September 10, 2018

Via Electronic Mail
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-P)

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Proposed CY 2019 Physician Fee Schedule Rule.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

AdvaMed supports the establishment of payment rates under the physician fee schedule that are appropriate to ensure access to advanced medical technologies by Medicare beneficiaries. We appreciate the effort you and your staff have devoted to the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule, we have concerns with other proposals and welcome the opportunity to provide several recommendations. We will comment on the following issues raised in the proposed 2019 PFS rule:

Bringing innovation to patient care worldwide
I. Provisions of the Proposed Rule for PFS
   A. Updates to Prices for Existing Direct PE Inputs
   B. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services
      1. Interprofessional Internet Consultation
      3. Expanding the Use of Telehealth for Individuals with Stroke under BBA 2018
      4. Medicare Telehealth Services under Section 1834(m)—Submitted Requests to Add Services to the List of Telehealth Services, Chronic Care Remote Physiologic Monitoring
   C. Payment Rates Under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider–Based Departments of a Hospital

II. Other Provisions of the Proposed Regulations
   A. Clinical Laboratory Fee Schedule
   B. Medicare Shared Savings Program Quality Measures

I. Provisions of the Proposed Rule for PFS

   A. Updates to Prices for Existing Direct PE Inputs

For CY 2019 CMS is proposing to use research data generated by StrategyGen to update the PFS direct practice expense (PE) inputs. CMS further proposed that the changes in input pricing be phased in over a four-year period. AdvaMed does not support use of the StrategyGen data in modifying PE input prices. The process used by StrategyGen to develop their recommendations lacks transparency and, in many instances, results in significant reductions in payment for devices. Because of the way in which the data were developed, manufacturers and other stakeholders are unable to fully understand the basis for the StrategyGen findings, including the method for evaluating and/or weighing the various data sources that were used to gather price information – leaving them in the position of trying to develop data that accurately reflects the costs of their equipment. Additionally, stakeholders were not given an opportunity to review and comment on the data used by StrategyGen in formulating its analysis for CMS despite significant payment changes created by the proposed inputs.

Another significant yet unexpected outcome of the movement to new PE data is the impact of indirect practice cost index (IPCI) changes on the overall PE inputs and resulting payment rates for specialists. In the rule CMS notes that “while there were no statistically significant differences in pricing at the aggregate level, medical specialties will experience increases or decreases in their Medicare payment if CMS were to adopt the pricing updates recommended by StrategyGen.” CMS does not explain these specialty level changes or discuss their impact on PFS payments. However, in looking more closely at the rule, it appears that the methodology for calculating the IPCI is the source of changes in specialty payments. This is largely attributable to the creation of practice expense inputs for a newly created EM specialty. AdvaMed is
concerned that CMS has not offered more information regarding the impact of changes to the IPCI calculation on specialty-based payment. We are further concerned by the potential negative impact of these changes on beneficiary access to appropriate services, technologies, and providers. Various analysts who have reviewed the claims data supporting this year’s rule have identified this concern. If CMS were to move forward with the PE changes as currently proposed, without addressing the impact of the IPCI issue, the agency runs the risk of substantially compromising Medicare beneficiary access to needed supplies and equipment. Lastly, CMS is soliciting comments on the need to update clinical labor wages used in developing PE RVUs during the four-year pricing transition for supplies and equipment. Given the high level of concern we have related to the supply and equipment proposals, AdvaMed recommends that CMS not make any changes to clinical labor costs for the foreseeable future.

- **AdvaMed recommends that CMS delay any phase in of changes associated with the StrategyGen data while stakeholders have an opportunity to submit additional invoice data.**
- **AdvaMed recommends that CMS arrange a stakeholder dialogue wherein they can describe the process used by StrategyGen to develop the information that the agency is relying upon and that stakeholders have access to and the ability to comment on said data.**
- **AdvaMed recommends that CMS provide more information and analysis demonstrating the impact of IPCI on specialty-based PE payments.**
- **AdvaMed recommends that CMS not make any changes to clinical labor inputs until all issues related to updated PE pricing for supply and equipment inputs are resolved.**

AdvaMed will also be submitting additional comments and analysis specific to the impact of PE input changes on Radiation Therapy equipment from our AdvaMed Radiation Therapy Sector. We encourage CMS to take these comments into consideration.

**B. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**

AdvaMed commends CMS for recognizing the rapid transformation of health care service delivery that has occurred because of the availability of a variety of technology-based communication modalities that can improve patient care outcomes if supported by public and private payers. We especially commend CMS for its desire to enhance the use of these various technologies by establishing new pathways of coverage and payment for services provided to Medicare beneficiaries. AdvaMed believes that we are only at the very earliest stages of the development of many new digital technologies that will require significant rethinking of the way health care services are paid by Medicare. We appreciate CMS proposing changes that will ensure Medicare beneficiaries access to the benefits offered by some of these technologies.
AdvaMed strongly supports the direction CMS has taken in each of the proposals in Modernizing Medicare Physician Payment section of the proposed rule: Brief Communication Technology-Based Service, Remote Evaluation of Pre-Recorded Patient Information, Interprofessional Internet Consultation, and Medicare Telehealth Services. CMS also reiterates its position that many technology-based communication services are not telehealth services, as those services are defined and limited in Medicare statute and regulations. Many of the proposals in this section are aimed at increasing access for Medicare beneficiaries to physician services that are routinely furnished by communication technology. AdvaMed is hopeful that the policies in the proposed rule are representative of a broader shift in CMS’s interest in providing Medicare beneficiaries access to various digital technologies and that forthcoming rules continue to articulate new pathways to coverage and payment for these services across Medicare’s various benefit categories and settings of care.

We offer specific comments on several topics included in this section of the rule.

1. Interprofessional Internet Consultation

AdvaMed strongly supports CMS’s proposals to make separate payment for specified Interprofessional Internet Consultation and Referral services described by CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449. We agree with CMS that making separate payment for interprofessional consultations and referring physicians, undertaken for the benefit of treating a patient, will contribute to payment accuracy for primary care and care management services. We also believe that separate payment for these services will also enhance care coordination and collaboration among practitioners serving Medicare patients not only in alternative payment models, such as ACOs, but also for practitioners not participating in these models. In both instances, we expect that patient care outcomes will be improved.

AdvaMed requests that CMS continue to refine its approach for reimbursing internet consultation services to incorporate live or historical video that make possible visual communication during the consultation. Today, secure cloud-based solutions exist that greatly expand the pool of potential expert consultants outside of one hospital or health system-- to enable a more reliable method for sharing the visual story of an episode of care in real-time. This technology advancement contrasts with older systems which have been designed to restrict access only to those with network credentials at a specific hospital. These secure cloud-based platforms will contribute to improved or more timely decision-making and potentially better medical and surgical outcomes for Medicare beneficiaries.

In addition, new physician-to-physician communication technologies have been developed that can help impact precision and accuracy of communication. For example, telestration allows the consultant physician to provide precise location feedback, marking the area of need on an image or video during a consult, versus verbal descriptions using anatomical landmarks. These methods of real-time collaboration may, over time, necessitate new reimbursement coding solutions, as will other advancements in physician-to-physician communication if they are to achieve their potential for improving a patient’s course of care.

AdvaMed commends CMS for its thoughtful approach to proposed implementation of those provisions of BBA 2018, which support innovative technological advances that help patients more easily access home dialysis therapy. Specifically, AdvaMed supports making the home or renal dialysis facility originating sites for purposes of home dialysis patients’ clinical assessment via telehealth. With this change, patients will no longer have to travel to a hospital or facility-qualifying site to interface with an approved practitioner face-to-face on a monthly basis—a task that is often difficult for dialysis patients and may act as a disincentive to adopting home dialysis as a treatment option.

3. Expanding the Use of Telehealth for Individuals with Stroke under BBA 2018

AdvaMed also supports the direction of CMS’s proposals for implementation of BBA 2018 provisions related to mobile stroke and stroke telehealth services. Mobile stroke telehealth has become more important in recent years as advances in stroke treatment offer new opportunities to reduce disability in acute ischemic stroke (AIS) if patients are seen by a qualified facility within the treatment window. Currently most stroke patients potentially eligible for mechanical thrombectomy, a procedure that peer-reviewed literature shows effectively reduces disability from AIS, are taken to hospitals that are not mechanical thrombectomy ready, thus requiring transfer of the patient and creating a barrier or delay for appropriate care. In addition, diagnostic tools are available to triage stroke patients in the prehospital setting, allowing more patients experiencing stroke to be evaluated remotely by a neurologist and directed to a thrombectomy ready hospital.

In its proposal to implement the BBA 2018 provisions on telestroke, CMS would define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke. AdvaMed supports this definition. We believe that it captures the services currently provided by mobile stroke units, including neurological consults via telehealth, and is comprehensive enough to encompass future advances in stroke care.

CMS would also specify the following additional sites of service as stroke telehealth originating sites: physician and practitioner offices, critical access hospitals, rural health clinics, federally qualified health centers, hospital, hospital-based or critical access hospital-based renal dialysis centers, skilled nursing facilities, and community mental health centers. AdvaMed supports this proposal, which would enhance timely stroke care in these settings. In response to CMS’s request for suggestions on other stroke telehealth originating sites, we recommend that CMS consider sites such as freestanding, off-campus emergency departments. We also suggest that CMS consider a criterion such as stroke referral volume in its designation of stroke telehealth originating sites. Additionally, CMS proposes using a new modifier to report acute stroke telehealth services. We agree with CMS that reporting a modifier imposes minimal administrative burdens on providers.
While we understand that there are currently CPT codes to report critical care telehealth consultations, such as acute stroke telehealth services, AdvaMed recommends that CMS work with relevant medical societies to determine whether additional coding is necessary to ensure full access to all stroke telehealth services. We also recommend that CMS engage stakeholders to discuss circumstances when coverage and payment might be appropriate for CT and tPA administration services when furnished in the mobile stroke unit site of care.

4. Medicare Telehealth Services under Section 1834(m)—Submitted Requests to Add Services to the List of Telehealth Services, Chronic Care Remote Physiologic Monitoring

AdvaMed strongly supports coverage of the CPT Editorial Panel’s adopted chronic remote physiology monitoring and management codes 990X0, 990X1, and 994X9. We agree that these codes not be added to the List of Telehealth Services, and be paid, instead, as remote patient monitoring services under the Physician Fee Schedule. We request that CMS ensure that the values for these codes be modified to reflect the costs of all non-physician and other practitioners supporting care teams and contributing to patient monitoring. Furthermore, we request that CMS revisit the proposed valuation and payment for 990X1 and include in this code the monthly licensing and cellular fees incurred and allocated per individual patient for individual services as part of the direct practice expense valuation.

C. Proposed Payment Rates Under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider–Based Departments of a Hospital

In the 2017 OPPS final rule, CMS did not finalize its proposal to limit service line expansion for excepted off-campus provider-based departments (PBDs). Excepted off-campus PBDs are those departments that billed for items and services under OPPS prior to November 2, 2015. In the 2018 OPPS proposed rule, the Agency seeks to continue this policy for another year as it continues to monitor claims data for changes in billing patterns and utilization.

For CY 2018, CMS revised the PFS Relativity Adjuster for nonexcepted items and services furnished by nonexcepted off-campus PBDs to be 40 percent of the OPPS payment rate. Nonexcepted off-campus PBDs are those departments that bill for items and services under HOPPS after November 2, 2015. In the 2017 final rule, CMS applied a PFS Relativity Adjuster of 50 percent to the rates of these same practices. AdvaMed has ongoing concerns regarding continued use of a PFS Relativity Adjuster of 40 percent creating instability in the market and situations where services are no longer provided due to such a significant reduction in reimbursement. AdvaMed urges CMS to reinstate the 50 percent PFS Relativity Adjuster.
• **AdvaMed recommends that CMS reinstate the 50 percent PFS Relativity Adjuster for CY 2019 until data are collected that will allow development of a more accurate payment methodology.**

II. Other Provisions of the Proposed Regulations

A. Clinical Laboratory Fee Schedule

The CY 2019 rule includes several proposals related to the Protecting Access to Medicare Act (PAMA) and the method for setting clinical laboratory fee schedule rates. AdvaMed has several recommendations related to these proposals which will be addressed in comments submitted by AdvaMedDx, a division of AdvaMed dedicated exclusively to issues facing diagnostic manufacturers in the United States and abroad. We encourage CMS to take the comments submitted by AdvaMedDx on these issues into consideration.

B. Medicare Shared Savings Program Quality Measures—Quality Payment Program

AdvaMed understands that the Quality Payment Program is very complex and supports CMS’s continued efforts to simplify the program as well as to implement it gradually and transparently over time. We appreciate the opportunity to offer our recommendations below.

**MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)**

1. **Cost performance category weights:** AdvaMed supports that the Cost performance category weights within the MIPS overall composite score as proposed by CMS: 15 percent weight for performance year 2019 followed by 5 percent increases each for 2020 and 2021 (to 20 and 25 percent, respectively). The Bipartisan Budget Act of 2018 (BBA) provided discretion to the Secretary regarding the weighting of the MIPS Cost performance category in the total MIPS composite score for the 2019-2021 performance years. The step-wise increase allows for continued clinician adaptation to the MIPS program’s Cost category requirements while episode-based cost measures are being added.

2. **Episode-based Cost Measures:** Regarding episode-based cost measures, AdvaMed recommends that all or at least key portions of the myriad resource materials be made publicly available by CMS or be consolidated on a single website to facilitate ease of access by stakeholders and patients and to aid their overall understanding of the episode-based measure approach. AdvaMed acknowledges the careful, multi-step, inclusive, and largely transparent process that CMS has adopted for episode-based cost measure development. We also appreciate the extensive amount of information that was made publicly available about the measures by CMS during the “field trial” of the measures (October-November 2017).
3. **Meaningful Measures Initiative and Proposed Measures:** AdvaMed supports the intent of CMS’s Meaningful Measures initiative to streamline the measure sets of the various Medicare quality programs into high-value, parsimonious sets that emphasize patient-centered outcomes and maintain a focus on patient quality of care and patient safety within each program. We also support the multiple recent efforts being made by CMS to harmonize measures across different parts of the Medicare programs (e.g., measures that address the same outcome modified to reflect specific hospital or clinician application). We note that CMS continues to approach streamlining measures through actions such as removing topped-out measures, eliminating duplicative measures, and careful addition of measures that address new quality challenges. While supporting these efforts, AdvaMed also recommends that CMS maintain/retain a focus on those measures most directly linked to patient quality and safety. AdvaMed encourages CMS to regularly assess the effects of streamlined measure sets to avoid having very narrow residual measure sets that are insufficient to allow all practitioners to participate in quality reporting of measures that are actionable and relevant to their practices.

In addition, AdvaMed encourages CMS to work to streamline cost-based measures across payment systems and other alternative payment models. We believe more consistent and focused cost-related measures across multiple payment systems will drive stronger alignment, coordination, and efficiencies among healthcare providers.

AdvaMed particularly supports the proposed addition of *NQF #2653 Average Change in Functional Status following Total Knee Replacement Surgery* to the MIPS quality measure set. This measure is a patient-reported outcome measure that satisfies the definition of a MIPS high-priority measure. Even more importantly, this measure offers an assessment from the patient’s perspective of how well the procedure has met the patient’s goal for the operation: functional improvement. AdvaMed further notes that this measure has been supported by the Measures Application Partnership for adoption into the MIPS program. We urge CMS to make this measure and other measures reflecting patients’ perspectives public on Physician Compare once validated and risk-adjusted, so that patients can learn more about the quality and functional status improvements of care from their physicians.

**ALTERNATIVE PAYMENT MODELS (APMs)**

AdvaMed supports the proposal by CMS to allow annual renewal of another Payer’s APM status as an Advanced Other Payer APM through a streamlined certification process rather than requiring complete resubmission of unchanged information by the APM to CMS for review. The more user-friendly proposed approach is consistent with private sector processes and agreements and importantly reduces regulatory burden, encouraging the development of more non-Medicare Advanced APMs.
Conclusion

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2019 PFS rule and looks forward to working with CMS to address our concerns. We would be pleased to answer any questions regarding these comments. Please contact me or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can further assist you.

Sincerely,

[Signature]

Donald May
Executive Vice President
Payment and Health Care Delivery Policy