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Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave SW
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]

Dear Acting Administrator Slavitt:

On behalf of the American Association of Diabetes Educators (AADE), thank you for the opportunity to submit comments to the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2017 (CMS-1654-P) on two significant policy areas of key interest to diabetes educators: 1) the proposed changes to Diabetes Self-Management Training (DSMT) included in Sec. II-F, and 2) the proposed expansion of the Diabetes Prevention Program for Medicare beneficiaries (MDPP) included in Sec. III-J.

AADE is a multi-disciplinary association of healthcare professionals dedicated to integrating self-management as a key outcome in the care of people with diabetes and related chronic conditions. AADE is also one of two National Accredited Organizations (NAO) which has been approved by the Centers for Medicare & Medicaid Services (CMS) to certify DSMT programs for Medicare, and is one of six organizations under a cooperative agreement with the Centers for Disease Control and Prevention (CDC) to scale and sustain the National Diabetes Prevention Program (National DPP). This makes AADE uniquely qualified to comment on both these areas.

The below summarizes our key issues of interest on DSMT (Sec. II-F of the PFS) and MDPP (Sec. II-J of the PFS) with specific comments on each issue following this list:

DSMT:

1. Eliminate beneficiary out of pocket expenses, such as the copayment and deductible for DSMT.
2. Increase Medicare payment for G0108 and G0109.
3. Allow eligibility for additional DSMT hours when change in medical condition warrants additional education, i.e. similar to the Medical Nutrition Therapy (MNT) benefit.
4. Adhere to ADA and American Association of Clinical Endocrinologists (AACE) guidelines and include A1C as one of the criteria for the diagnosis of diabetes.
5. Allow hospital-accredited DSMT programs to provide DSMT in off-site locations more convenient to beneficiaries.
6. Allow for self-referral or expand providers that can refer for DSMT.

MDPP:

1. Increase the number of high-quality MDPP suppliers.
2. Modify the MDPP reimbursement structure.
3. Ensure quality program delivery and staffing requirement considerations.
4. Increase outreach to potential and current DPP participants with diagnosed diabetes.
5. Modify MDPP session duration guidance.

AADE would like to applaud and thank CMS for the opportunity to share valuable information about the barriers to access and the underutilization of the DSMT benefit and comment on the proposed expansion of the National DPP.

General Comments Regarding DSMT:

Despite the demonstrated value of patient education programs improving outcomes, diabetes education programs continue to close at an alarming rate and patients continue to experience significant barriers to accessing DSMT. Since 2014, AADE is aware of the closing of 219 out of 750 programs accredited by AADE. These programs reported closing for various reasons, including:

- Hospital Outpatient Departments have reported that despite improved clinical outcomes, the hospital administration does not feel reimbursement rates are adequate to sustain their program, especially with the additional barrier of site restrictions.
- Pharmacies report having difficulty with the Medicare Part B applications due to the complexity and lack of understanding from some of the regional Medicare Administrator Contractors. Often it takes an additional 6 months to a year to receive approval from Medicare to bill after they receive accreditation/recognition. Pharmacies have also been told they are not a recognized provider of DSMT and have never received the ability to bill.

In 2015, AADE surveyed its programs and the results showed the top barrier to maintaining accreditation/recognition was lack of reimbursement (29%).

AADE applauds CMS's ongoing commitment to ensuring the availability of high quality diabetes education programs and appreciated CMS's request for feedback on ways to remove barriers and improve the sustainability of those programs. AADE would also like to inform CMS that the *National Standards for Diabetes Self-Management Education and Support* are due to be reviewed and revised for a late 2017 release. The timing of this revision is optimal given CMS's acknowledgement of the underutilization of this benefit. AADE and the American Diabetes Association (ADA) have developed a workgroup to begin the process and have invited representatives from the CMS quality and standards division to attend.

AADE is submitting comments as part of the formal comment period, but due to the importance of this issue, AADE would also like to request a face-to-face meeting with CMS to further discuss our comments.

The below summarizes our key issues of interest on DSMT (Sec. II-F of the PFS):

1. Eliminate Medicare beneficiary out-of-pocket expenses, such as the copayment and deductible for DSMT

AADE requests that CMS designate DSMT as an "*additional preventive service*." Just as CMS noted with proposed coverage for diabetes prevention, DSMT is also "*consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries*." Medicare has the authority to waive certain requirements and AADE believes that DSMT would meet the requirements of section 1861(ddd)(1)(A) of the Act because DSMT is specifically designed to prevent diabetes complications and advancement of the disease.

Data pulled from AADE Diabetes Education Accreditation Programs (DEAP) showed a reduction in A1Cs of 1.2% on average, from over 500 programs in the DEAP 2015 annual status reports. This reduction is clinically significant and supports a reduction in risk for developing complications. Specifically noted in a study by the Harvard Law School in 2015, a *1% reduction in mean A1C levels has been found to be associated with risk reductions of: 21% for death related to diabetes, 14% for myocardial infarction, and 37% for microvascular complications.*

In addition, AADE surveyed all DEAP programs in 2015, and the programs reported the biggest barrier to continue service was reimbursement. As stated above, 29% of DEAP programs listed this as the number one barrier to patient access. In addition, the Harvard Law School study found similar results stating "many patients, educators and providers report that coverage and costs of DSME services are preventing access to care."

Specifically, AADE recommends the following modifications to the existing DSMT coverage:

- Eliminate the copayment of 20%.
- Eliminate the requirement to meet the Medicare deductible.

2. Medicare payment for G0108 and G0109 must be increased in order to maintain viability of DSMT programs

- Medicare payment for G0109 has decreased 23% from $18.69 in 2011 to $14.32 in 2016
- Correlating with decreased reimbursement, Medicare claims data show that G0109 also had a 23% decrease in utilization. G0109 had $136,103 in claims in 2011, and with the latest available data being 2014 – it had decreased to $105,116.
- 219 AADE-accredited programs have closed in just the past two years.

In order to get a better understanding of the costs to operate a DSMT program, AADE recommends that CMS conduct a cost analysis study with current accredited/recognized DSMT programs. For example, Medicare allows up to 20 people per group however the average group size based on 2015 program data indicates nearly 45% of programs do not have a group larger than 5 people. At current rates of reimbursement, it would be hard to sustain a program with the small group sizes programs are experiencing. AADE would be happy to meet with CMS to discuss the structure of a survey and the information needed to calculate a more accurate payment.

3. DSMT should follow MNT coverage guidelines and allow beneficiaries to be eligible for additional hours of DSMT when a change in medical condition warrants it

AADE believes a beneficiary should not lose their initial 10 hours of DSMT if it is not completed within the first 12 months after referral. Currently, the MNT benefit allows for additional hours for a change in medical condition, treatment and/or diagnosis.

CMS should also consider allowing additional hours of DSMT during the four critical times defined in the recently published *Joint Position Statement on DSMT in Type 2 Diabetes* including an algorithm of care, published by AADE, ADA and the Academy of Nutrition and Dietetics (AND). This DSMT algorithm provides an evidence-based visual depiction of when to assess, provide and adjust DSMT in individuals with type 2 diabetes:

1. New diagnosis of type 2 diabetes.
2. Annually for health maintenance and prevention of complications.
3. When new complicating factors influence self-management.
4. When transitions in care occur.

People with diabetes have continuous need for DSMT as their life and lifestyle changes and as their disease progresses. In particular, at these four critical times, people with diabetes require assessment and, if needed, intensified and/or additional education and self-management planning and support.

4. CMS should adhere to ADA and AACE guidelines that A1C be used as one of the criteria for diagnosing diabetes

The DSMT benefit statute now states that to be eligible for the benefit, a beneficiary with type 1 or type 2 diabetes must have a diagnosis of diabetes, which is defined by CMS through one of the following lab tests:

1. Fasting plasma glucose (FPG) ≥126 mg/dl on two different occasions,
2. 2-hour oral glucose tolerance test (OGTT) ≥200 mg/dl on two different occasions, or
3. A random glucose test ≥200 mg/dl for a person with symptoms of uncontrolled diabetes.

AADE has observed that these approved lab tests are often difficult to obtain from the referring provider, and therefore recommends that CMS expands the current set of approved lab tests to include the A1C test. In fact, the A1C test is actually more commonly used than the lab tests in the statute, and AADE has seen DSMT programs close despite receiving adequate referrals from qualified providers because those providers use the A1C test to diagnose diabetes. (AADE notes that it is pleased that CMS is now considering the A1C test to diagnose prediabetes).

In 2015, AADE published a systematic review of DSMT effects on glycemic control. This review included 118 unique interventions, with 61.9% reporting significant changes in A1C. In patients with persistently elevated glycemic values (A1C > 9), a greater proportion of studies reported a statistically significant reduction in A1C (83.9%). The report concluded that the robust data reviewed demonstrated that engagement in DSMT results in a statistically significant decrease in A1C levels. Results from DEAP programs stated above.

5. Hospital accredited DSMT programs should have the same ability to provide DSMT in off-site locations as physician offices

Restriction on the location of delivery of DSMT is a significant barrier to access. Hospital outpatient patient departments (HOPD) should be allowed to furnish its DSMT program at the same alternate, off-site payable places of services that CMS has approved for physician office DSMT and MNT benefit.

Many beneficiaries simply cannot get to a hospital-based facility due to transportation, work hours and general anxiety associated with the hospital setting. Hospitals that maintain traditional DSMT programs in their outpatient settings should be allowed to provide DSMT in the community and other convenient settings. As an NAO, AADE understands the landscape of DSMT programs and the types of sites where they take place. Currently 51% of all DEAP programs are located in an HOPD. AADE also knows that the ADA has a higher percentage of HOPD in their network of programs. This equates to more than 1,200 programs unable to reach out into the communities they serve. AADE is looking forward to further clarification on this rule. The hospital setting should not be treated any differently than physician office settings.

HOPDs should be allowed to furnish its DSMT program at the same alternate, off-site payable places of services that CMS has approved for its MNT benefit.

6. Self-Referral or expand providers that can refer for DSMT

AADE supports the CMS proposal to allow Medicare beneficiaries to self-refer for DPP. CMS has repeatedly acknowledged that DSMT remains grossly underutilized. Access to DSMT could be dramatically increased by allowing self-referral. There is a lot of confusion about DSMT and whether or not the beneficiary has received formal DMST through an accredited or recognized DSMT program. Treating providers simply are not aware that DSMT is available for their patients.

Only if self-referral is not an option, AADE requests at a minimum that CMS expand the list of providers who can refer Medicare beneficiaries for DSMT. Currently, only the "*treating provider managing the patient's diabetes*" can refer a patient for DSMT. AADE recommends expanding this to allow specialists that are treating a beneficiary's comorbidity (e.g., gangrene, vision loss) as well as physicians and qualified non-physicians treating the patient in the hospital or emergency room to be able to refer for DSMT.

CMS should also consider requiring formal DSMT for all beneficiaries with diabetes who are readmitted to the hospital with complications of diabetes and those who are frequently in emergency rooms. If CMS implements self-referral or expands the list of who can refer this requirement, it would be much easier.

Additional Considerations

Virtual means

Many programs are now exploring other means of providing DSMT to people with diabetes by leveraging digital technologies. AADE applauds CMS for its openness in the diabetes prevention benefit to allow coverage for nationally accredited virtual DPP programs.

Consistent with CMS's proposal to extend coverage for both virtual and in person DPP programs beginning in 2018, AADE requests that CMS solicit public feedback during the 2017 regulatory cycle on creating a coverage pathway, beginning in 2018, for virtual DSMT programs that are accredited by national organizations such as AADE and ADA. While AADE strongly supports the CMS proposal to provide coverage for both virtual and in person DPP programs to beneficiaries with prediabetes, we believe it is important for CMS to also create a similar range of coverage options for DSMT programs for Medicare beneficiaries who are already diagnosed with diabetes to help them self-manage their condition.

Expand providers who can bill for DSMT

Another consideration AADE would like CMS to consider as a means to increase utilization is to expand the providers who can bill for this service to include the very healthcare professionals who provide the service. These providers are clearly defined in the *National Standards for*

Diabetes Self-Management Education and Support, standard 5, instructions staff. This includes an RN, RD or pharmacist with training and experience pertinent to DSMT, or another professional with certification in diabetes care and education, such as a CDE or BC-ADM. There are also a couple of states that have implemented licensure for diabetes educators who would also have the same qualifications as noted in standard 5.

Comments Regarding the MDPP Portion:

AADE fully supports coverage of the National DPP for the Medicare population (MDPP).

As mentioned earlier, since 2012 AADE has joined the Centers for Disease Control (CDC) in a cooperative agreement to scale the number of accredited/recognized DSMT programs becoming CDC-recognized to implement the National DPP according to CDC's Diabetes Prevention and Recognition Program (DPRP) standards.

Based on expertise in the DSMT arena and experience and success within the National DPP, AADE asks CMS to consider the following:

1. **Increasing the number of high quality MDPP Suppliers**

   The AADE DPP Model of implementing the National DPP within accredited/recognized DSMT programs has proven to be extremely successful in the National DPP delivery. As of July 2016, 30 AADE accredited/ADA recognized DSMT programs achieved full DPRP recognition. This represents approximately 50% of all the CDC fully recognized DPRP programs. AADE's results demonstrate the efficacy of the AADE National DPP model by national accredited/recognized DSMT programs as assessed by the CDC's DPRP recognition standards, including >5% body weight loss on average among participants, over the course of 36 months. (Craver JM, Blum NM, O'Brian CA, Kolb LE and Lipman RD. Achievement of Weight Loss and other Diabetes Prevention and Recognition Program (DPRP) Requirements by a National Diabetes Prevention Program Network Using Nationally Certified Diabetes Self-Management Education Programs. *The Diabetes Educator 2016*, in press.)

   Based on the Centers for Medicare & Medicaid Innovations (CMMI) demonstration project with the Y-USA, CMMI concluded an estimated cost of the delivery of the National DPP per participant in a well-established, in-person delivery setting. CMMI also calculated an ROI to ensure that this program is not only cost effective, but also provides cost savings. The AADE DPP model has similar costs as the Y-USA delivery of DPP. AADE estimates an average cost of the program as between $370-$470 per participant. (AADE plans to publish cost effectiveness analysis data in 2017.) The CMMI demonstration does not, however, address the additional costs of requirements of an MDPP Supplier as well as the costs associated with scaling the program within a network. AADE is not recommending that CMS reimburse for overhead or administrative costs, but simply requesting that CMS consider the costs,

timing of payment and risks programs assume when implementing and maintaining a quality program. If additional program costs are not accounted for in some manner, it could inhibit the vast majority of potential MDPP Suppliers from being able to deliver the program to the Medicare population, thereby limiting access to eligible participants.

Specifically, AADE recommends adjusting the payment structure in the following manner in order to increase the number of programs able to become MDPP Suppliers:

- Proposed Rule payment structure is 50% outcomes based. This means that programs that start delivery of the MDPP must assume 50% of the risk in the infancy of their delivery of the MDPP when most of the costs are incurred. AADE recommends the payment structure proportion of risk be decreased to a maximum of 25% outcomes based in the first year, which would increase the number of programs able to assume the risk of becoming an MDPP supplier.
- Payment structure should be adjusted to be "*front loaded*" with the payment amounts at the beginning of the program increased to enable sites to cover the actual of costs of delivery. This will allow current accredited/recognized DSMT programs as well as other non-traditional Medicare providers to afford to become quality MDPP Suppliers. We recommend increasing the amount per payment markers in the Core (Phase 1) of the program.
- AADE recommends the overall payment amount of $450 increase by at least 15% to account for the cost of various program settings, implementation in less established networks and cost associated with quality assurance to implement a successful program.

2. Recommendations for modifying the Reimbursement Structure

The Proposed Rule outlines the DPP Payment Model (Table 35). AADE raises the following concerns as they relate to MDPP Supplier reimbursement structure:

- There is a payment marker for those who achieve the goal of 5% weight loss from baseline. The achievement of 5% weight loss from baseline statement needs to be clarified that this can be redeemed by the program when the participant achieves this anytime throughout the duration of the entire (12 month) program. The program is defined as one year long, and those that complete the program and achieve weight loss goals reduce their risk by 71% (in those over 60 years old). AADE recommends this payment can be achieved anytime throughout the year-long program.
- In the Proposed Rule on Table 25, the all Maintenance Session Payments state, "*X maintenance sessions attended (with maintenance of minimum required weight loss*

from baseline)" for both the Maintenance sessions in the 12-month program and the maintenance sessions after the yearlong program, weight loss requirements are attached to attendance. As we have seen in our successful delivery of the program, many successful participants have lost 5% from their base line weight in months 7-12, obtaining their reduction in risk (and the associated ROI). Some participants will lose, regain and then lose weight again before they are able to maintain their weight loss. It has been proven that there is a direct correlation to sessions attended and success (reduction in risk) of the program. If the 5% weight loss from baseline is required for reimbursement for attendance in the second half of the program (months 7-12), there will be a vast gap of participants potentially not receiving the second half of the program. Or, if people achieve the weight loss and regain weight at some point, the way the proposal is written, participants will not have an opportunity to get back on track with the program and lose their weight again, therefore reducing their risk. The National DPP is a yearlong program and participants should have access to the program for the entire year. AADE recommends that weight loss caveats be separated from the attendance payment markers.

- Quality monitoring and reporting: There is no measurement of a reimbursement milestone for people who lower their risk of developing type 2 diabetes by lowering their A1C value. Although the weight loss was the measurement of success in the DPP study and is a DPRP standard (due to it being a non-invasive and cost-effective measurement of reduction in risk) there is also an evidenced-based correlation between a drop in A1C and reduction in risk. These two measurements can be independent of one another. DPRP does not require all participants to enter with a blood-based value. The CMS proposal does require initial blood-based values for participants, therefore a payment marker based on an A1C would be feasible to track and report. AADE recommends including a payment measure for reduction in weight from baseline by 5% or a reduction in A1C to below 5.7. This addition would align with the value-based payment mechanism and allow programs to demonstrate ROI reduction risk based on blood-based values.

3. Staff requirements

The proposal recommends that there be a requirement for all staff implementing the MDPP ("*coaches*") to obtain an NPI, however this does not ensure quality of staff. The Proposed Rule does not mention requiring or tracking staff training in the DPP program or certifications. AADE recommends CMS require staff to take and provide proof of Lifestyle Coach training from approved entities for all coaches (both for paraprofessionals and healthcare professionals) in order to implement the program with fidelity. Currently, CDC's

DPRP recognition does not collect any documentation on staff implementing the National DPP nor does it have a mechanism to ensure coaches have been trained to deliver the program as intended. Currently, there are a variety of Lifestyle Coach training entities, but no "*certification"* offered to ensure training attendees have ascertained the appropriate knowledge, skills and abilities to implement quality programs. AADE sees this a potential gap in fidelity to ensure the program is delivered as designed according to standards and we have witnessed the program being implemented by coaches without proper training in evidence-based curriculum, decreasing potential effectiveness of the program.

Specifically, AADE recommends the following to address this issue:

- MDPP Suppliers be required to provide proof of training certification for all coaches
- Requirement of ongoing continued education of the coaches to standardize delivery, ensure fidelity and assure quality implementation of the program.
- Consideration of a required certification and ongoing education requirements for Lifestyle Coaches.

As a CDC approved Lifestyle Coach training entity and a healthcare professional membership organization providing continuing education, AADE is positioned to offer additional recommendations and/or oversight to this process and would be in support of discussing this further with CMS.

4. Diagnosed Diabetes

In the CMMI Y-USA DPP HCIA demonstration project, the Actuary's report showed that 38% of participants in the treatment group were diagnosed with diabetes at some point. AADE has serious concerns that as the MDPP coverage expands, more people will be diagnosed with diabetes during not only the screening process but throughout the implementation of the program without a proper protocol for referral into DSMT services. CDC's DPRP standards do not offer guidance on how to handle current participants who receive a diabetes diagnosis while they are a participant in the National DPP.

Specifically, AADE recommends the following to address this issue:

- MDPP coverage to include a protocol of how to address those potential and current MDPP participants that receive a diagnosis of diabetes either during the screening process or during the participant's participation in the year-long DPP program to ensure patients receive proper care and a referral into a DSMT program.

5. Duration

In the Proposed Rule, it is stated that "*programs must be 1 hour in duration*." CDC's DPRP standards require programs to adhere to frequency and duration of the program over the course of the year, but does not require session length time in order to maintain compliance.

Specifically, AADE recommends the following to address this issue:

- AADE recommends that CMS not require that sessions be approximately 1 hour in duration but rather implement a purely value-based payment mechanism.

AADE responses to other Proposed Rule comments areas

- **Program Integrity**: AADE agrees with the Proposed Rule of policies and system checks to monitor the MDPP expansion to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards. As a Nationally Accrediting Organization for DSMT, AADE would be pleased to add further insight and input to CMS in this topic area.
- **Site of Service:** AADE agrees with the Proposed Rule of consideration of allowing MDPP services via remote technologies. We understand that quality of all Sites of Services must be considered and can make recommendations on oversight methods of various MDPP implementation services to ensure quality and fraud avoidance. AADE recommends oversight continue to be discussed and explored to allow for remote MDPP delivery to increase participant access and choice of mode of delivery. AADE is also recommending clarification on in-person delivery programs that may also deliver only a portion of their program through integrated telecommunication and telehealth technologies.
- **Requirements for Eligibility:** AADE agrees with the Proposed Rule when it states "*existing Medicare Providers and suppliers that wish to bill for MDPP services would have to inform Medicare of the intention and satisfy all other requirements but would not need to enroll a second time*" (no alternative approach listed).
- **Learning Activities:** As an organization that supports both Medicare providers and National DPP programs in education, training, and technical assistance, claims submission and medical record keeping, AADE would like to offer to explore this more with CMS.
- **Timing of the Medicare Expansion:** AADE agrees that the Medicare coverage of MDPP should roll out nationally in its first year, versus the alternate approach limited to only certain geographies or regions.

AADE is asking for clarification from CMS on the following topic areas

1. Definitions and requirements for Preliminary Recognition as there is no description of the Preliminary Recognition in the current 2015 DPRP standards.
2. Billing and coding of reimbursement- AADE is asking for more clarification regarding specific G-codes and billing process of the Reimbursement Structure (Table 35).
3. Additional payment marker set at 9% weight loss from base line weight when CDC DPRP goals are 5%-7%. AADE recommends the additional value-based payment marker align with the DPP study to allot for >7% weight loss be considered for the additional payment.
4. A history of Gestational Diabetes Mellitus be self-reported for eligibility (aligning with the DPRP eligibility requirements).
5. Confirmation that this service will not be an out of pocket expense for the people with prediabetes.
6. Clarification that the MDPP Supplier can use "a" CDC approved Curriculum (versus "The" CDC approved curriculum, implying there is only one approved curriculum).

Additional Considerations

- AADE cautions CMS that the DPRP standards are revised by OMB Circular every three years. Although requiring MDPP Suppliers to be a "*CDC Recognized DPRP Program*" and aligning reimbursement to the standards is encouraged by AADE, tying any payments to specifics in the current 2015 DPRP standards is discouraged as these may change and the CMS ruling may not. We recommend that the NAO have the responsibility of interpretive guidance of the standards to ensure consistency and provide assistance and training with these changes. Another option is Medicare oversight by a contracted entity with basic quality standards that meet the DPRP requirements.
- AADE requests that CMS consider additional quality oversight for MDPP Supplier staff and coach training requirements to ensure quality programming and fraud avoidance.
- AADE is concerned with DPP being a year-long implementation, there should be consideration of how to handle transient/seasonal ("*snow-bird*")/retired population coverage.
- AADE seeks further insight on CMS's statement on a cross-walk between CMS claims and DPRP data reports.

AADE would like to applaud and thank CMS for the opportunity to share valuable information about the quality assurance and fraud avoidance concerns with the Medicare expansion of the

MDPP benefit. As stated throughout the document, AADE is an organization that has experience as a National Accrediting Organization, implementation and oversight of a successful model of DPP program implementation and as a CDC approved Lifestyle Coach training entity. AADE believes as an expert in DPP we provide a unique view of diabetes educators and their barriers. We would like to extend the opportunity to discuss this further with CMS in person when appropriate.

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