September 1, 2017

Submitted via the Federal eRulemaking portal: http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1676-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

Dear Secretary Price and Administrator Verma:

The American Association of Diabetes Educators (AADE) appreciates the opportunity to provide comments related to the Centers for Medicare & Medicaid Services’ (CMS’) CY 2018 Physician Fee Schedule Proposed rule (the “Proposed Rule”), published July 21, 2017.¹

AADE is a multi-disciplinary professional membership organization dedicated to improving diabetes care through innovative education, management and support. With more than 14,500 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by, or are at risk for diabetes and other chronic conditions. CMS has granted AADE the status of a National Accredited Organizations (NAO). Under this status, AADE certifies Diabetes Self-Management Education and Support (DSMES) programs to bill for DSMT services. In addition, over the past five years AADE has developed a strong successful network of National Diabetes Prevention Programs (DPP). As such, AADE and our members are in a unique and important position to provide diabetes prevention education to Medicare beneficiaries.

Summary of Comments
Our comments herein focus on the following areas in the Proposed Rule:

- **Medicare Diabetes Prevention Program (MDPP) Start Date:** AADE supports the proposed effective date of April 1, 2018.

¹ 82 Fed. Reg. 33950 (July 21, 2017)
• **Mid-Program Diabetes Diagnosis:** We support the participation of beneficiaries in MDPP who have been diagnosed with diabetes during the program.

• **Ongoing Maintenance Sessions:** AADE supports the importance of ongoing maintenance sessions, but encourages CMS to limit these sessions to 12 months.

• **Once-Per-Lifetime Restriction:** We urge CMS to establish a “major life event” exception to this proposed restriction on MDPP to ensure that certain events do not preclude beneficiaries from participating in the program.

• **Switching MDPP Suppliers:** AADE asks CMS to provide additional guidance regarding the circumstances under which a beneficiary would need to switch MDPP suppliers and strongly encourages CMS to permit MDPP to be provided as a covered telehealth service.

• **MDPP Payment Structure:** AADE strongly recommends that CMS make changes to the payment structure as currently proposed. AADE provides specific comments below, but recommends reallocating more payment during core sessions to align with the burden and risk programs incur.

• **MDPP Supplier Enrollment:** AADE asks CMS to provide additional guidance regarding supplier enrollment and to establish an ombudsman program for MDPP suppliers and participating beneficiaries.

• **MDPP Beneficiary Incentives:** We support CMS’ proposal to allow for the furnishing of beneficiary engagement incentives and seek clarification regarding the use of certain technology incentives.

**Comments**

**MDPP Start Date**
AADE commends CMS for moving forward with MDPP implementation in a timely fashion and are delighted that services will begin on April 1, 2018. We agree that a 90-day delay from January 1, 2018, is both reasonable and necessary to ensure MDPP suppliers will be ready to deliver services by April 1, 2018. AADE awaits further guidance on the application process in order to help guide our members.

**Mid-Program Diabetes Diagnosis**
AADE supports CMS’ intention of allowing beneficiaries who develop type 2 diabetes to continue to receive the MDPP benefit after they have begun the program. We support the justifications given – “the DPP model test, which demonstrated cost savings did not exclude from the model individuals who developed diabetes” and it would be “impractical and unduly burdensome” for suppliers to verify diabetes status and blood test results continually. ² Additionally, we note that

² Id. at 34133.
the education gained in MDPP programs is also appropriate for individuals with type 2 diabetes and will help them better manage their disease and thereby lower future costs to the Medicare program.

While AADE supports this proposed change, we recommend CMS clarify the language included in the MDPP final rule regarding beneficiaries with diabetes to align with The National Standards for Diabetes Self-Management Education and Support. The National Standards for Diabetes Self-Management Education and Support do not require health professionals to hold a certification in diabetes education. The Proposed Rule states – “If, for example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and lifestyle changes including blood sugar monitoring, insulin usage, medication management, and crisis management.” AADE suggests replacing “certified diabetes educators” with “health professionals who have experience in diabetes education” to recognize that Medicare DSMT programs can be given by non-certified diabetes educators.

In addition, AADE is concerned with the discrepancy between the Proposed Rule and the proposed 2018 Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures on how to address participants who are diagnosed with type 2 diabetes during their MDPP benefit period. The proposed DPRP standards suggest that DPP programs should no longer submit data to CDC via the DPRP data sheets on any participant that has received a type 2 diabetes diagnosis. However, CMS has clearly stated these beneficiaries can still participate in the DPP program, with services billable to CMS. This will cause a gap in the MDPP suppliers required crosswalk between their DPRP data sheet and their documentation for these specific participants when billing CMS. AADE highly recommends that CMS and CDC’s DPRP align on this topic of how to address, track and best support participants that receive a type 2 diabetes diagnosis during the MDPP benefit period.

**Ongoing Maintenance Sessions**

AADE is pleased that CMS reduced the burden on MDPP suppliers by limiting the ongoing maintenance period. However, while we are supportive of ongoing maintenance sessions in concept, we are concerned that this part of the program is a departure from the MDPP model test. To better align with the National Institutes of Health (NIH) study (total period of 24 months, consisting of 16 sessions in the first core 6 months and 18 months of ongoing maintenance), AADE recommends that CMS cover ongoing maintenance sessions for the length of 12 months beyond the 12-month MDPP core benefit, for a total MDPP benefit period of 24 months rather than the proposed 36 months. This will alleviate administrative burden and risk on the MDPP supplier, while still providing adequate time for ongoing support to participants, and aligns with

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the evidence-based program. AADE also recommends the potential reimbursement for months 24-36 be redistributed to reimburse for sessions during months 12-24.

**Once-Per-Lifetime Restriction**
AADE is concerned that a once-per-lifetime limit may actually increase Medicare costs and deny some beneficiaries’ access to MDPP. AADE encourages CMS to make an exception to the once-per-lifetime limit for participants who experience a major life event. Major life events should include, but are not limited to:
- Newly diagnosed health condition,
- Major surgery,
- Change in medications,
- Permanent change in residence,
- A catastrophic event that may reduce ability to participate in physical activity, or
- Use of medications that impeded a beneficiary’s ability to successfully participate in a MDPP program.

**Switching MDPP Suppliers**
AADE commends CMS for addressing the notion that a participant may change MDPP suppliers. As CMS finalizes this part of the Proposed Rule, we urge CMS to consider that many seniors travel to warmer climates seasonally or to be near family (often for a period of 3-6 months) and, therefore, it may be a common occurrence that a participant would need to change their supplier during their MDPP core benefit. This has important implications not only on the ability of seniors to switch MDPP suppliers mid-program, but also during the ongoing maintenance sessions. AADE strongly recommends at minimum that additional guidance provided to address this likely common occurrence.

Additionally, were CMS to allow virtual MDPP sessions, this could be one solution to avoiding beneficiaries from having no alternative but to switch MDPP suppliers. Allowing beneficiaries to virtually attend sessions from their MDPP supplier would allow them to continue their sessions with their enrolled MDPP supplier and achieve greater success. AADE urges CMS to consider allowing telehealth to be an alternative to in-person session attendance.

**Payment Structure**
AADE applauds CMS for moving toward performance-based payment. This structure, in accordance with how the MDPP model test was performed and CMS’ stated goals, can promote valuable, cost-saving interventions. However, AADE has a number of concerns related to the proposed framework.

First, we have significant concerns with entities electing to become MDPP suppliers based on the proposed payment schedule. AADE urges CMS to reconsider the distribution of payments over the course of the program compared to the burden and the risk of the MDPP supplier. For example, most supplier costs (e.g., administrative costs, staffing, beneficiary engagement, marketing, materials, recruitment, etc.) are acquired up front in the initial 6 months of the
program (and are incurred regardless of beneficiaries meeting weight loss criteria). As proposed, MDPP suppliers would be faced with covering the initial overhead expenses without timely reimbursement. As a result, these costs may preclude entities from becoming an MDPP supplier.

Second, we are concerned with how reimbursement would be distributed when a beneficiary “switches” between suppliers. While we applaud CMS for anticipating this and proposing a bridge payment to make up for costs, this may not be enough depending on the timing of the switch. For example, if the beneficiary has already met most of their weight goals or entered the maintenance portion of the program, most of the payments will have already gone to Supplier A. Meanwhile Supplier B is then responsible for administering the entire maintenance session portion of the benefit without reaping any of the rewards of the performance-based payment. Even if the volume of such switching is low, capital will still be required to fill in the gap between the cost to administer the program and the amount of funds Supplier B is eligible to receive based on how far the beneficiary has gone through the program.

To address both of these payment concerns, AADE highly recommends that CMS consider shifting a portion of the payments to be aligned with the suppliers’ actual costs incurred between the attendance payments and/or the payments based on weight loss. As described in the chart below, AADE recommends decreasing the payment for 5% weight loss from $160 to $100. The remaining $60 payment should be distributed to the core sessions attended. AADE also recommends removing the payment for the 9% weight loss completely (as this is highly irregular and not specifically tied to outcomes of the program) and distribute the remaining $25 to the payment toward attendance of the sessions in months 7-12. AADE also highly recommends removing the various payments for the participant in months 7-12 that depends on whether or not that participant achieves 5% weight loss, and making these payments $72.50.

<table>
<thead>
<tr>
<th>Type of Performance Payment</th>
<th>2018 PFS Proposed Rule: Maximum Performance Payment for Achieving Attendance and/or Weight Loss Performance Goals</th>
<th>AADE Suggested Payment Structure Reform: Maximum Performance Payment for Achieving Attendance and/or Weight Loss Performance Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Session Attendance</td>
<td>$105</td>
<td>$165</td>
</tr>
<tr>
<td>Core Maintenance Session Intervals (intervals in months 7-12)</td>
<td>$120</td>
<td>$145 (regardless of weight loss)</td>
</tr>
<tr>
<td>Weight loss Goal Achieved at any time during the Core or Core Maintenance Sessions (5% from baseline)</td>
<td>$160</td>
<td>$100</td>
</tr>
<tr>
<td>Bonus payment for 9% weight loss</td>
<td>$25</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Total Payment Possible during Core</strong></td>
<td><strong>$410</strong></td>
<td><strong>$410</strong></td>
</tr>
</tbody>
</table>
**Ongoing Maintenance Session Intervals**

<table>
<thead>
<tr>
<th>Intervals</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months 12-36</td>
<td>$400</td>
</tr>
<tr>
<td>Months 12-24</td>
<td>$400*</td>
</tr>
</tbody>
</table>

*AADE recommends reducing the number of ongoing maintenance session intervals to a total of 4 over a 12-month period and allow attendance for all participants (regardless of weight loss), which would reduce the total maximum ongoing maintenance session interval payments.

AADE understands CMS’ need to balance Medicare program costs, but also believes that to increase Medicare beneficiary access to MDPP, we must ensure that suppliers are incentivized to invest in these critical programs. If CMS does not consider a redistribution of payments, AADE recommends an increase in total overall payments.

**MDPP Supplier Enrollment**

On these sections, AADE would emphasize the need for timely guidance from CMS. To help ensure a successful implementation of MDPP, we suggest:

1) Creating a timeline for when suppliers and other stakeholders can expect to receive guidance from CMS and what will be contained in each portion of the guidance.

2) Creating a process (i.e., an ombudsman program) through which MDPP suppliers as well as beneficiaries can get questions answered outside of the regular rulemaking process as they begin the process of enrollment and claims submission, which will be new to most MDPP suppliers as well as the Medicare program. CMS should consider making some answers public if the topic is not proprietary for an individual MDPP supplier. AADE can assist with this support and guidance to programs, similar to how we provide guidance and support for DSMT.

**Incentives**

AADE is pleased that CMS is contemplating beneficiary engagement incentives that support beneficiaries’ in their pursuit to achieve MDPP clinical goals. Items or services that are not traditionally covered by Medicare may significantly improve beneficiary access and use of the MDPP benefit and even further enhance its savings potential. Additionally, CMS can learn from the proposed incentives to determine whether beneficial in other parts of the Medicare program. We note that Medicare Advantage plans already provide beneficiaries with non-covered items and services, which has helped those plans lower chronic disease costs among their plan members.

Specifically, with respect to the use of technology incentives, we urge CMS to clarify and revisit its proposal. The Proposed Rule states that smartphones are “broadly used technology that is more valuable to the beneficiary” and therefore forbidden. However, the Proposed Rule also states that a tablet or smartwatch or fitness tracker pre-loaded with apps that would support the beneficiary’s weight loss goals is an example of an acceptable incentive. We ask that CMS clarify its distinction between the smartphones and other forms of mobile technologies with apps.

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5 Id. at 34168.
Further, we encourage CMS to increase the $100 (permanent use) to a $200 threshold in order for programs to supply things, such as wearable trackers and other incentives that often cost more than $100 per item.

Other Considerations
In addition to the above comments on the Proposed Rule, the AADE asks that CMS take into account the following additional considerations.

Delivery Options: AADE very much looks forward to future rulemaking including coverage of virtual MDPP services, as this is vital to addressing access for various populations and has shown to be a very successful and increasingly popular delivery option for many who prefer this mode. Given new data and an already strong evidence base, we encourage CMS to continue to consider coverage of virtual MDPP. Furthermore, AADE would like to emphasize that if CMS does not include virtual MDPP coverage in its final rule, CMS should include telehealth coverage for MDPP in the final rule. There is precedent for telehealth coverage, as both DSMT and Medical Nutrition Therapy (MNT) are currently covered via telehealth. To that end, clinical staff at a distant facility could oversee an in-person weigh-in and the collected weights would be entered as the “in-person” weights. As such, AADE highly recommends allowing MDPP to be offered via telehealth as interchangeable with in-person to address rural and seasonal populations and reduce beneficiaries from “switching” programs or not completing their MDPP program.

Consideration for A1C Milestone: Although weight was the measurement of success in the NIH 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 for developing diabetes. These two measurements – weight and A1C – should be independent of one another. While DPRP does not require all participants to enter with a blood-based value, the CMS proposal does require initial blood-based values for participating beneficiaries and allows A1C as an eligibility criteria. Therefore, a payment marker based on an A1C would be a feasible and cost effective option for MDPP suppliers to track and report as a milestone for success (i.e., a value-based payment marker). AADE recommends including a payment measure for reduction in weight from baseline by 5% or a reduction in A1C to below 5.7 (“normal range”). If a beneficiary is able to achieve a normal classification of A1C, they have, in essence, reduced their risk. This addition would align with the value-based payment mechanism and allow programs to demonstrate reduction risk based on blood-based values.

Conclusion
AADE sincerely thanks CMS for the opportunity to provide comments on the Proposed Rule and for considering our comments. We look forward to continuing to engage with the agency as the regulatory process proceeds. As an organization that provides education, guidance and support to diabetes educators, Medicare certified DSMT providers, as well as supporting a network of DPPs, we would like to offer to meet with CMS to further clarify our comments or offer our assistance throughout the implementation and coverage of MDPP.
If there are questions or if additional information is needed, please do not hesitate to contact me at: lkolb@aadenet.org

Sincerely,

[Signature]

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