycemia and hypoglycemia outcomes is the key issue.

Cohort

- Clinician Committee members generally supported the use of a broad cohort.
    - Four members supported the use of a broad cohort, while the others did not specifically comment on cohort.
    - One member noted the use of a broad cohort would help to reflect many of the decisions that go into the choice of medication to treat diabetes.
    - One member added he is developing a measure for health plan-level accountability that captures hypoglycemic events only, and the measure also has a broad cohort. The hypoglycemia rates for the health plan measure were similar to rates reported by CORE.

- One member suggested adding two exclusions for 1) steroid-induced diabetes and 2) gestational diabetes. The member noted that these are self-limiting and exceptional diagnoses that should be excluded.
    - Another member disagreed with this and added that a patient can have steroid-induced hyperglycemia on top of preexisting diabetes that is caused by medications (for example, glucocorticoids) prescribed by other clinicians such as ophthalmologists, orthopedists, or rheumatologists.

Outcome

- One member asked about the ICD-9 codes for hypoglycemia. The member noted that in the literature, there is a narrow set of ICD-9 coding for hypoglycemia, but it is more expansive in other algorithms. The member preferred keeping the outcome definition narrow but specific.
    - CORE noted they would share the ICD-9 and -10 codes used to define the outcomes to the Clinician Committee for review and feedback.
- Two members brought up variation in coding and the importance of validation of the capture of the outcome. They noted there is a significant amount of variation in coding practices. There is also variation from the outpatient to the inpatient setting. In the outpatient setting, hypoglycemia may be coded as a sign or symptom, rather than as "hypoglycemia." They asked if the measure would include hypoglycemia based on laboratory values (for example, a glucose level of 43 milligrams per deciliter [mg/dl]).
- One member raised concerns about regional variation in EMS transport rates for hypoglycemia as an issue. The member also raised concerns that the measure could potentially lead to perverse counseling of patients to avoid being transported by EMS to the emergency room for hypoglycemia.
- One member foresaw challenges with reliability testing based on their own health plan-level measure. The member added that although the health plan-level of accountability he is developing is broad, the reliability may not be high. The models that for the health plan-level measure may not converge to adequately show health plan-level accountability. This issue extends into risk adjustment, because the sample may not be large enough to adequately test a risk-adjusted model. The member noted that these may or may not be concerns for CORE's MIPS measure.
- One member noted CORE is more interested in a subset of hypoglycemia and suggested CORE note this explicitly.
- One member suggested hypoglycemia is not frequently addressed by EMS, but by family members. If family members do call EMS, they do not want to pay the ambulance bill and they may negotiate to keep the patient at home. This will not be captured in the measure.

Attribution

- Several Clinician Committee members suggested attributing the outcome of short-term diabetes complications to the provider who prescribed glucose-lowering medication.

- One member suggested if a clinician belongs to an entire health system then it would be the health system that should be attributed, as there may be multiple providers who are managing several of these medications.
- One member suggested the provider who is most often billing for the care of the patient could be held accountable.
- One member noted sometimes providers are forced to use the wrong medication – for example, a sulfonylurea (which increases the risk of hypoglycemia) – because of the patient's insurance status. The member added it is important to examine if the patient was denied other medications that may not have led to the hypoglycemia.

- Three members suggested a multiple provider attribution approach in which both the endocrinologist and the primary care provider would be held accountable.
  - One member pointed out that in rural/remote communities, patients may drive 2 hours to see an endocrinologist once a year. The member noted the primary care provider is involved with the day-to-day management, while the endocrinologist may provide recommendations for how treatment may need to be tailored. The member suggested using billing for drawing the A1C to discern who is the most responsible. The member also suggested that if patients experience a complication, both the endocrinologist and the primary care provider could be alerted, which would encourage more communication and collaboration between the two providers who would be sharing responsibility for the patient.
  - Another member agreed with this approach, as it would encourage collaboration. The member highlighted that it would be very challenging to identify who owns the patient in a health system based on A1C draws. Epic is used in the member's practice, and patients can have an A1C drawn by the primary care provider at one visit and by the endocrinologist at the next visit. The member asked if the patient would potentially appear on two different clinician's lists in this scenario. In the member's own experience, the goals of the endocrinologist may differ from those of the primary care provider and there are often discordant guidelines between the American College of Physicians (ACP) and the American Diabetes Association (ADA) with respect to glycemic targets. The member asked how to account for what a clinician's actual target is for a given patient.
- Two Clinician Committee members questioned whether providers should be responsible for short-term complications.
  - A member noted that hyperglycemia and hypoglycemia are very short-term complications. The member said that patients with type 1 diabetes commonly experience fluctuations in their blood glucose levels daily, and that there are many factors contributing. The member added that while a provider is responsible for their patient, the patient should also be held responsible for

themselves. The member questioned why providers should be considered "responsible."

- One member noted other providers who may not be treating diabetes can prescribe medications, which in turn affect blood sugars. For example, ophthalmologists, orthopedists, or rheumatologists often prescribe medications they do not think will affect blood sugars. The member found out about these medications after a complication already occurred. This means clinicians must focus on education to other providers and to patients to prevent another complication from happening.

Risk Adjustment

- One member asked about risk adjustment, specifically, the ability to examine and include social risk factors. The member noted that if a provider uses the various medical problems that a patient has, the provider would miss factors that drive outcomes and are related to education level and/or income level.
- One member highlighted the importance of comorbidities. For example, patients with chronic kidney disease have an increased risk of hypoglycemia when prescribed sulfonylureas. The member also noted the presence of cognitive dysfunction, depression and lack of resources in this population. These factors are important to consider because hypoglycemia risk may be reduced with the use of Continuous Glucose Monitoring Systems (CGMs), which provide alarms when blood glucose levels go down.
- One member pointed out that differences in insurance coverage may drive selection of glucose-lowering drugs, and that this in turn will affect hypoglycemia outcome.

Summary

- Cohort: The Clinician Committee generally supported the use of the broad cohort and suggested cohort exclusion criteria.
- Outcome: Clinician Committee members discussed several concerns pertaining to the outcome, which included the codes to be used, variation in coding practices, inability to capture events that do not end up in the ED, regional variation in EMS practices with respect to transporting patients to the ED for hypoglycemia, and the possibility of issues with reliability testing.
- Attribution: Clinician Committee members suggested several potential approaches to attribution including attribution based on which clinician is prescribing diabetes medications, which clinician is ordering A1C tests, which clinician is billing for services the most, as well as shared attribution between primary care and endocrinology.
- Risk adjustment: Clinician Committee members discussed the importance of adequate risk adjustment to ensure the measure is fair. Beyond usual medical comorbidities, members underscored the importance of cognitive impairment and depression, patient resources, education, income, access to technologies (such as CGMs), prescription coverage (which affects selection of specific drugs for diabetes), and access to specialty care (endocrinology) as factors that may impact measure outcomes.

Wrap-Up

CORE Presentation to the Clinician Committee

- CORE thanked the Clinician Committee members for their valuable feedback and, reviewed the next steps for the project. CORE will distribute a summary of the meeting, develop an approach to attribution, and hold the next Clinician Committee meeting in February 2019 in person.
- CORE invited Clinician Committee members to reach out via email with any additional input.

Key Issues Discussed During Clinician Committee Meeting 2

Prior to Clinician Committee Meeting 2, CORE provided the Clinician Committee members with materials for review. Materials prepared for the meeting included:

- The slide deck for the meeting
- The meeting agenda
- The supplemental file which includes information on the cohort and outcomes definitions in ICD-9 and ICD-10, as well as the preliminary list of candidate risk factors to be used for risk adjustment

During the meeting, CORE solicited feedback from the Clinician Committee on the outcome definitions, the attribution options, and the selection of risk variables.

Executive Summary of Clinician Committee Meeting 2

Overview of Information Presented by CORE

CORE reviewed:

- The goals of the meeting.
- The development of the MIPS short-term diabetes complications measure.
    - Project overview and timeline.
    - Measure concept.
    - Measure specifications: cohort, outcome, attribution, and risk adjustment.

Overview of Clinician Committee Feedback

<u>Outcome Definitions</u>

- *Broader hypoglycemia outcome definition*: Two Clinician Committee members discussed the importance of capturing less severe hypoglycemic events, for example, by using data from a continuous glucose monitor. They were concerned that the current measure outcome based on administrative data was too narrow, and suggested that CMS consider a broader outcome of hypoglycemia in the future. CMS expressed interest in gaining more feedback from the committee on obtaining more data to better measure hypoglycemia in the future.
- *Variation in Emergency Medical Services (EMS) protocols for hypoglycemia:* Three members noted there are many other factors, aside from EMS protocols, that influence the underlying variation in EMS transport versus non-transport for hypoglycemia. Some members recommended adjustment for the type of EMS protocol by county/state but others stated challenges associated with adjustment.
- *Specific outcome definitions:* Eight members supported the proposed outcome definitions and exclusions and noted they are reasonable compromises given the data limitations; some members provided exceptions or caveats to their support.

- *Outcome exclusions*: Member feedback on the 10-day buffer period (i.e., exclusion of outcomes within 10 days of discharge from the hospital, SNF, or acute rehabilitation facility) was mixed. Four members supported the 10-day buffer period although they raised questions whether the 10-day buffer period should include business, as opposed to calendar, days. Three members commented that the 10-day buffer period is too short.

Attribution Options

- *Non-physician clinicians:* Members had varying opinions on whether non-physician and non-clinical providers should be included in the attribution model. Three members discussed diabetes educators and the importance of non-physicians in caring for patients with diabetes. Five members commented on the definition and care process for non-physician PCPs.
- *Attribution to an endocrinologist*: Eight members discussed the varying subspecialties of endocrinology and whether an endocrinologist should be held responsible for diabetes care regardless of the primary reason for the patient visit. One member was concerned that attribution to endocrinologist based on the number of visits (regardless of reasons for visits) may change the work-flow and tax the capacity of endocrinologists.
- *Specific attribution options*: Six members favored option one (multiple provider attribution), one member favored option two (single provider attribution, majority of visits), and six members favored option three (single provider attribution, ≥2 endocrinologist visits). Two members who favored option one preferred option three to option two if single attribution was being considered.

Risk Adjustment

- *Approach to risk adjustment*: Overall, members agreed with the conceptual model and approach to risk adjustment.
- *Candidate clinical risk factors for adjustment:* Members provided additional risk factor variables for adjustment, including history of a gastric bypass procedure, diabetic foot ulcers, stages of kidney disease, individual components of the diabetes complications severity index, measures of literacy, numeracy, and food insecurity. Some members favored including A1C in the list of risk factors, but others did not.
- *Social risk factors*: Four members suggested accounting for lack of access and cost of medication. Three members suggested adding drug coverage in addition to dual eligibility to the list to capture patients who fall through the "donut hole" of coverage for a three-month period.

Other Considerations

- Multiple members raised the issue of patients in hospice and palliative care – stating that they should not be included in the cohort for the measure.

Detailed Summary of Clinician Committee Meeting 2

Welcoming Remarks

- The CORE team welcomed the Clinician Committee members to the meeting to discuss the development of outpatient outcome measures for MIPS. The CORE team reviewed the confidentiality agreement and the funding source for the project.
- CORE provided an overview of the project to develop an outcome measure for MIPS. Measure development will be completed in July 2019.
- CORE conducted roll-call of meeting participants and members introduced themselves; 9 of 15 committee members attended in-person, and four attended remotely.
- CORE provided an overview of their organization mission and contract with CMS.

Measure Concept

CORE Presentation to the Clinician Committee

- CORE reviewed the measure rationale:
    - Improve the safety of diabetes management for millions of Americans;
    - Fill an important quality measurement gap; and
    - Measure outcomes that capture preventable healthcare utilization.
- CORE reviewed the components of outcome measures which include:
    - The cohort or the group of patients included in the measure;
    - The outcome which is the result of care or what happens to the patient;
    - Risk adjustment which is the process that helps to account for differences in patient characteristics so that variation in performance reflects differences in care quality and not differences in patient mix; and
    - Attribution which is the process of assigning patients to providers accountable for their care.
- CORE reviewed approaches to getting stakeholder input during development, noting the input of the TEP as well as the Clinician Committee. Stakeholder input informs measure development and the proposals made to CMS, but CMS is the final decision-maker when it comes to the usage and implementation of this measure.

Measure Cohort

CORE Presentation to the Clinician Committee

- CORE summarized its preliminary approach to the development of the MIPS short-term diabetes complications measure.
    - The data sources for measure development include the Medicare Fee-for-Service (FFS) administrative claims data (Part A [hospital], Part B [outpatient], Part D [drug/pharmacy]) from years 2013 through 2015. Should CMS implement this

measure, they will use the most recent data available in alignment with the MIPS program year.
    - The cohort is broadly defined as: Medicare FFS beneficiaries ages 65 and older with a diagnosis of type 1 or type 2 diabetes who are enrolled full-time in Medicare Part A and B during, and one year prior to, the measurement period.
    - There are no exclusion criteria.
- CORE reviewed Clinician Committee feedback on cohort codes. Based on previous Clinician Committee discussion, the measure cohort does not include gestational diabetes or secondary causes of diabetes and incorporates type of diabetes diagnoses in risk adjustment.

Measure Outcome

<u>CORE Presentation to the Committee on Measure Outcome Overview and EMS Protocols for Hypoglycemia</u>

- CORE provided an overview of the proposed definitions of the two outcomes from Meeting 1. The measure is split into two outcomes and two risk models for:
    - Hyperglycemia (diabetic ketoacidosis [DKA], hyperosmolar hyperglycemic state, or uncontrolled diabetes)
    - Hypoglycemia
- CORE reviewed the feedback from the Clinician Committee and Technical Expert Panel regarding the outcome and how it was incorporated into the measure.
    - The primary concerns raised in both groups were missing events outside of the ED or hospital setting and outcomes secondary to comorbid conditions.
    - CORE incorporated Clinician Committee and TEP feedback by:
        - Exploring variation in EMS protocols for hypoglycemia;
        - Examining the use of primary/principal vs. secondary codes for hypoglycemia; and
        - Considering additional exclusions for both outcomes such as a 10-day buffer period post-hospitalization and outcomes prior to the first visit with the attributed provider.
- CORE reviewed research on EMS protocols for hypoglycemia.
    - Some protocols specify non-transport as an option for patients with hypoglycemia under some circumstances and some do not specify non-transport as an option.
    - One member asked if the states not highlighted in the materials had missing data.
        - CORE clarified that data is available for these states, and that the team did not look at their protocols at this time. There is a large variation in

rates regionally. CORE plans to examine these rates further with future risk-adjusted data.

- CORE noted that the protocols are difficult to categorize because the language is not always clear or present surrounding transport versus non-transport.

- CORE asked the Clinician Committee if they had any recommendations about how to further explore this issue in the future.

<u>Clinician Committee Feedback</u>

Broader Hypoglycemia Outcome Definition

- Two members raised concerns about the measure concept.
  - One member noted the importance of capturing moderate hypoglycemia, which causes a lot of symptoms but does not usually result in patients going to the hospital. The member added that this is difficult to capture without using continuous glucose monitoring (CGM) data. One stumbling block here is that Medicare does not cover CGM for patients unless they are checking blood sugars four times daily or more.
    - CORE agreed with this comment and noted self-reported/milder forms of hypoglycemia increase the chance of ending up in the ED with more severe cases. The hope is that this measure will provide the signal of troublesome hypoglycemia, despite not being able to capture the full spectrum of events.
    - The member responded that the signal being developed is not perfect and that this may be problematic.
  - One member noted that CMS may be interested a measure based on administrative data because it had difficulty extracting data from records. The member noted the impact of CGM data in the field of hypoglycemia and suggested revisiting the goal of this measure while keeping the affected patients in mind. The way to accomplish the improvement in quality of care through measures might be very different from just assigning attribution to those who are responsible for the care of patients who experience events.
    - CORE responded that the goal of this discussion is not to revisit the concept of the measure. CORE will review missing data from EMS records. This measure is not perfect but is meant to provide signal, direction, and attention to a neglected adverse event. As measure development proceeds and gains access to better data on hypoglycemia, CORE can improve and broaden the outcome to include self-reported events.
  - One member noted hypoglycemia was chosen based on patient stakeholder input. They suggested that CORE should call for future changes for future measures. Their biggest concern is the cost of CGM and the resulting inability to get the data required to build these measures.

- CORE noted the importance of continuing this discussion to obtain more feedback.
    - CMS agreed and responded that they would like to get feedback from the group in terms of the hypoglycemia concept. They added that what is accessible sometimes drives how the measure is developed. CMS agreed that these concepts are great, and while this feedback is useful, they do not have access to these data.

Variation in Emergency Medical Services (EMS) Protocols for Hypoglycemia

- One member thought that it is reasonable to risk adjust if you have the EMS protocol data but asked how to risk adjust if there are missing data for the rest of the country.
    - CORE responded the data are not missing, rather the team has not looked at all the EMS protocols because they are constantly changing.
        - The member suggested incorporating the reevaluation of change in EMS protocols in the annual review and update of MIPS measures.
- One member asked if the mortality data for states with non-transport is available, specifically, to determine if there is a long-range difference between non-transport and transport states.
    - CORE responded they have not looked at this in the United States. In other countries, data suggests that non-transport should be an option. At the state level, this measure could provide incentive to revisit protocols and see if a non-transport option makes sense. However, MIPS program clinicians have less leverage in terms of changing EMS protocols.
- One member suggested consulting the literature regarding similar phenomenon in syncope or stroke and EMS protocol to help gain more context into the underlying reasons for variation. They asked if the variation could somehow be risk adjusted for at the end.
- One member asked if EMS-level data are available through CMS.
    - CORE noted we have claims/charges data for patients who are transported but no data for patients who are not transported.
        - The member expressed concern over the delay in submitted claims and thus calculating results based on claims made two to three years ago. This further compounds the challenges of risk-adjustment for EMS protocols.
- Three members noted there are many other factors that influence the underlying variation in EMS transport versus non-transport.
    - One member provided the example of non-medical factors that influence transport such as if someone is with the patient at the time of EMS arrival.
    - One member suggested CORE not focus too much on EMS protocol because it is one of many sources of variation that need to be accounted for.

- One member worked closely with EMS groups at the county level and noted there are factors that can cause disputes for payment such as city council funding and changes in leadership. They raised concern that these confounding variables will undermine the analysis.

CORE Presentation to the Clinician Committee on Primary/Principal vs. Secondary Codes

- CORE reviewed the codes for hyperglycemia and hypoglycemia.
  - Based on previous feedback from stakeholders on the hyperglycemia outcome CORE decided to:
    - Use outcome only when coded as primary/principal discharge diagnosis;
    - Make updates to include outcome codes associated with secondary diabetes; and
    - Use uncontrolled diabetes outcome as the principal discharge diagnosis from hospital stay to eliminate cases of hyperglycemia secondary to other causes.
  - Based on previous feedback from stakeholders on the hypoglycemia outcome, CORE examined the associated primary/principal diagnosis codes when hypoglycemia is coded in any position (either primary or secondary). Using these findings, CORE proposed the following outcome definitions:
    - For admissions and observation stays, use hypoglycemia codes in the principal position, and
    - For ED visits, use hypoglycemia codes in any position when combined with symptom codes (780.xx).

Clinician Committee Feedback

Specific Outcome Definitions

- Two members noted that for the hyperglycemia outcome, ICD-9 codes specify diabetes without complications, but diabetes with complications should be included when also associated with hyperglycemia. Other members noted that codes should be validated through chart review or other methods. Another member noted that clinicians may not code accurately and that there may be geographic variation in coding practices or even accuracy.
  - CORE responded that when a patient is admitted with diabetes and something else (for example, nephropathy), it is not clear from ICD-9 codes whether diabetes is the reason for admission or if it is the other condition (nephropathy). For this reason, it is cleanest to use diabetes that is uncomplicated with hyperglycemia as an outcome here. However, CORE will reexamine these codes both in ICD-9 and ICD-10 to ensure complete capture of the outcome.
  - CORE noted that other researchers have performed chart reviews using the Ginde algorithm for validation and the algorithm was pretty good at identifying hypoglycemia, but not perfect. CORE acknowledged the limitations of claims data;

however, a strength of hospital-based data is that the payment is derived from what is coded so these data are audited.

CORE Presentation to the Clinician Committee on Additional Outcome Exclusions

- CORE reviewed additional outcome exclusions including:
    - Exclusion of outcomes within 10 days after discharge from three inpatient facilities: hospitals, SNFs, or acute rehabilitation facilities (10-day "buffer" period).
    - Exclusion of outcomes occurring prior to first visit with attributed clinician.
- CORE reviewed the revised outcome definitions for hyperglycemia and hypoglycemia for input (slide 47).
- CORE asked the Clinician Committee to provide feedback on two questions:
    - What feedback or questions do you have about the 10-day buffer period?
    - What concerns do you have with the proposed hyperglycemia and hypoglycemia outcome definitions?

Clinician Committee Feedback

Specific Outcome Definitions

- Eight members supported the proposed outcome definitions and exclusions and noted they are reasonable compromises; some members provided exceptions or caveats to their support.
    - One member noted the caveat of including complicated diabetes and uncontrolled ICD-9 codes.
    - One member noted if a patient comes in with these outcomes and is assigned to them at their critical access hospital, they send them to a higher-level facility before then are generally sent back to the PCP. They expressed concern with who is held responsible for these outcomes.
    - One member noted they would put an asterisk next to the 780.xx symptom group because it has not yet been studied.
    - One member felt the definitions are appropriate, but wanted to ensure that the outcome did not include DKA occurring in the hospital, which is already a quality measure.
    - Two members flagged the potential changes that may occur to coding practices.
    - One member noted the inclusion of secondary codes for hypoglycemia may change coding practices when implemented as a quality metric, specifically when it comes to hypoglycemia versus altered mental status.
    - One member noted people can quickly learn how to game the coding of these quality metrics, however the proposed definitions will prevent much of that.

Outcome Exclusions

- Member feedback on the 10-day buffer period was mixed.
    - Three members commented that the 10-day buffer period is too short.
        - One member agreed with excluding outcomes occurring immediately after hospital discharge, but asked why a 10-day buffer period was selected and noted that a 10-day period is too short to transition care to a PCP or to follow-up with the attributed physician.
            - CORE responded they are currently developing a suite of MIPS measures. This outcome exclusion was first considered when developing the Multiple Chronic Conditions (MCC) measure, which includes diabetes in the cohort. When looking at the hospitalization rate, 10 days was a compromise; it is open for input whether this time holds for the patients in the diabetes measure cohort.
        - One member asked for clarification of transitional care management with billing; they suggested CORE specify if it is in business or calendar days. If using calendar days, the 10-day buffer period is tight.
        - One member agreed that we want to incentivize quicker follow-up appointments but noted the 10-day buffer seems tight because there may be issues with patient access to care where there are no appointment slots available.
    - Four members supported the 10-day buffer period.
        - One member agreed that 10-day is reasonable and incentivizes practices to have care teams reach out. From rural perspective, where a patient must fly to the nearest city, there are potential breakdowns for care. The 10 business days is critical here rather than 10 calendar days.

<u>Summary of Outcome Definition Feedback</u>

- *Broader Hypoglycemia Outcome Definition:* Two clinician committee members discussed the importance of capturing less severe hypoglycemic events, for example, by using data from a continuous glucose monitor. They were concerned that the current measure outcome based on administrative data was too narrow, and suggested that CMS consider a broader outcome of hypoglycemia in the future. CMS expressed interest in gaining more feedback from the committee on obtaining more data to better measure hypoglycemia in the future.
- *Variation in Emergency Medical Services (EMS) Protocols for Hypoglycemia:* Three members noted there are many other factors, aside from EMS protocols, that influence the underlying variation in EMS transport versus non-transport for hypoglycemia. Some members recommended adjustment for the type of EMS protocol by county/state but other stated challenges associated with adjustment.

- *Specific Outcome Definitions:* Eight members supported the proposed outcome definitions and exclusions and noted they are reasonable compromises given the data limitations; some members provided exceptions or caveats to their support.
- *Outcome Exclusions*: Member feedback on the 10-day buffer period was mixed. Four members supported the 10-day buffer period although they raised questions whether the 10-day buffer period should include business, as opposed to calendar, days. Three members commented that the 10-day buffer period is too short.

Attribution

CORE Presentation to the Clinician Committee

- CORE reviewed the process for selecting and designing the attribution approach. Criteria included:
    - Attribution models should be fair and accurate;
    - Align with stated goals and purpose of the measure; and
    - Be transparent.
- CORE reviewed the MIPS program and the updated list of MIPS-eligible clinicians for the 2019 performance period.
- CORE reviewed the work to date on determining which clinician is responsible for the outcome.
    - CORE selected primary care providers and endocrinologists as eligible providers for attribution.
    - To determine if nurse practitioners (NPs), clinical nurse specialists, and physician assistants (PAs) are involved in diabetes care, CORE evaluated practice patterns for each group.
- CORE reviewed the results of analyses to determine who is seeing patients with diabetes using the expanded PCP definition to include both physicians and non-physician clinicians. Results are summarized as follows:
    - 89% of patients see only PCP;
    - 9-10% of patients see PCP and endocrinologist; and
    - 1-2% of patients see endocrinologist only.
- CORE presented the three attribution model options:
    1. Multiple provider attribution (assign to endocrinologist and PCP if seeing both).
    2. Single provider attribution, majority of visits (favor endocrinologist over PCP based on number of visits).
    3. Single provider attribution, ≥2 endocrinologist visits (favor endocrinologist over PCP based on ≥ 2 visits with endocrinologist).
- CORE presented the analyses using Part D data to determine diabetes medication prescription by the assigned TIN provider. CORE used Part D data for all patients who

had at least one diabetes medication filled by their assigned provider. Analyses captured 75% of patients with diabetes in the cohort. Most patients were assigned to physician PCPs.

- CORE asked Clinician Committee members to respond with which of the three attribution options they preferred and to share any concerns about attribution.

Clinician Committee Feedback

Non-Physician Clinicians

- Members had varying opinions on whether non-physician and non-clinical providers should be included in the attribution model.
    - Three members discussed diabetes educators.
        - One member asked if certified diabetes educators are included in the clinical nurse specialist category or as a potential MIPS provider. They noted many of the MIPS providers can be certified diabetes educators. PCPs and endocrinologists frequently order diabetes education that is reimbursed at the payer level and is sometimes implemented by certified nurse specialists. They also added that there is data to support having a diabetes educator reduces hyperglycemic events.
            - CORE responded it depends on what category they start as. For example, a nurse may also be certified as a diabetes educator. CORE noted that it is important to consider whether the hyperglycemia and hypoglycemia outcomes of this measure reflect the quality of care provided by the educator or by the endocrinologist or clinician supervising the overall care.
        - One member noted the importance of educators in their practice.
        - One member noted given the variety of factors a practice can influence when it comes to these outcomes, the attributable physician should be someone who has the influence in the practice. For example, food insecurity leads to more admissions for hypoglycemia particularly toward the end of the month if they receive supplemental nutrition assistance. If a person can try to provide support for low income patients to connect them with services, they have more of an influence on the factor that leads to the development of hypoglycemia. They would not expect diabetes educators to have that type of influence in the practice.
    - Six members commented on the definition and care process for non-physician PCPs.
        - One member asked if clinical nurse specialists can prescribe medication. They noted pharmacists are not currently considered MIPS-eligible providers.
        - One member noted the importance of defining who is included under clinical nurse specialist. They added their practice has a program called

"Diabetes Pathway" for uncontrolled diabetics which is staffed by diabetes educators but signed off by an NP, endocrinologist, or other specialist. In this case, the educator should not be attributed.

- CORE noted providers are defined using Medicare specialty codes. There are codes that identify providers and are available in administrative claims data.

- One member asked if non-physician clinicians who are not PCPs would be lumped in with endocrinologists. For example, a PA that works solely in an endocrine office with diabetes patients.
    - CORE responded based on these categories, it is not possible to distinguish if such a provider is working with endocrinology, cardiology, nephrology, or is a PCP. Although it is possible these providers can be practicing in a specialty practice (endocrine), it is assumed that most non-physician clinicians will be practicing as PCPs.
- One member noted most of the NPs and PAs they have in their system practice in specialty offices rather than primary care.
- One member did not think clinical nurse specialists should be attributed to because they are not truly acting as PCPs.
- One member expressed concern that the number of non-physician providers seems low and asked if these are appointments billed as "incident to," which hides the work a PA or NP does under the MD identification code.

Attribution Approach

- Two members raised the differences between the group and individual levels of attribution.
    - One member asked what the implications are of rolling the attribution up to the group level if you have physicians and NPs in the same group.
        - CORE noted if a patient is assigned to the NP, assignment would go up to the TIN level and the patient will be assigned to that group. CORE also noted that the algorithms are based on single provider and their National Provider Identifier. If CMS decides to use TINs, attribution will roll that provider up to the TIN-level rather than going backwards.

Attribution to an Endocrinologist

- Eight members commented on the differing reasons for a patient visit with an endocrinologist.
    - One member noted their practice is very subspecialized and it would be inappropriate to assume that an endocrinologist seeing a patient for a pituitary diagnosis who also has uncontrolled diabetes should take ownership of diabetes care. The member suggested that CORE look at the visit plus the visit diagnosis.

- One member provided the example of a patient with a diabetes diagnosis that is being overseen by their PCP and asked how they would be attributed if they are seeing an endocrinologist for hyperparathyroidism. Another member brought up an example of a patient who was seeing an endocrinologist twice a year for a thyroid nodule, but never billing for diabetes.
- One member stated that it would be important to collect data on how many patients seen in the endocrine practice have a secondary diagnosis of diabetes to understand the extent to which workflow would have to change to accommodate diabetes care.
- One member noted that quality measures improve care by changing physician behavior. The member felt that when patients come in for consultations for non-diabetes related endocrine disorders and their diabetes is neglected, it is doing them a disservice. They noted that it gives endocrinologists a license to ignore what is in front of them and that should not be allowed.
- One member expressed concern about providers opting out of the measure due to concerns over the fairness of the attribution. They stressed the importance of thinking ahead to how this measure can be used or misused so doctors and other providers are not running away from the measure because they think it is not fair.
    - CORE noted if an endocrinologist has frequent contact with the patient and the patient has diabetes, the endocrinologist has expertise in treating metabolic disorders. If there is a problem with the diabetes, the endocrinologist should intervene before the patient ends up hospitalized with a diabetic emergency. It is correct that there are patients with endocrine disorders whose diabetes care is directed by a PCP; however, if those patients are not doing well, the proposed measure would incentivize the endocrinologist to intervene. If the specific endocrinologist is sub-specialized and does not treat diabetes, they could and should refer the patient to someone who has the expertise to address their diabetes.

Specific Attribution Options

- Six members favored option one. Rationale included:
    - One member noted that this option incentivizes collaboration across the medical community. The member also noted that prescribing data may not be accurate in identifying the clinician responsible for care as some PCPs prescribe all medications for convenience, even when the choice of medications is guided by an endocrinologist.
    - One member supported the team-based approach. The pharmacy field is currently trying to work toward this to incentivize accountability across multiple providers. The member favored incorporating some of the medication use in attribution.

    - One member noted that a multidisciplinary team approach is key in diabetes care. Evaluating the care of one provider alone will not be fully accurate for many reasons. For instance, endocrinologists are a limited workforce, so less endocrinology visits in rural areas is expected. Similarly, in urban areas it's expected to have less PCP involvement.
- One member favored option two. Rationale included:
    - One member noted that endocrinologists may be managing endocrine disorders other than diabetes so the option which is simply based on two or more visits with an endocrinologist would make endocrinologists accountable for managing a condition which they may not even be coding for. The member noted that many patients in endocrine clinics may have a diagnosis of diabetes and would therefore be assigned to endocrinologists.
- Six members favored option three. Rationale included:
    - Members noted that endocrinologists should step in to intervene when diabetes was uncontrolled or the patient was at risk for hypoglycemia, even when the primary reason for a visit with an endocrinologist was not diabetes. The option does not assign patients to an endocrinologist when they only have one visit in a year while seeing a PCP every two months, which seemed appropriate. In addition, the option does not count simply one-time consults with endocrinology, i.e., patients who do not return to see the specialist.

Additional Feedback on Attribution

- Three members supported multiple options depending on whether shared or single provider attribution was selected.
    - Two members who favored option one said they supported option three over option two, if single attribution was chosen. In option two, sicker patients who come in to see their PCP more often will always get assigned to PCP even if they see their endocrinologist frequently, which is not appropriate.
    - One member favored single-provider attribution options (either option two or three). The member stated that there is a single clinician who is driving diabetes care for patients. The member also stated that the measure must be designed in the way that it is intended to be used: either for individual clinicians or for groups of clinicians. They noted that at the individual level, multiple providers would be held accountable only if they both chose to report the measure.
- Members had varying opinions on attributing to the prescribing provider. Some favored using prescribing data, including the last prescription written for diabetes medication. However, other members noted that prescribing data may not accurately identify the clinician driving care. In many settings, the PCP will prescribe medications even if the specialist is guiding which medications should be used.
- Two members raised concern over using data from previous years. One member noted that patients may spend part of their time in their community and part of their time elsewhere. When people move, the attribution can be delayed and will stick to a

provider who saw the patient three years ago. One member noted that treatment of diabetes has changed over the last few years and there really should not be any hypoglycemia in type 2 diabetes when newer medications are prescribed. Therefore, the measure should not punish a provider who is doing everything correctly in terms of care, but the patient can't afford the medication due to their prescription drug coverage. This member felt that they understood the need to use past information for development, but do not think developing measures based on old information is a good idea.

Summary of Feedback

- *Non-physician clinicians:* Members had varying opinions on whether non-physician and non-clinical providers should be included in the attribution model. Three members discussed diabetes educators and the importance of non-physicians in caring for patients with diabetes. Five members commented on the definition and care process for non-physician PCPs.
- *Attribution to an endocrinologist*: Eight members discussed the varying subspecialties of endocrinology and whether an endocrinologist should be held responsible for diabetes care regardless of the primary reason for the patient visit. One member was concerned that attribution to endocrinologist based on the number of visits (regardless of reasons for visits) may change the work-flow and place burden on endocrinologists.
- *Specific attribution options*: Six members favored option one (multiple provider attribution), one member favored option two (single provider attribution, majority of visits), and six members favored option three (single provider attribution, ≥2 endocrinologist visits). Two members who favored option one preferred option three to option two, if single attribution was being considered.
- *Additional feedback*: Three members supported multiple options depending on whether shared or single provider attribution was selected. Members also had varying opinions on attributing to the prescribing provider. Two members raised concern over using data from previous years.

Risk Adjustment

CORE presentation to the Clinician Committee

- CORE reviewed the goals of risk adjustment for:
    - Clinical factors;
    - Demographics;
    - Functional status/frailty; and
    - Health behavior/health choices.
- CORE reiterated the goal to adjust for patient mix, but not for the overall quality of care.
- CORE reviewed the conceptual framework for MIPS short-term diabetes complications measure risk adjustment.

    - Risk variables are assessed in the year prior to measurement.
    - Two separate risk-adjustment models will be designed; one for hyper- and one for hypoglycemia, respectively.
- CORE reviewed the list of candidate risk factors. These include demographic, clinical, frailty risk factors, and other potential clinical risk factors.
- CORE presented other potential clinical risk factors such as type of medication prescribed, adherence to medications, self-monitoring blood glucose levels, use of continuous glucose monitoring (CGM), HbA1c level, and adherence to screening for retinopathy. However, CORE noted that these factors should not be adjusted for because they are related to the quality of care that is being measured.
- CORE reviewed the approach to social risk factors (SRFs) through risk adjustment when a provider has a reasonable ability to mitigate risk. They noted risk adjustment is not the only method of accounting for SRFs. The five available SRFs for evaluation include:
    - Medicare/Medicaid dual-eligibility status;
    - Agency for Healthcare Research and Quality Socioeconomic Status (AHRQ SES) Index;
    - Rural residence;
    - Density of PCPs; and
    - Density of specialists.
- CORE asked the Clinician Committee to provide feedback on:
    - The candidate clinical risk factors; specifically, if any clinical factors are missing and what clinical factors (if any) should not be adjusted for;
    - Whether they agree with the conceptual model and approach to risk adjustment for the measures; and
    - Any questions, suggestions, or concerns they have.

<u>Clinician Committee Feedback</u>

Approach to Risk Adjustment

- Overall, members agreed with the conceptual model and approach to risk adjustment.
    - One member supported accounting for SRFs using claims and publicly available data sources. They noted there are a lot of factors that affect diabetes outcomes but felt that the presented set is good based on what can be captured.
    - Two members did not think adjusting for SRFs in this way disincentivizes care for at risk populations. Practices that go out of their way to provide better care will perform better on these indices regardless of whether they are risk adjusted or not.
    - One member noted SRFs are a broad category and CORE is doing a very thorough job trying to capture them.
    - One member supported the list and thinks SES index should be weighted.

Candidate Clinical Risk Factors for Adjustment

- Members provided additional risk factor variables for adjustment, including history of a gastric bypass procedure, diabetic foot ulcers, stages of kidney disease, individual components of the diabetes complications severity index, measures of literacy, numeracy, and food insecurity.
    - Some members favored including A1C in the list of risk factors, but others did not.
    - One member asked for the methodology used to form the candidate risk variable list.
        - CORE responded this list is comprised of the groupings used by CMS; risk factors were compiled based on the review of literature, clinical expert input, and risk factors used in other utilization-based quality measures for patients with diabetes. Each row of variables includes a multitude of codes. For established diabetes complications, outcomes take a long time to accrue and would be difficult to not include and/or attribute to the current provider.
    - One member noted there is a claims-based frailty measure developed by Cynthia Boyd.
        - CORE responded that they have used these clinical groupings recently, including for some of the other MIPS measure work developed by CORE. Frailty has come up as an important set of variables for risk adjustment. CORE has used Durable Medical Equipment (DME) data to better predict the patient's risk profile. This is based on literature and empirical review.
    - One member asked about using the combined diabetes severity index versus individual components.
        - CORE noted we have not yet built these models, so CORE can consider both.
    - Members suggested additional risk factors for inclusion in the risk model, including:
        - Gastric bypass procedures because this procedure greatly increases the risk of hypoglycemia;
        - Lack of access and cost of medication because this affects transportation, and ability to come to appointments, medication choices, and adherence;
        - Density of pharmacies to account for pharmacy deserts that affect access;
        - Time on each hypoglycemic medication (30 days vs 2 years);
        - Diabetic foot ulcers, specifically separate from diabetic neuropathy;
        - Patient literacy, numeracy, and food security;

        - Advanced stage of kidney disease, for example, end stage renal disease and CKD stage 5;
        - Diabetes complications severity index (which has a weighted system for some codes) to determine the weighting of risk factors. One member noted grouping neuropathy together would be less helpful than grouping by severity or length of diabetes; and
        - Movement and coordination disorders, including arthritis and visual impairment, which may alter capacity to manage diabetes and increase treatment errors.
    - Members did not reach consensus regarding whether A1C should be included in the list of risk factors.
        - One member supported including A1C because the measure should factor in achievement of good glycemic control with lower risk of hypoglycemia.
        - Two members did not support including A1C because it is associated with physician behavior and aspects of quality.
    - Members had varied feedback on including adherence to medication.
        - One member noted as care gets more complex and more medications are added, it becomes a cost issue and will affect adherence and the outcome.
        - One member added there is a diagnosis code for non-adherence but it is socially constructed and subject to bias on the clinician's part, and is therefore an imperfect measure in the claims data.

Social Risk Factors

- Seven members provided suggestions for accounting for social risk factors.
    - One member noted that some risk factors tend to be more amplified in urban areas and others in rural areas.
    - One member noted it would be interesting to consider the distribution of PCPs and specialists in suburban/urban/rural areas because groups at social risk may not be taken care of well.
    - Two members noted the outcome rate depends on the ability of patients to have access to medication. The outcome can be considered an adverse drug event related to medication or an adverse drug event related to not getting medication. Medications that are not associated with hypoglycemia are more costly. Therefore, density of pharmacies or other measures of access play an important role.
    - Three members suggested adding drug coverage in addition to dual eligibility to the list of risk factors to capture patients who fall through the "donut hole" of coverage for a three-month period.

        - One member raised that there are states that have not expanded Medicaid which will affect dual-eligibility.
        - One member added Medicare Part D limited-income subsidy may be another good proxy to look at income and wealth and suggested looking at dual-eligibility across states.
- Seven members raised concerns about accounting for SRFs.
    - Two members noted that if the measure accounts for mix of patients in terms of SRFs including race, it may unintentionally mask poor care.
    - One member stressed the importance of not incentivizing providers to preferentially "cherry-pick" their patients for lower social risk.
    - One member added that SRFs may not be entirely out of control of the provider. For example, for low income and food insecurity there are practices around the country that are doing things for patients with diabetes such as food pharmacies or referring patients who screen to have food insecurity to social workers to get connected with services. Adjusting for these issues sends the message that these are not things clinicians need to address.
        - CORE noted a similar concern was raised in the MIPS heart failure measure meeting. We want to recognize this initiative and incentivize the right care.
    - Two members urged the careful consideration of unintended consequences, such as being okay with poor quality care for certain populations.
    - One member noted risk factor stratification doesn't weigh the scoring but allows for comparison to people with a similar profile.
        - CORE responded this is correct but the measure could be readjusted for demographics and clinician variables and CMS can report stratified measure scores by social risk factors.
- CORE noted the MCC measure will be posted for public comment soon. CMS is not recommending adjusting for AHRQ SES index and density of specialists; however, CMS is taking comment on whether to adjust or not for dual eligibility status.

<u>Summary of Feedback</u>

- *Approach to risk adjustment*: Overall, members agreed with the conceptual model and approach to risk adjustment.
- *Candidate clinical risk factors for adjustment:* Members provided additional risk factor variables for adjustment, including history of a gastric bypass procedure, diabetic foot ulcers, stages of kidney disease, individual components of the diabetes complications severity index, measures of literacy, numeracy, and food insecurity. Some members favored including A1C in the list of risk factors, but others did not.
- *Social risk factors*: Four members suggested accounting for lack of access and cost of medication. Three members suggested adding drug coverage and dual eligibility to the

list to capture patients who fall through the "donut hole" of coverage for a three-month period.

Other Considerations

Clinician Committee Feedback

- Multiple members raised the issue of patients in hospice and palliative care – stating that they should not be included in the cohort for the measure.
    - One member suggested excluding these patients because we do not want to hold clinicians accountable for outcomes that occur when a patient is in the very end stages of life. These patients typically should not go to the hospital anyways.
    - One member noted the importance of stopping aggressive monitoring and medication management when someone is reaching the end stages of life. Patients who are high on the frailty index should not have medications pushed on them.

Summary of Feedback

- Multiple members raised the issue of patients in hospice and palliative care – stating that they should not be included in the cohort for the measure.

Wrap-Up

CORE Presentation to the Clinician Committee

- CORE asked members to comment on their experience on the Clinician Committee and provide any suggestions for improvement.
    - Overall, Clinician Committee members had positive experiences with the meeting and had some questions for the CORE team. Specific comments included:
        - One member asked to what extent the discussion will be contributing to this measure to be sure the comments are targeted to their optimal use.
        - Four members suggested having person and family engagement representatives involved in the meeting and conversation.
        - One member asked about the upcoming public comment period and if Clinician Committee members representing societies should separate themselves from their society when publicly commenting or if they should spearhead the comments from their society.
            - CORE responded the public comment will be posted on CMS's website and members can choose to submit a comment as an individual or as an organization.
- CORE thanked the Clinician Committee members for their valuable feedback and reviewed the next steps:
    - To distribute a summary of the meeting.

    - Hold a specific time to talk about visionary/data collection.
    - A tentative webinar after measure testing and public comment.
- CORE invited Clinician Committee members to reach out via email with any additional input. CORE will keep members updated on measure development via email in the coming months.

Appendix A. CORE Measure Development Team

Table A1. Center for Outcomes Research and Evaluation (CORE) team members for MIPS short-term diabetes complications measure development

Name	Team Role
Faseeha K. Altaf, MPH	Project Co-Lead
Kasia J. Lipska, MD, MHS	Project Co-Lead
Mariana L. Henry, MPH	Project Coordinator
Craig S. Parzynski, MS	Lead Statistical Analyst
Haikun Bao, PhD	Senior Statistical Analyst
Zhenqiu Lin, PhD	Analytic Director
Julia McMahon, BS	Research Assistant
Jeph Herrin, PhD	Statistical Consultant
Megan LoDolce, MA	Project Manager
Harlan M. Krumholz, MD, SM	Principal Investigator
Elizabeth E. Drye, MD, SM	Project Director

Appendix B. Clinician Committee Meeting Schedule

Clinician Committee feedback on CORE's approach to measure development will inform the MIPS short-term diabetes complication measure specifications. CORE will engage and seek input from the Clinician Committee as they develop the measure through email communication and at least three meetings:

1. **Clinician Committee Meeting 1:** Monday, December 10, 2018; 6:00 PM – 7:30 EST (Location: teleconference/webinar).
2. **Clinician Committee Meeting 2:** February 28, 2019 (Location: in-person in Baltimore/Washington D.C. area).
3. **Clinician Committee Meeting 3:** May 2019 (Location: teleconference/webinar).
4. Additional meetings to be determined.