September 21, 2018

Via Electronic Mail Only
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Request for Information on Promoting Interoperability and Electronic Health, Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS innovation Center Model (CMS-1695-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 Calendar Year (CY) 2019 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Rule and the Quality Reporting Programs.

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.

Our comments will address the following issues:

I. Proposed Updates Affecting OPPS Payments
   i. Comprehensive APCs
   ii. Complexity Adjustments

II. Proposed New Technology APCs—Establishing Payment Rates for Low-Volume New Technology Procedures

III. Proposed OPPS APC-Specific Policies
i. Endovascular Procedures (APCs 5191 through 5194)
ii. Musculoskeletal Procedures (APCs 5111 through 5116)

IV. Proposed OPPS Payment for Devices—Proposed Changes to the Device-Intensive Procedure Policy for CY 2019

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status—Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

VI. Proposed Changes to the Inpatient Only List

VII. Proposed Nonrecurring Policy Changes
i. Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services
ii. Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Provider

VIII. Hospital Proposed Changes to the Ambulatory Surgical Center (ASC) Payment System
i. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

IX. Requests for Information (RFIs)

X. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

I. Proposed Update Affecting OPPS Payments

AdvaMed has several comments related to the proposed payment updates for OPPS services in CY 2019. Our comments will cover areas including APC development, complexity adjustment, and payment for devices. AdvaMed appreciates the ongoing effort on the part of CMS to stabilize the variation in APC payment rates. Comments on specific provisions are provided below.

i. Comprehensive APCs

CMS introduced the concept of comprehensive APCs (C-APCs) in the CY 2014 Outpatient Prospective Payment System rule. Since that time the agency has continued to create additional comprehensive APCs (C-APCs) and to make modifications to the policies governing development and use of these payment groupings.

C-APCs were first used on Medicare claims in CY 2015. The CY 2017 OPPS rates represented the first full year of claims data used for rate setting since establishment of C-APCs. AdvaMed has previously expressed and has ongoing concerns regarding whether the rates associated with the comprehensive APC’s adequately or accurately reflect all the procedures and costs associated with those APCs especially as CMS continues to expand the number of packaged and bundled services.
• **AdvaMed encourages CMS to continue to analyze claims data and to report on the impact of comprehensive APC changes on all affected codes and any potential impacts to patient access to services that are bundled under the comprehensive APCs.**

**ii. Complexity Adjustments**

CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as a part of the comprehensive APC policy. AdvaMed supports the complexity adjustment as an important tool to help ensure payment under the comprehensive APC methodology is adequate. However, AdvaMed has repeatedly expressed concerns regarding appropriate application of complexity criteria and the resulting APC assignments for codes within the comprehensive APCs, and we believe that important opportunities to refine the methodology remain.

In the CY 2019 proposed rule CMS is proposing a modification to its existing complexity adjustment policy. Currently, only paired J1 services are eligible for complexity adjustment. In the proposed rule, CMS is recommending that a single primary J1 code when reported with any number of units of a single add-on code be eligible for complexity adjustment assuming that the existing frequency (25 or more claims) and cost (violation of the two times rule in the originating C-APC) thresholds are met.

• **AdvaMed is supportive of the proposal to modify the existing complexity adjustment policy to apply to single primary service claims with any number of units of a single add-on code and recommends that CMS finalize this proposal.**

• **AdvaMed requests that CMS expand its review of procedure combinations to include clusters of J1 and add-on codes, rather than only code pairs, to more closely reflect medical practice when multiple procedures are performed together.**

• **AdvaMed requests that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.**

**iii. Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management**

The proposed rule includes a discussion regarding the impact that OPPS and ASC payment policies may have on the ordering and use of non-opioid alternatives in treating Medicare beneficiaries. AdvaMed appreciates CMS’s soliciting input on this issue of national importance – as opioid abuse reaches epidemic proportions. In the rule, CMS proposes that payments for certain non-opioid alternatives be unbundled in the ASC and
AdvaMed supports CMS’s discussion to change its payment policies for certain non-opioid therapies. We encourage CMS to promote the use of alternatives to opioids, including devices, to combat this crisis. As we have stated before, there are many innovative medical technologies that are already available that can help play a role in combating this national crisis. These medical devices, including ones that provide effective pain management solutions, have the potential to reduce Medicare beneficiaries’ dependence on opioids and help curb opioid misuse, abuse, and overdose. We also encourage CMS to explore mechanisms that would incentivize surgical approaches (i.e. minimally invasive surgery) which reduce post-surgical pain and the need for opioids to manage it.

Unfortunately, in too many instances, CMS reimbursement for pain managing interventions under the OPPS is inadequate, meaning that the cost is more than the reimbursement. This is clearly a disincentive to use such therapies, which can result in underutilization.

- **AdvaMed supports CMS’s proposal to pay separately for certain non-opioid pain therapies in the ASC that demonstrate a reduction in opioid usage through currently available or prospective published evidence. Given the urgency of the opioid crisis, we urge CMS to finalize and implement this policy in CY 2019.**

AdvaMed believes that CMS can use its equitable adjustment authority under 42 U.S.C. § 1395l(t)(2)(E), and we encourage CMS to explore mechanisms, such as add-on payments, to ensure payments under the OPPS are adequate for alternative, non-opioid pain therapies and other treatment approaches shown to reduce the need for opioids.

AdvaMed also supports CMS’s focus on the use of data to target prevention and treatment efforts, and to identify fraud and abuse. An excellent opportunity to advance the collective body of evidence regarding the opioid epidemic would be for CMS to release the Medicare Part D prescription claims data, linked at the patient level to Part A and B claims, in the Limited Dataset Standard Analytic Files for research purposes.

**II. Proposed New Technology APCs—Establishing Payment Rates for Low-Volume New Technology Procedures**

The CY 2019 proposed rule includes a recommendation to modify the number of years of claims data that may be considered for New Technology APC devices for which fewer
than 100 claims are expected each year. In many cases these devices are used for rare disease states that occur in a very small population of patients. Unfortunately, the small number of claims can lead to significant shifts in payment caused by variability in claims reporting. To reduce variation and create some level of payment consistency, CMS historically has used its equitable adjustment authority to set payment rates for these low volume procedures. The proposed rule includes a recommendation to use up to 4 years of claims data to set the payment rates for these low-volume new technology procedures.

- **AdvaMed supports the CMS recommendation to use up to 4 years of claims data to set payment rates for low-volume new technology procedures and encourages the Agency to finalize the proposal.**
- **AdvaMed further recommends that CMS use its equitable adjustment authority, to establish payment rates, in other instances where a procedure that has recently been introduced to the outpatient setting has inconsistent payment data due to small number of claims.**

### III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies—Proposed OPPS APC-Specific Policies

#### i. Endovascular Procedures (APCs 5191 through 5194)

For several comment cycles AdvaMed has expressed concern regarding the composition of the Endovascular procedure APC groupings. While CMS is proposing to maintain the existing four level structure for CY 2019, we appreciate the Agency’s being responsive to stakeholder input by also soliciting comment on the development of a 5 or 6 level structure for Endovascular APC procedures.

While AdvaMed does not have a recommendation on the proposals included in the CY 2019 proposed rule we appreciate CMS’s interest in this issue and encourage the Agency to continue to work with stakeholders.

#### ii. Musculoskeletal Procedures (APCs 5111 through 5116)

The proposed rule solicits feedback from stakeholders regarding the creation of a new level between levels 5115 and 5116 of the Musculoskeletal APC grouping. AdvaMed appreciates the Agency’s interest in these issues. Unfortunately, due to the lack of claims data, for total knee arthroplasty (TKA) at this time we recommend that CMS not finalize any structural changes to the Musculoskeletal APCs until at least 2020.
CY 2018 was the first year in which TKA procedures were removed from the inpatient only list and assigned to an APC grouping. Due to a 2-year data lag, the claims data for CY 2020 will be the first data available for use in appropriately setting the rate for these services in the outpatient setting. AdvaMed believes that it is prudent for CMS to wait until a full year’s claims data are available prior to making any changes to the Musculoskeletal APC grouping.

Based on research conducted by Chris Hogan of Direct Research, Inc., on the one-day inpatient and outpatient costs of TKA when appropriate devices are included on the claim, we believe that CMS should assign TKA, on an interim basis, to New Technology APC 1575, Level 38 ($10,000 to $15,000). This assignment would match the resources for this procedure which, based upon the Direct Research analysis, shows a geometric mean cost of $13,794 for TKA claims which include the total knee joint. This cost is on par with the median and mean payment rates for one-day inpatient cases within MS-DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity w/o MCC), of $12,941 and $14,400 respectively, based on a Direct Research Inc. analysis of 2016 MedPAR data. We expect these cases to be most representative of the ones that may migrate to the outpatient setting. Furthermore, assignment to this New Technology APC will provide CMS with an additional year to evaluate TKA outpatient claims data prior to considering any changes to the Musculoskeletal APCs.

- **We recommend that CMS delay making any changes to the Musculoskeletal APC grouping until 2020.**
- **We also recommend that CMS place TKA (27447) in new technology APC 1575, level 38 for CY 2019. This will provide appropriate payment for the procedure and will also ensure that physicians are not dissuaded from rendering this service to the patients who might benefit from outpatient treatment.**

**IV. Proposed OPPS Payment for Devices—Proposed Changes to the Device Intensive Procedure Policy for CY 2019**

AdvaMed has previously expressed concern regarding the device threshold applicable to device-intensive procedures asking that it be lowered. Additionally, in last year’s final CY 2018 OPPS rule CMS clarified that its device intensive policy only applied to surgically implanted devices that remain in the patient’s body after the conclusion of the procedure. This second change created angst among makers of beneficial, but high-cost, single-use devices that may be inserted and/or implanted and removed during a surgical procedure. AdvaMed raised this concern in meetings with CMS staff following publication of the final CY 2018 rule.
The proposed rule includes recommendations to lower the device intensity threshold from 40% to 30%. Additionally, CMS is also changing the definition to recognize single-use devices that remain in the patient’s body post-procedure and meet the device offset threshold.

- AdvaMed is supportive of both changes and views them as a positive step in ensuring patient access to necessary technologies. We recommend that CMS finalize both proposals.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status—Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

For CY 2019 CMS is proposing to continue its policy of packaging payment for skin substitute products and paying for these products via a low or high-cost APC structure. The Agency will however consider feedback from stakeholders on four alternatives for consideration in restructuring payment for these devices effective CY 2020. AdvaMed appreciates CMS’s efforts to ensure appropriate payment for these important devices and in the Agency’s interest in stakeholder feedback.

- In considering the alternatives presented by CMS, AdvaMed would like to express support for and recommend implementation of an episodic payment model in CY 2020.

We believe such a model will provide clinicians with the flexibility to make the best treatment decisions for their patients while eliminating perverse incentives to select one product over another. We encourage CMS to move expeditiously towards implementation of a policy change that will stabilize and provide appropriate payment for these devices.

AdvaMed recommends that CMS consider several issues as it develops an episodic payment. First, we ask that the Agency consider a 12-week episode as recommended in the proposed rule, as this aligns with Medicare local coverage polices on skin substitutes. We further recommend that, when structuring payments associated with a 12-week episode CMS use hospital outpatient claims data only, as the episode payments should be specific to hospital outpatient departments and should not include payments to physicians or other providers. We also ask CMS to consider factors such as wound type and comorbidities— as these factors frequently affect the rate of healing for a patient and may impact the type and length of time a skin substitute is used.

We also encourage CMS to develop and apply quality measures, that are flexible and accommodate physician decision making regarding the need to continue to apply skin
substitute products to a wound, beyond a pre-set number of applications, based on medical necessity.

Any quality measures for these services should also drive improvement in patient outcomes and discourage providers from stinting on care to reduce costs.

Lastly, we recommend that CMS create a simple outlier payment adjustment policy to accommodate patients with larger wounds and high-cost patients with extensive comorbidities. Adoption of such a policy will discourage cherry picking and ensure that patients requiring a higher number of applications, given the nature of their wounds, may be appropriately treated.

VI. Proposed Changes to the Inpatient Only (IPO) List

In recently proposed OPPS rules, CMS solicited public comment on removing total knee and hip arthroplasty from the inpatient only list to allow these procedures to be done in outpatient settings. CMS finalized a rule removing total knee arthroplasty from the list but did not do so for hip replacement. In both instances, AdvaMed emphasized the need to proceed with careful deliberation under the premise that Medicare patients are more complex than the under-65 population and often have more specialized needs – both in terms of the quantity and severity of medical comorbidities, as well as in limitations that exist in Medicare’s coverage of post-acute care benefits following an outpatient procedure vs. an inpatient stay.

AdvaMed believes that these special needs require new quality measures that will ensure the best possible outcomes for patients undergoing outpatient arthroplasty procedures. We recommend that CMS move forward quickly with the development of specific quality measures for outpatient knee procedures, against which both institutions and providers will be assessed. At the appropriate time, we also ask that CMS consider the use of existing claims-based total joint arthroplasty (TJA) quality measures capturing inpatient quality, as these would also be suitable for OPPS. In addition, we ask that CMS develop new quality measures for outpatient hip procedures if hip arthroplasty is removed from the inpatient only list.

In developing quality measures for these procedures, we recommend that CMS consider incorporating the following elements into the foundation for the new quality measurement program:

- Criteria for appropriate patient selection for outpatient hip and knee replacement;
- Requirements for patient and family education both before and following the procedure;
• Thorough assessment of social supports and home environment for functional recovery;
• Expertise and experience of the clinical and surgical teams managing same day discharge;
• Experience of the outpatient facility and the program itself with the procedures; and
• Evidence-based protocols and pathways for both the surgical procedure and care immediately following the procedure.

In addition, AdvaMed recommends that patients should be informed about the existence of a specific quality measurement program for outpatient knee and hip replacement procedures and physicians/surgeons should discuss the elements of the program with their patients. It is through discussions across the elements of the quality measurement program that a decision about the most appropriate setting for knee and hip procedures can be a genuine shared decision between patients and their surgeons.

VII. Proposed Nonrecurring Policy Changes

i. Proposal and Comment Solicitation on Method to Control Unnecessary Increase in Volume of Outpatient Services

The proposed rule includes several recommendations that target increases in outpatient department volume. In this section of the rule CMS expresses concern regarding the growth in the rate of utilization, and resultant costs for services rendered in this setting. The Agency also expresses concern over the level of Medicare spending attributable to services rendered in this care setting and the resultant level of beneficiary co-pays tied to these services, especially when compared to the cost of receiving similar services in the physician office.

While AdvaMed understands CMS’s concern, we would caution the Agency to be judicious in making any changes that could adversely impact beneficiary access to care in the most appropriate setting. Increases in the volume of outpatient services could be tied to several causes. For instance, an increase in volume in one setting, such as outpatient, could signal a decrease in services in another setting (i.e. migration of services that were previously inpatient to the outpatient department). To better understand the basis for these changes CMS should evaluate the trends in volume (increases, decreases, and consistency) across settings prior to making any adjustments to control for volume increases in the outpatient setting. We further ask CMS to consider the ability of some beneficiaries to access care in a physician office and to make sure that any changes that are made allow patients the ability to access services at outpatient departments as needed.
During a recent meeting of the Advisory Panel on Hospital Outpatient Payment (Panel) there was significant discussion by Panel members and interested stakeholders regarding this proposed policy. In response the Panel issued the following recommendation, “The Panel recommends that CMS study the matter to better understand the reasons for increased utilization of outpatient services.”

- **AdvaMed recommends that CMS adopt the Panel recommendation to continue to study this issue for CY 2019.**

CMS is also soliciting comments on specific questions related to increases in outpatient volumes. While AdvaMed is aware of the CMS concerns, we are also cognizant of the multitude of factors and safeguards that must be considered and put in place to ensure against adverse outcomes from implementation of a policy change. Specifically, AdvaMed urges the Agency to consider the impact of severity of illness and patient demographics on outpatient volume prior to moving forward with any changes. These factors are critical in beneficiary decision making regarding the site of service in which they seek care. For these very same reasons, we would discourage CMS from implementing any prior authorization requirement as such policies could have negative effects on the health and safety of beneficiaries and could result in significant financial burdens for providers. Although a proposal to reduce outpatient service payments to physician office rates could result in lower co-payments, the reasons for which beneficiaries seek care in both settings are not fully vetted enough to validate changing the current policy. Beneficiaries should continue to have the choice to seek care in the setting that they deem to be most convenient and most appropriate.

- **AdvaMed recommends that CMS not make any modifications to the outpatient payment policy to control for volume increases for CY 2019.**

ii. **Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider**

CMS proposes to pay for certain services in “excepted” off-campus provider-based departments (PBDs) under the Physician Fee Schedule (PFS) instead of the OPPS. “Excepted” off-campus PBDs are those that billed Medicare under the OPPS for covered outpatient services furnished prior to November 2, 2015, and currently are paid for their services under the OPPS. An off-campus PBD’s services would be subject to this proposed change if the department did not furnish services in the same clinical family during a baseline period, such as November 1, 2014 through November 1, 2015. CMS would pay for these services at 40 percent of the OPPS rate, an amount CMS has determined to be a “PFS-equivalent” rate. For example, if an off-campus department that provided medical oncology services prior to November 2015 subsequently added radiation oncology services, the radiation oncology services would represent a new
“clinical family” and would be reimbursed at 40 percent of the OPPS, effective January 1, 2019, instead of the full OPPS rate that applies now. CMS should not implement the proposed change in payment for expanded service lines at excepted off-campus provider-based departments.

AdvaMed opposes expansion of the PBD restrictions to clinical families and the proposed severe cut in payment – that could discourage hospitals from expanding their services lines to offer the most appropriate care, including care using advanced medical technologies, in clinically appropriate and convenient settings. It would hurt hospitals’ ability to adjust their service offerings to meet newer standards of care and the ever-changing needs of their patients. If implemented, this drastic payment cut would penalize hospitals that invested in providing new lines of service and would impede further investment in new innovative technologies.

We also oppose the proposal because it conflicts with the statute’s clear requirements that certain off-campus PBDs departments continue to be paid for their services under the OPPS. As amended by section 603 of the Bipartisan Budget Act of 2015, the statute provides that, as of January 1, 2017, “applicable items and services” furnished by “an off-campus department of a provider” would not be included in the definition of “covered OPD services” that are reimbursed under the OPPS. These services would be reimbursed under “the applicable payment system,” which CMS has determined to be the PFS. The definition of “off-campus department of a provider” excludes departments that were billing under the OPPS for covered OPD services furnished prior to November 2, 2015. However, this definition does not differentiate between families of covered OPD services. Thus, these “excepted” off-campus PBDs should continue to be paid under the OPPS for all items and services furnished to Medicare outpatients. It is unreasonable for CMS to claim that these departments are “excepted” for some services but not others. If an off-campus PBD was billing Medicare under the OPPS as of November 2, 2015, then that department should be excepted from the change in payment methodology that otherwise applies under section 603, regardless of any changes in the services it offers.

Additionally, although the statute requires “nonexcepted services” to be paid under another payment system, which CMS has identified as the PFS, the proposed payment rates are not “PFS-equivalents.” CMS arrived at the “PFS relativity adjuster” of 40 percent by comparing the OPPS and PFS rates for the services most commonly billed in off-campus departments, including clinic visits. CMS has acknowledged, however, that “due to the more extensive packaging that occurs under the OPPS for services provided along with clinic visits relative to the more limited packaging that occurs under the MPFS for office visits, these payment rates are not entirely comparable.” As a result, the actual PFS rate for a service might be far more than 40 percent of the OPPS rate. Moreover, because some services, such as radiation therapy services, do not have national rates established under the PFS, there is no clear basis for comparing the OPPS and PFS rates.
for these services. CMS should not subject services in excepted off-campus PBDs to a drastic and arbitrary reduction in payment based on a flawed comparison based on payment rates across payment systems.

Finally, the proposal would be extremely burdensome for hospitals and CMS to implement. Each hospital would need to examine the services it billed in the relevant baseline period, identify the APCs for those services, and compare those APCs to the list of clinical families to determine which payment methodology and modifier applies to each service provided in 2019. As CMS describes in the Proposed Rule, numerous stakeholders and the Medicare Payment Advisory Commission advised that a similar proposal in the CY 2017 proposed rule was “unnecessarily complex” and would create “significant operational challenges and administrative burden for both CMS and hospitals.”

- **AdvaMed urges CMS to reject this proposal in the final rule.**

The Advisory Panel on Hospital Outpatient Payment also deliberated this issue during their recent meeting on August 20, 2018. Considering discussion among panel members and based in part on stakeholder feedback, “The Panel recommends that CMS not implement the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions.”

- **AdvaMed also recommends that CMS adopt the HOP Panel’s recommendation, as it relates to service line expansions, and not implement this proposal.**

**VIII. Proposed Update to the Ambulatory Surgical Center (ASC) Payment System**

The CY 2019 proposed rule includes a recommendation to revise the update factor for ASCs. In lieu of continuing the current update factor of CPI-U CMS is proposing to use the hospital market basket. The proposal would include use of the market basket update through 2023 while CMS collects additional data and information related to the change.

- **AdvaMed supports changing the update factor for ASCs and believes that it will promote site neutrality in the way envisioned by the Agency. We encourage CMS to finalize the proposal.**

CMS is also proposing that the ASC Covered Procedures List (CPL) policy be modified to require that all procedures added to the list within the last 3 years be reviewed to assess safety, effectiveness, and beneficiary experience. AdvaMed is supportive of processes to maintain the integrity of the Medicare program and to protect its beneficiaries. We are also supportive of the concept that devices should operate in a manner which limits the
risk of beneficiary harm. We would encourage CMS to be judicious in moving forward with a policy to review procedures on the CPL. In formulating any review process the Agency should consult with an array of external stakeholders. Additionally, any stakeholder whose procedure is found to be deficient should be given an opportunity to provide comment and response to CMS on the issue via an administrative or other formal appeals process prior to having their procedure removed from the CPL.

i. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

AdvaMed thanks CMS for the opportunity to comment on its proposal to add to the list of Ambulatory Surgical Center (ASC) Covered Surgical Procedures and its feasibility assessment on collection of ASC cost data.

CMS is proposing expanding the list of ASC Covered Surgical Procedures to include twelve cardiac catheterization procedures which involve major blood vessels.

AdvaMed is concerned that payments rates in all settings reflect the relative resource use of each site of service and the relative risk and complexity of patients’ clinical treatments. Performing these procedures in the ASC without a mechanism to adjust for risk and the payment differential between the outpatient and ASC settings could lead to cherry picking and leave outpatient departments to treat sicker and more high cost patients.

- AdvaMed urges CMS not to add these coronary procedures to the ASC allowed list.

X. Request for Information (RFIs)

AdvaMed applauds CMS’s decision to seek information on issues related to improving the Medicare program and reducing unnecessary burdens on hospitals, physicians, and most importantly patients. Medicare’s historic mission has been to assure affordable access to the best care the U.S. health care system can offer. As the federal government’s largest health program, Medicare should also support the national mission to advance medical progress. Several Medicare regulations, policies, and procedures place unnecessary burdens on medical technology companies’ ability to provide, and Medicare patients’ ability to benefit from, new technology-based treatments, diagnostics, and cures. These burdens not only deprive Medicare beneficiaries of prompt access to appropriate treatments for their conditions but have also contributed to a significant slow-down in early stage investment in the treatments and cures of the future. We submit the following recommendation for your consideration.
Coverage and Payment of Breakthrough Technologies.

The 1997 Food and Drug Administration Modernization Act (FDAMA) legislation established a category of medical devices and diagnostics that are eligible for priority FDA review. To qualify, products must be designated by the clinical experts at FDA as offering the potential for significant improvements in diagnosis or treatment of the most serious illnesses – those that are life-threatening or irreversibly debilitating. Because these products are typically truly novel technologies, only about half the products that receive this designation are approved by the FDA—an average of about three a year. The processes by which products meeting the statutory standard for priority treatment by the FDA were spelled out in greater detail in FDA’s Expedited Access Program (EAP), and in the recently passed 21st Century Cures legislation. A review of eighteen of these products that were approved by the FDA over the last ten years found that almost all were ultimately granted Medicare coverage, but some faced significant delays, depriving patients of timely access to important treatment. It is not surprising that almost all of these products were ultimately found to be “reasonable and necessary,” since the FDA’s criteria for the designation assures that the treatments or diagnostics were effective in treating the most serious illnesses and were superior to existing alternatives.

Programs exist within the outpatient (and other payment) system(s) to accommodate additional payment for novel technologies. The outpatient program, commonly referred to as Transitional Pass-through allows patient access to novel technologies, which satisfy certain criterion, by providing hospitals with the additional resources needed to procure and disseminate them without the fear of suffering financial loss. Pursuant to this program, CMS provides payment adjustments if a novel technology used in treatment is substantially more expensive than other technologies. As data accumulate over time (generally 2-3 years), CMS may adjust its payments to reflect the cost of the new technology.

Legislation (HR 5997) has been introduced which addresses our concerns with payment for Pass-through and other technologies. Pursuant to the legislation, technologies satisfying the FDA breakthrough criteria shall automatically be deemed to have satisfied

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1 The study, which was conducted internally by AdvaMed, did not analyze whether delays were due to time needed to gain a coverage decision, a new code, or some combination of the two. Even when access was finally granted, it was not necessarily for all the FDA approved indications or in all areas of the country, since many product coverage decisions are made by local Medicare carriers rather than through national coverage decisions and the study characterized the technology as receiving a favorable coverage decision if it was covered anywhere. The technologies that were covered without any delay typically fit into an existing code and payment category, so no special Medicare coverage decision was required. The analysis excluded technologies that did not receive Medicare coverage because they were not approved by FDA for the elderly population or because they were deemed outside the scope of services covered under the Medicare statute.
the newness and substantial clinical improvement requirements for transitional pass-through and NTAP payments.

- **Advamed recommends that following FDA approval or clearance of a breakthrough device or diagnostic and application for the add-on status, CMS should provide add-on payment via the transitional pass-through or NTAP program.**

- **Advamed further recommends that Medicare Administrative Contractors (MACs) be prohibited from denying coverage and add-on payments for medical services or technologies approved for Pass-Through or NTAP status by the Secretary. Coverage should also extend to the associated service codes that are required to utilize the device or procedure.**

XI. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)—Changes to the Meeting Schedule

The announcement for the HOP Panel meeting along with the deadline for submitting statements is typically published in the Federal Register several months prior to display or publication of the proposed rule. In recent years delayed release of the proposed rule has led to a truncated period for stakeholders to develop comments for the Panel meeting – necessitating the extension of the deadline by which to submit statements. The proposed CY 2019 rule was released on July 25, 2018, two days after the initial deadline (July 23rd) for filing statements. In anticipation of a delayed rule release, CMS extended the statement filing deadline from the initial date of July 23rd to July 30th. However, despite the extension, statements for the Panel meeting were due only 2 1/2 business days following release of the proposed rule. This led to a very hasty and truncated period for stakeholders to analyze the rule and to submit relevant comments.

While stakeholders are appreciative of extensions, and the flexibility shown by CMS in granting them, that process has proven to be ineffective for the past two comment cycles. A reasonable period between publication of the rule and submission of statement is needed to allow stakeholders an opportunity to fully comprehend proposed changes and to synthesize those changes into coherent and reasonable recommendations for the Panel members. Continuing to relegate stakeholders to such abbreviated period for filing comments is a disservice to both stakeholders and Panel members. Consequently, we recommend that the approach to setting deadlines for the meeting statements be modified to avoid this situation from arising in the future.

- **Advamed recommends that the HOP Panel meeting statement submission deadlines published in the Federal Register be changed from**
a firm date to 21 days from the display of the proposed rule to permit definitive timeframes for claims analysis and statement development.

Conclusion

AdvaMed appreciates the opportunity to comment on the CY 2019 proposed OPPS and ASC rules and urges CMS to consider and incorporate our recommendations into the final rules for these payment systems. We also urge CMS to work with us and other stakeholders as the agency moves forward with the implementation and development of new and modified payment policies and to consider comments from AdvaMed members and others who will be providing detailed recommendations on both rules.

We would be pleased to answer any questions regarding these comments. Please contact DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery