September 27, 2019

Via Electronic Mail Only
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-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; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals (CMS-1717-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) 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Rule, Price Transparency of Hospital Standard Charges, the Quality Reporting Programs, and Potential Changes to the Laboratory Date of Service Policy.

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 will be commenting on a number of issues in this letter but we want to first highlight our strong support for CMS’s proposal to create a pathway for FDA-designated breakthrough technologies to more easily qualify for outpatient transitional passthrough payments. We believe that the proposed changes will provide Medicare beneficiaries more rapid access to breakthrough technologies and encourage investment in development of these technologies.
CMS recently finalized a similar provision in the final FY 2020 IPPS rule, and AdvaMed encourages CMS to similarly finalize a streamlined pathway for approving add-on payment applications for transformative innovative medical devices in the outpatient hospital setting.

AdvaMed’s detailed Comments will address the following issues:

I. Proposed Updates Affecting OPPS Payments
   i. Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices
   ii. Technical Correction to Device-Intensive Procedure List
   iii. Comprehensive APCs
      1. Payment for New Technology APCs in C-APCs: New Technology APC
      2. Placement for Radiofrequency Spectroscopy Real-Time Intraoperative Margin Assessment
   iv. Complexity Adjustments
   v. Device Edits
   vi. Evaluation and CY 2020 Proposal for Payment for Non-Opioid Alternatives
   vii. Request for Information on Specific Unfavorable Utilization Trends of Non-Opioid Alternatives

II. Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

III. Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters,

IV. Proposed OPPS APC-Specific Policies
   i. Deep Brain Stimulation
   ii. Insertion of Interlaminar/Interspinous Process Stabilization/Distraction Device
   iii. Transurethral destruction of prostate tissue by radiofrequency water vapor (steam) Thermal Therapy
   iv. Radiofrequency Magnetic-guided AV Fistula
   v. Genicular Nerve Ablation
   vi. Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS)
   vii. Hospital Outpatient: Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299)

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
   i. Coronary Interventions
   ii. Removal of Total Hip Arthroplasty (THA) from the Inpatient Only List

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

VIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
IX. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
X. Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

I. Proposed Updates 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. **Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices**

CMS is proposing to create an alternative payment pathway for transformative medical devices that are approved as breakthrough devices by the FDA and have received FDA marketing authorization. CMS is proposing that, beginning with applications submitted on or after January 1, 2020, these transformative technologies would automatically be considered to meet the outpatient transitional pass-through criteria for “substantial clinical improvement,” and would be approved for add-on payments once they demonstrate that they meet the program’s cost and other criterion.

AdvaMed applauds CMS’s proposal to create this alternative payment pathway for breakthrough technologies. AdvaMed has long advocated for immediate transitional coverage and add-on payments for breakthrough technologies and we enthusiastically support CMS’s efforts to create a more streamlined pathway for approving add-on payment applications for these transformative innovative medical devices. We believe that the proposed changes will provide Medicare beneficiaries more rapid access to breakthrough technologies and encourage investment in development of these technologies.

AdvaMed believes that this proposal will help ensure that patients have seamless access to new innovations and we urge CMS to apply the pass-through add-on for breakthrough technologies for the full three-year period. We also urge CMS to provide three-full years of coverage for all technologies approved for transitional pass-through.

AdvaMed appreciates CMS’s proposal to establish an alternative pathway for device pass-through payment status applications for devices that are part of the FDA’s Breakthrough Devices Program. CMS recently finalized a similar provision in the final FY 2020 IPPS rule, and AdvaMed encourages CMS to similarly finalize a streamlined pathway for approving add-on
payment applications for transformative innovative medical devices in the outpatient hospital setting.

The breakthrough devices program has replaced the Expedited Access Pathway program [FDA, Breakthrough Devices Program, last accessed at https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program on September 9, 2019.] AdvaMed recommends that CMS also consider devices that had previously entered the FDA’s Expedited Access Pathway program and are subsequently granted breakthrough status as breakthrough for purposes of the proposed alternative pass-through program.

CMS proposes to apply this new alternative to applications for pass-through payment that are received on or after January 1, 2020. Presently pass-through applications are received and evaluated on a quarterly basis. CMS proposes to continue this schedule for evaluating and approving applications and AdvaMed supports this.

The current schedule for submitting applications is as follows:

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<th>Complete application submitted by the first business date in:</th>
<th>Earliest effective date for pass-through status:</th>
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<tr>
<td>March</td>
<td>July 1</td>
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<td>June</td>
<td>October 1</td>
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<tr>
<td>September</td>
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<td>December</td>
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The quarterly submission schedule that is currently in effect would require applications to be submitted by the September 2019 deadline to be considered for pass-through status effective January 1, 2020. Applications filed by the December 2019 deadline would be eligible for pass-through status no earlier than April 1, 2020. The intent of the proposal appears to support the ability of these FDA Breakthrough Program approved devices to get to patients as soon as possible assuming they meet the other established criterion. Therefore, AdvaMed does not believe applicants should be required to hold off on applying for pass-through status until January 1, 2020, which is out of alignment with the current application calendar (and would delay pass-through status until July 1st), to qualify for the new alternative.

- **To minimize confusion and in order to align with the current process for review of applications that would have been eligible for pass-through payment on January 1, 2020, AdvaMed recommends that the new breakthrough alternative apply to any applications submitted by or after the September 2019 due date.**

AdvaMed also believes there is an opportunity to further clarify and improve the cost criterion for transitional pass-through. Section 1833(t)(6)(D)(ii) of the Social Security Act allows the Secretary to determine costs associated with the pass-through device, as do the 2002 and 2004 final outpatient rules. However, the CMS pass-through application only considers device costs in determining eligibility for pass-through status. Some procedures require other devices in order to properly place or utilize the novel device. In these instances considering only the cost of the
novel device can lead to an understatement of true costs. It is therefore critical to include the cost of the other devices in calculating the true total cost of the procedure for purposes of determining whether the novel device meets the transitional pass-through cost criterion.

- AdvaMed asks CMS to consider these additional device costs when determining whether the transitional pass-through criteria have been satisfied.
- For purposes of the proposed pass-through alternative, AdvaMed also asks CMS to clarify that APC rate data for the year closest to when the applicant expects to obtain pass-through status will be used for the pass-through cost test.

ii. Technical Correction to Device-Intensive Procedure List

CMS does not include CPT code 22612, Lumbar spine fusion, on 2020 NPRM Device Intensive List. However, Addendum P, 2020 NPRM HCPCS Offsets, indicates that CPT code 22612 has a device offset of 43.50%, which exceeds the CMS threshold of 30%. AdvaMed requests that CMS correct the 2020 Final Device Intensive List by adding CPT code 22612.

iii. 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 concerns regarding whether the rates associated with the C-APCs adequately or accurately reflect all related procedures and costs. This is of concern as CMS continues to expand the number of packaged and bundled services, including proposing the addition of two additional C-APCs in CY 2020.

- AdvaMed recommends that CMS continue to analyze the claims data and to report on the impact of comprehensive APC changes on all affected codes and any impacts on patient access to services that are bundled under the comprehensive APCs.

In the CY 2020 proposed OPPS and ASC rule, CMS proposes to create two new C-APCs: C-APC 5182 (Level 2 Vascular Procedures) and C-APC 5461 (Level 1 Neurostimulator and Related Procedures).

- AdvaMed supports CMS’s proposal to create C-APC 5182 (Level 2 Vascular Procedures) and C-APC 5461 (Level 1 Neurostimulator and Related Procedures) and encourages CMS continue to evaluate outpatient charge and cost data for additions to the list of C-APCs during future rulemaking periods.

1. Payment for New Technology APCs in C-APCs
CMS clarifies its Comprehensive APC policy in the proposed CY 2020 OPPS rule stating, “As discussed in section II.A.2.b.(1) of the CY 2019 OPPS/ASC final rule with comment period (82 FR 58837 through 58843), we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service.” The rule also includes a proposal to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a “J1” service assigned to a C-APC.

New Technology APCs were developed by CMS so that hospitals could be reimbursed for new procedures or services while CMS collects and reviews sufficient single claims data to determine appropriate clinical APC assignment.

In the CY 2016 OPPS/ASC final rule with comment period, CMS expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the “Comprehensive Observation Services” C–APC (C–APC 8011). Services within this APC are assigned status indicator “J2”.

In the proposed CY 2020 OPPS/ASC rule, CMS is proposing to package payment for new technology APC services that appear on a claim with another service, that is assigned to a C-APC with a J2 status indicator, into the comprehensive service. CMS explains their concern that all of the costs may not be included in claims for unpackaged new technology procedures – which could impact assignment of the new service to the most appropriate clinical APC. CMS also states that New Technology APCs represent new procedures or specialized diagnostic tests for small populations, and, in the case of the former, could be billed as a separate primary procedure, and separate from C-APC 8011.

The proposal to package New Technology APCs within C-APC 8011 is contrary to the logic of CMS’s policy to pay separately for new technology services for all other C-APCs with “J1” indicator – namely to track the claims associated with them for future APC assignment.

- **AdvaMed disagrees with the proposal and requests that CMS allow separate payment for new technology services when billed on a claim for observation service under C-APC 8011.**

2. **New Technology APC Placement for Radiofrequency Spectroscopy Real-Time Intraoperative Margin Assessment**

The AMA created a new CPT code for radiofrequency spectroscopy real-time intraoperative margin assessment at the time of partial mastectomy with report that went into effect on July 1, 2019. The test is presently proposed to be bundled under the CY 2020 OPPS. This procedure could greatly impact the outcomes for breast cancer patients by reducing the risk of re-excision
and other effects associated with post-surgical discovery of positive margins. For this reason, AdvaMed believes that it should be unbundled and billed as a stand-alone procedure, per the intent of the AMA, and should be placed in a new technology APC for CY 2020 so that additional data regarding use of the procedure can be collected.

- **AdvaMed recommends that CPT code 0546T be assigned to new technology APC 1518 (Level 18, $1601-$1700) for CY 2020.**
- **Alternatively, AdvaMed recommends that 0546T be assigned to APC 5091 and designated for complexity adjustment to APC 5092 for CY 2020.**

iv. **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 adequate payment under the comprehensive APC methodology. We supported the changes made to the complexity adjustment criteria in the CY 2019 final rule but believe that important opportunities to refine the methodology remain.

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

v. **Device Edits**

AdvaMed has previously expressed concern regarding the elimination of device edits outside of the context of device-intensive procedures. Device edits have historically been very useful in ensuring the collection of accurate cost data.

- **AdvaMed requests that CMS continue to monitor claims to evaluate the need to reinstate all device edits.**
- **AdvaMed notes that CMS requires providers to accurately report items and services furnished to patients. Therefore, AdvaMed recommends that CMS require hospital outpatient departments to report the appropriate device code rather than “any device code” consistent with long-standing Medicare billing guidelines.**

vi. **Evaluation and CY 2020 Proposal for Payment for Non-Opioid Alternatives**

AdvaMed has raised concerns in the past regarding the impact of surgical supply packaging policies on the use of non-opioid alternatives. Specifically, we have commented on the need to
unbundle certain of these supplies to incentivize use of devices which could be instrumental in helping to combat the opioid crisis that is confronting our nation. While we appreciate CMS considering this issue, we do not agree with the outcome that CMS has reached in the proposed rule—namely that CMS will, “continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020”.

The proposed rule cites CMS evaluation for one drug that functions as a surgical supply in making its determination that the packaging of drugs into surgery costs does not create a disincentive to their use in the outpatient department. CMS similarly cites review of the utilization for nerve block and neuromodulation alternatives, without providing any detail or data, and states that they have shown increased utilization thereby giving the agency justification to continue packaging device costs into the surgical procedure. Nowhere in the rule does CMS reference the inability of other devices to gain uptake in use because of their packaged payment policies.

Several devices, outside of those cited in the rule, are bundled and will likely not show improvements similar to what CMS cites for Exparel, nerve blocks, and neuromodulators. We believe that evaluating the impact of packaging policies by focusing solely on whether there has been a decline in the use of some non-opioid medical devices misses the mark. In order to make a more reasoned determination regarding the need to unpackaged opioid alternative devices in the outpatient setting, AdvaMed believes that CMS should evaluate the utilization of all said devices and assess their rate of utilization as compared to post-surgical prescribing of opioids.

Removing the barriers created by bundled payment and establishing separate payment for the opioid alternative devices used in surgical procedures gives healthcare providers the freedom to evaluate pain management treatments based on effectiveness and appropriateness without being unduly influenced by the costs of the available options.

In some situations, packaging policies are reasonable and not detrimental to larger interests. However, when hospitals have almost no additional post-operative pain management costs associated with opioids versus, for example, an average of $359 in additional costs for an ambulatory disposable continuous nerve block infusion pump, packaging creates a financial barrier to viable and effective non-opioid pain management alternative.

- **CMS should pay separately for non-opioid device alternatives in both the HOPD and ASC setting, especially when there is peer reviewed, published evidence demonstrating opioid reduction and effective pain management.**

  vii. **Request for Information On Specific Unfavorable Utilization Trends Of Non-Opioid Alternatives**

CMS has requested information on the types of incentives the health system creates that unfavorably impact utilization trends of non-opioid alternatives. One important unintended
deterrent to non-opioid alternatives is related to mental health requirements for access. There are FDA-approved therapies that could help patients better manage their pain where access is currently impeded due to the requirement that a psychological evaluation be done in person before the patient can receive certain therapies. Specifically, patients who want to use spinal cord stimulation (SCS) to manage chronic pain are first required to undergo an in-person psychological evaluation. This poses a significant barrier to treatment, as patients may be delayed in finding a provider with availability and often must travel far distances for their evaluations, which may not be possible for socioeconomic or health reasons. We propose the requirement for these evaluations for SCS should be eliminated or, at a minimum, these evaluations should be allowed to be done via telehealth instead.

- **AdvaMed recommends that CMS either eliminate this requirement or add the CPT codes listed below to the list of payable telehealth codes:**
  - 96130 - Testing & evaluation (first hour)
  - 96131 - Testing & evaluation (each additional hour)
  - 96136 - Test administration & scoring by a professional (30 minutes)
  - 96137 - Test administration & scoring by a professional (additional 30 min)
  - 96138 - Test administration & scoring by a technician (additional 30 min)
  - 96139 - Test administration & scoring by a technician (additional 30 min)

- **AdvaMed also urges CMS to continue to work with interested stakeholders to monitor and correct policies that discourage use of non-opioid alternatives.**

II. **Proposed Requirements for Hospitals To Make Public a List of Their Standard Charges**

As part of its ongoing focus on reducing health care costs through hospital cost and charge transparency improvements, CMS is proposing to require hospitals to make their standard charges for all items and some “shoppable” services publicly available. The proposal would extend to charges that have been negotiated between hospitals and third-party payers.

AdvaMed agrees with the concept of providing patients with information that allows them to make informed decisions regarding their health care choices, including spending. We believe that any such information should be delivered to consumers in a format that is transparent and that meets consumer needs related to both price and quality of care. Determining the types of information to make available for this purpose is critical.

AdvaMed would like to comment on the importance of market competition within the US health care system. The reliance on private negotiations among many individual stakeholders is a hallmark of this system. While there are certainly aspects of the US health care system where improvements are possible, we are generally concerned about this and other proposals that may threaten some of the fundamental aspects of a competitive market that relies on private negotiations.
The proposed rule lists several reasons why CMS believes that access to hospital charges, negotiated with third parties, can benefit consumers. The rule includes an example regarding a health care consumer’s coinsurance amount being a percentage of hospital charges for a service and infers that lower negotiated charges result in a lower coinsurance amount. The rule also notes that a growing number of insured consumers who are choosing to pay cash out-of-pocket for some services, as opposed to paying the coinsurance, can benefit from this type of information.

CMS also acknowledges that the potential impact resulting from the release of negotiated rates is largely unknown. In a statement on this proposal, the American Hospital Association expressed its concern that the proposal “could seriously limit the choices available to patients in the private market and fuel anticompetitive behavior among commercial health insurers.” Similar views on price transparency have been previously expressed by the Federal Trade Commission (FTC) policies. In these statements the FTC has stated, “When networks are selective, providers are more likely to bid aggressively, offering lower prices to ensure their inclusion in the network. But when providers know who the other bidders are and what they have bid in the past, they may bid less aggressively, leading to higher overall prices.” In a letter from the FTC on this same issues that agency addresses the many challenges in presenting information in a format and medium that is meaningful to and understood by consumers.

AdvaMed would note that the type of data disclosure being requested from hospitals in the proposed rule is prohibited for laboratory services. Section 1834A of the Social Security Act requires private payer rates reported by applicable laboratories to be kept confidential by CMS—thereby requiring CMS to keep contracted rates between hospitals and third-party payers for laboratory services confidential. The logic undergirding that provision should apply to the disclosure of similar information by hospitals.

- **AdvaMed urges CMS to proceed cautiously as it considers policies that could be detrimental to existing competitive health care markets.**

### III. Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters, and Related Medicare Payment Issues

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CMS is soliciting feedback related to the value of chargemaster charges in setting hospital payment. AdvaMed believes that this issue is one that is highly complex and will merit extensive thought and discussion prior to reaching a determination regarding next steps. The chargemaster has been in use for many years as the means of tracking and reporting hospital costs. Consequently, we ask CMS to be cautious in the development of any policy changes in this area due to the potential of system disruption. We recommend that CMS convene a series of meetings and other public forums wherein they solicit the input and feedback of interested stakeholders regarding the best way to resolve concerns related to hospital cost reporting, chargemaster updates, and patient costs.

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

i. Deep Brain Stimulation

CPT codes 95983 and 95984 were approved for use effective January 1, 2019. The primary CPT code for deep brain stimulation (DBS) programming, 95983, was assigned to APC 5741 (Level I Electronic Analysis of Devices) and is proposed to remain in that same grouping for CY 2020. The add-on CPT code, 95984, describes additional time spent on DBS programming and is proposed to be packaged, consistent with its predecessor code. AdvaMed has concerns regarding the placement of CPT code 95983 into APC 5741 as we do not believe that payment for this grouping adequately reflects the resources used by hospitals in performing these procedures and does not align with the assignment of the predecessor CPT code which was included in APC 5742 (Level 2 Electronic Analysis of Devices). The HOP Panel was sympathetic to these concerns and recommended that CMS move CPT code 95983 to APC 5742 (Level 2 Electronic Analysis of Devices) for CY 2020, if the final data that are available in time for consideration of the Final Rule are consistent with preliminary data.

- **AdvaMed recommends that CMS move CPT code 95983 to APC 5742 (Level 2 Electronic Analysis of Devices) for CY 2020.**

ii. Interlaminar/Interspinous Process Stabilization/Distraction Device

CMS has proposed for January 1, 2020 to move CPT code 22869 “Insertion of interlaminar/interspinous process stabilization/distraction device without open decompression or fusion, including image guidance when performed, lumbar; single level” from APC 5116 to 5115. This change in 2020 would result in a 22% decrease in payment to Outpatient Hospital and Ambulatory Surgical Center facilities.

The charges that led to changing the APC placement for these procedures are the result of incorrect facility reporting. This is supported by the fact that the geometric mean cost for CPT 22869 from 2018 to 2019 decreased by 30% while the median cost only decreased by 4%, indicating that one or more outlier facilities could have drastically changed the results. AdvaMed believes that CPT code 22869 should remain in APC 5116 in CY 2020, as it was in 2019.
Had procedures been properly reported with all claims appropriately representing the charges for the operating room costs and the cost of the implantable device, the geometric mean costs for CPT code 22869 would be more like those for APC 5116. The hospital in question has indicated its intent to correct issues with the charges and costs reported for procedure 22869, therefore we anticipate that geometric mean costs will ultimately return to the levels previously seen. At the recent meeting of the HOP Panel members recommended that CMS review claims from the outlier hospital for HCPCS code 22869 and consider the appropriate APC for CY 2020 assignment on the basis of the review.

- **Thus, to avoid creating payment instability and placing an undue financial burden on facilities performing this procedure, and to avoid unintentionally creating a payment deterrent to a proven opioid alternative, AdvaMed requests that CMS maintain the current assignment of this procedure to its current, CY 2019, APC assignment of 5116 rather than reassigning to APC 5115 as proposed for CY 2020.**

iii. **Transurethral destruction of prostate tissue by radiofrequency water vapor (steam) Thermal Therapy**

AdvaMed believes that CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy) should be placed in APC 5374 (Level 4 Urology and Related Services).

The procedures that are most clinically similar to 53854 are the other two benign prostatic hyperplasia (BPH) procedures:
- 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy)
- 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy)

The primary difference between each of these codes is simply the energy source used to destroy or shrink prostate tissue: 53850 uses microwave energy, 53852 uses radiofrequency energy, and 53854 uses radiofrequency generated water vapor thermotherapy. Otherwise, the procedures and resources used in these procedures are similar.

Likewise, the CY 2020 proposed rule claims data for C9748 (the predecessor for 53854) supports reassignment. The geometric mean cost for C9748 has increased significantly to $2,321, placing it more in line with APC 5374 (APC geometric mean cost of $2,986) rather than APC 5373 (APC geometric mean cost $1,755).

- **AdvaMed recommends that CPT 53854 be assigned to APC 5374 for CY 2020 as that APC is more clinically and resource similar.**

In the proposed rule, 53854 is not assigned device intensive status and the predecessor code, C9748, was not listed in Addendum P. AdvaMed believes that based on the cost of the disposable insertable devices used in the procedure, 53854 should be designated as an ASC device intensive procedure for 2020 because the 30 percent device threshold would be exceeded.
for both APC 5373 and APC 5374. We request that CMS compute the device offset for C9748 in the final rule to determine if the device exceeds the threshold. If so, AdvaMed recommends that CMS assign ASC device intensive status to CPT code 53854.

iv. **Radiofrequency Magnetic-guided AV Fistula**

AdvaMed appreciates CMS’s decision to create Level II HCPCS code C9755 (RF magnetic guided AV fistula) and to assign the code to C-APC 5193 for CY 2019. That decision enabled providers to begin utilizing this technology in the ESRD patients who need it. However, we are concerned that the payment associated with the APC in which C9755 is housed is insufficient and is thereby impairing patient access to this technology.

Data were presented to the HOP during its annual meeting, and discussed with the Division of Outpatient Care indicating the following:

- Geometric mean costs for C9755 were $12,960.
- 2019 national payment for APC 5193 is $9,669
- Thus, costs for C9755 exceed payment by $3,291.

Presently, C9755 is in the same APC grouping as CPT codes 36903 and 36905 which describe re-interventions to existing AV fistulas (i.e., after fistulas have already been created) – not the creation of an AV fistula. Additionally, CPT 36906, which also represents a re-intervention into an existing AV fistula, is assigned to APC 5194. The geometric mean costs for C9755 exceed those of CPT 36906 by nearly $1,000. Of note, C9755 a novel AV fistula procedure that provides substantial clinical benefits and has higher geometric mean costs is assigned to a lower paying APC. This seems contrary to the Agency’s goals and impedes adoption of C9755.

We are therefore asking CMS to assign C9755 to APC 5194 for CY 2020. Given the focus on this costly and challenging patient population, as well as the data analysis presented, we believe that transitioning C9755, RF magnetic guided AV fistula from APC 5193 to APC 5194 is merited for CY 2020, and would benefit providers and Medicare beneficiaries.

- **AdvaMed recommends that CMS reassign C9755, RF magnetic guided AV fistula to APC 5194 based on available cost data. This change also supports HHS’s and the Administration’s priorities to better manage patients suffering from ESRD.**

v. **Genicular Nerve Ablation**

The CPT Editorial Panel developed the following new codes to diagnose and treat chronic nerve pain in the genicular nerves of the knee and nerves in the sacroiliac (SI) joint:

**Genicular Nerves:**

Ablation Procedure
Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed.

**Sacroiliac Joint Nerves:**

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<th>Ablation Procedure</th>
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<td>6XX01</td>
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<td>Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography).</td>
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These codes are important steps toward treating chronic pain at the nerves that cause pain, rather than through the less effective and more problematic use of systemic opioids. Previously, genicular and SI denervation was reported using CPT code 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) which did not properly capture the work and resources required for genicular or SI denervation using radiofrequency ablation.

In the CY 2020 proposed rule, CMS assigned 64XX1 (genicular nerve) to APC 5443 which is for Level 3 Nerve Injections and is proposed to pay $808.58. In contrast, CMS assigned 6XX01 (SI joint nerve) to APC 5431 which is for Level 1 Nerve Procedures and is proposed to pay $1,747.26.

AdvaMed believes that 64XX1 (genicular nerve) has been assigned to the wrong APC and should, instead, be properly assigned to APC 5431. Assigning this procedure to APC 5431 will maintain consistency with the SI joint nerve ablation code, 6XX01, as well as other nerve destruction codes. 64XX1 is not a nerve injection, as suggested by APC 5443; it is a nerve procedure just like 6XX01. Moving 64XX1 to APC 5431 will recognize the device costs and procedure time associated with genicular nerve ablation and will help to ensure that providers are able to offer patients with chronic knee pain an effective alternative to systemic opioids.

- **AdvaMed recommends that CMS assign 64XX1 to APC 5431 for CY 2020.**

vi. **Magnetic resonance image guided high intensity focused ultrasound (MRgFUS)**

Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed (0398T) received FDA approval in July 2016. In CY 2019 the procedure was assigned to C-APC 1575 and reimbursed at $12,500.51. This APC placement was
determined using a variety of different sources of information to establish payment rates for such services.

CMS is proposing that 0398T continue to be included in C- APC 1575 for CY 2020 as well. For CY 2020, CMS used their equitable adjustment authority to stabilize the payment rate between CY 2019 and CY 2020 considering the limited number of claims data to determine an appropriate APC assignment.

CMS is also soliciting comments on establishing a methodology to create payment rates for low-volume new technology services described by CPT code 0398T. To ensure that severe underpayment for this procedure does not deter hospitals from furnishing it to qualified beneficiaries, and does not deter further development of this technology, we respectfully urge CMS to use median costs for rate setting for CPT code 0398T until such time that enough claims data are available.

- **AdvaMed recommends that CMS finalize assignment of 0398T to C-APC 1575.**
- **AdvaMed recommends that CMS employ utilizing the median cost for the rate setting of CPT code 0398T.**

vii. **Hospital Outpatient: Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299)**

AdvaMed requests that CMS continue to provide a hospital outpatient payment for implantable cardiovascular physiologic monitor system and subcutaneous cardiac rhythm monitor system remote device interrogations. Currently these services are reported with CPT 93299, which is assigned to APC 5741 with a status indicator of Q1. On January 1, 2020, CPT code 93299 will be deleted. CMS is proposing to create a new HCPCS code GTTT1 to be used by hospitals and physicians to report this service. The intent of deleting 93299 was to eliminate the need for a separate code and to report the services with a technical component to 93297 and 93298.

- **AdvaMed recommends that CMS aligns its payment policy with the coding change rationale and continue to allow hospitals to bill for this service using CPT codes 93297 and 93298. AdvaMed recommends that the technical component of these codes be assigned to APC 5741.**

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 2020 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. CMS is also proposing two other polices that would involve a complexity adjusted 4- to 12-week payment for skin substitutes products and a single payment for all skin substitute products. AdvaMed
appreciates the time and thought that CMS put into the various policies that were included in the proposed rule and CMS’s recognition of the wide array of stakeholder views and concerns. The host of options presented reflect the investment of substantial time and effort in being responsive to stakeholder input. While AdvaMed appreciates this effort we are unable to affirmatively support any of the proposals at this time.

We are unable to weigh in definitively on any of the options as we still have outstanding questions, especially regarding the complexity adjusted 4- to 12-week payment. That proposal would appear to create payment for wound care treatment rendered over a 4- to 12-week period of time that are subject to complexity adjustment. AdvaMed has several questions regarding how this would work in reality and offers some observations that may improve the feasibility of this concept. For example, would CMS plan to create separate APCs to accommodate the payments for the 4- to 12-week period and if so, when would a complexity adjustment be applied? We note that for complexity adjustment to have a meaningful payment impact, there must be adequate payment levels to adjust into. What factors would CMS consider in determining complexity adjustment criteria (i.e. would traditional OPPS criteria apply)? It is our observation that the traditional criteria may need to be modified to be workable in this policy context. If CMS were to place the codes comprising these 4- to 12-week periods into existing APCs which ones are contemplated? Our initial analysis reveals that many of the patients treated with skin substitute products receive 3 or more applications during a 4-week period, some of which are billed with add-on codes, and that complexity adjustment can capture some of the variation in costs. However, CMS would need to consider more than just code pairs for the purposes of determining the applicability of a complexity adjustment in order for that cost variation to be captured by complexity adjusted payments.

AdvaMed realizes the difficulty in resolving issues related to payment for skin substitute products and appreciates CMS’s ongoing effort to reach a resolution that not only is responsive to the needs of manufacturers but that ultimately serves the purpose of ensuring patient access to the products that best suit their treatment needs. We look forward to continuing to weigh in on this important issue as more information is made available and look forward to more guidance on a complexity adjusted option from CMS. We note that the payment system may better capture variation in costs and improve payment accuracy for resource intensive cases if payments were risk adjusted for diagnoses and co-morbidities. Recognizing the realities of the outpatient prospective payment system we, encourage CMS to consider developing a mechanism for better determining the care received by patients by implementing methods (e.g. requiring use of a diagnosis code on claims) that will provide a fuller picture of the patients receiving care and the factors that may influence the level of treatment they require.

VI. Removal of Total Hip Arthroplasty (THA) from the Inpatient Only List

CMS proposes to remove from the inpatient only (IPO) list the following CPT code:

27130, Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft.
AdvaMed recommends that CMS consult with the appropriate specialty societies on the suitability of removing THA from the IPO list. If CMS does remove THA from the IPO list, we encourage CMS to work with those specialty societies on patient selection criteria and facility qualifications to perform outpatient THA procedures. For instance, this could involve CMS guidance on patient risk profile predictive tools and patient education regarding potential risks and benefits of same day discharge.

If CMS removes THA from the IPO list, CMS must ensure that surgeons and their patients ultimately decide whether the inpatient or outpatient setting is most appropriate, based on individual patient clinical considerations. We therefore recommend that CMS issue educational guidance to providers and Medicare contractors, similar to MLN Matters article (SE 19002), reinforcing that surgeons determine whether a particular THA procedure should be performed on an inpatient or outpatient basis, and there is no presumption that THAs should be performed on an outpatient basis. Similar guidance should be provided specifically to Medicare Advantage (MA) plan sponsors to ensure that physicians may select the appropriate site of surgery, inpatient or outpatient, for MA beneficiaries.

AdvaMed supports CMS’s proposal to provide an exemption from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organizations referrals to Recovery Audit Contractors (RACs), and RAC “patient status” site-of-service reviews for procedures that are removed from the IPO list. This policy would apply to THA procedures if CMS finalizes removal from the IPO list. However, we believe that this exemption period should be extended to two years, rather than one, to align with CMS policy when TKA was removed from the IPO list, and to provide adequate time for provider and contractor education and for developing appropriate patient and facility selection criteria.

Finally, we encourage CMS to require that hospitals report a specific joint implant code (C1776), rather than any device code, on OPPS THA claims. This would promote more accurate collection of cost data to ensure appropriate APC assignment. More generally, we believe that requiring a specific device-to-procedure edit would be valuable whenever device-intensive procedures come off the IPO list or when new device-intensive procedure codes are established.

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

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i. **Coronary interventions**

AdvaMed urges CMS to consider delaying further expansion of coronary interventions to the ASC covered procedure list until CMS can analyze the data from its addition of the twelve cardiac catheterization procedures earlier at the beginning of CY 2019.

AdvaMed continues to be concerned by the differences in mandated safety requirements between ASCs and hospital outpatient departments, particularly when dealing with cardiac procedures where complications can be complex. ASCs currently have minimal emergency requirements and carry a minimal set of emergency equipment. When patients need emergency care beyond the capabilities of the ASC, the facility is required to have an “effective procedure” for the immediate transfer to a “local hospital”. However, “local” is undefined, meaning patients could be transferred over significant distances to receive emergency care. Currently, we do not have adequate information regarding the safety of patients being seen in the ASC, as only one-third of ASCs voluntarily disclose how often patients experience emergencies that necessitate transfer to an emergency department. In the interest of patient safety, ASCs should be required to meet the same cardiac procedure safety standards as hospital outpatient departments before any additional cardiac procedures are moved to the ASC setting.

- **AdvaMed recommends that CMS not continue adding coronary interventions to the list of ASC covered procedures until further analysis is undertaken and new standards are developed to adequately protect patients.**

ii. **Addition of Total Knee Arthroplasty (TKA) to ASC Covered Procedures List**

CMS proposes adding TKA procedures (CPT code 27447) to the ASC Covered Procedures List effective January 1, 2020. AdvaMed encourages CMS to consult with the relevant specialty societies on the clinical suitability of adding TKA procedures to the ASC setting for the Medicare population. If CMS adopts this policy, CMS should work with the specialty societies to identify appropriate protocols for candidate and facility selection and for patient education on benefits and risks. Again, it is imperative that physicians have the choice of the appropriate site of care for their particular patients, whether that setting is the inpatient hospital, outpatient hospital, or ASC. Furthermore, this physician discretion must apply with regard to both FFS and MA patient treatment decisions. We urge CMS to undertake contractor and provider education to underscore the primacy of clinical considerations in site of care determinations. Furthermore, if CMS adds TKA to the ASC Covered Procedures List, we recommend that CMS monitor the results of ASC-17 (NQF 3470), Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, to assess any changes in complication rates as TKA procedures are introduced into the ASC setting.

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7 Patient education should also include a discussion of the implications of ASC selection on beneficiary cost sharing obligations.
Finally, we note that under current law, beneficiary copayments for OPPS procedures are capped at the inpatient deductible whereas no such cap exists for beneficiary copayments for ASC procedures. Beneficiaries will thus pay more for a TKA procedure in an ASC as compared to a hospital outpatient department (approximately $1,728 versus $1,364). We therefore recommend that CMS ensure beneficiaries have advance information regarding cost-sharing obligations to inform their decisions regarding site of service for procedures.

VIII. Hospital Outpatient Quality Reporting Program

AdvaMed supports CMS’s proposal to adopt for the Hospital OQR Program the following four ASC Quality Reporting Program measures: ASC-1: Patient Fall; ASC-2: Patient Burn; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; ASC-4: All-Cause Hospital Transfers/Admissions. Given that many procedures may be performed in either the hospital outpatient department or ASCs, aligning these critical patient safety measures may help beneficiaries make more informed site of care decisions.

IX. ASC Quality Reporting Program

AdvaMed supports CMS’s proposed adoption of the following quality measure under the ASCQR Program beginning with the CY 2024 payment determination:

ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

AdvaMed agrees that this measure would provide valuable information to ASCs and beneficiaries regarding the incidence of unplanned hospital visits after general surgery at an ASC and thereby foster quality improvement.

X. Revisions to Laboratory Date of Service Policy

With limited exceptions, the date of service (DOS) for a laboratory test is the date the specimen is obtained from the patient. If the DOS occurs during an outpatient encounter, payment for the laboratory test is either packaged into the OPPS service payment or, if separately payable, must be billed by the hospital. Most laboratory tests are packaged. Molecular pathology and advanced diagnostic laboratory tests (ADLTs) are paid separately. ADLTs are tests that are performed by a single laboratory only and meet other criteria specified in statute.

Beginning in 2018, CMS created a new exception to the DOS rules. For hospital outpatients only, the DOS for molecular pathology tests or advanced diagnostic laboratory tests (ADLTs) is the date the test is performed if:

8 Most laboratory tests are packaged. Molecular pathology and advanced diagnostic laboratory tests (ADLT) are paid separately. ADLTs are tests that are performed by a single laboratory only and meet other criteria specified in statute.
• The test was performed following discharge from the hospital outpatient department;
• The specimen was collected from a hospital outpatient;
• It was medically appropriate to collect the sample during the hospital outpatient encounter;
• The test results do not guide treatment provided during the hospital outpatient encounter; and
• The test was reasonable and medically necessary for the treatment of an illness.

This exception allows a laboratory to bill for a molecular pathology test or ADLT that it performs after the patient has left the hospital. CMS adopted the exception as a result of stakeholder input that stated, “because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform” (84 FR 39600). AdvaMed supported CMS’s 2018 policy change.

The proposed rule indicates that “many hospitals and laboratories [are] having administrative difficulties implementing the DOS exception” (84 FR 39600). As a result, CMS is applying an enforcement moratorium on application of the DOS rule for molecular pathology tests and ADLTs that began July 3, 2018 and will run through January 2, 2020.

CMS is further considering three potential changes to the DOS rule to address the administrative difficulties that hospitals and laboratories have encountered. These changes, if finalized, would be effective January 1, 2020.

1. Changing the Test Results Requirement:

Under this change, the exception to the DOS policy would not be met unless the ordering physician determines the test does not guide treatment in any past or future outpatient encounter.

• AdvaMed opposes this change and urges CMS not to adopt it in the final rule.

CMS allows molecular tests and ADLTs to be paid separately precisely because it believes these tests are:

“less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, …are used to guide and manage the patient’s care after the patient is discharged from the hospital outpatient department…and can legitimately be distinguished from care the patient receives in the hospital.”

Further, CMS also expressed a preference for consistency between the laboratory DOS rules and the OPPS packaging policies (84 FR 39600).

All of this remains as true and accurate today as it did in 2017 when CMS adopted the most recent exception to the DOS rule for 2018.

This option would also substantially expand the bundling rules for hospital outpatient services well beyond the outpatient encounter where the specimen was originally obtained. Even though
molecular pathology tests and ADLTs are not packaged, CMS describes the DOS rule as a bundling rule, as it requires the hospital to bill for tests that are “appropriately associated with hospital treatment” (84 FR 39600).

This option would expand the bundling rule to include any future outpatient encounter where test results may guide treatment. Such an expansion would make the hospital responsible for billing for services which it had no part in ordering or furnishing merely because, at some future point, the patient may return to the hospital to receive additional services related to a previously treated condition.

The policy would also be administratively burdensome for the physician ordering the molecular pathology test or ADLT. The ordering physician would, in effect, be required to predict whether the test being ordered would guide treatment for a future outpatient encounter—something the ordering physician may have no reasonable way of knowing.

- **CMS should not include this change to the test result policy in its final rule.**

2. **Limit the DOS Exception only to ADLTs and not Molecular Pathology Tests.**

Under this option, CMS would limit the DOS exception adopted in 2018 to ADLTs. Molecular pathology tests would continue to be billed by hospitals when the patient sample upon which the test is performed is obtained from a hospital outpatient. CMS suggests limiting the DOS exception under this policy to ADLTs because “hospitals and independent laboratories are not prevented from performing molecular pathology tests [like ADLTs]” and FDA approved kits are available to allow hospitals to more easily perform molecular pathology tests.

- **AdvaMed opposes this change as well and urges CMS not to adopt it in the OPPS final rule.**

It is unclear why CMS is distinguishing between ADLTs and molecular pathology tests regarding whether a hospital should be required to bill for a test that is being performed on a former patient. As noted above, the requirement to bill for the service is a function of who provided the service as well as whether there is a nexus between the test being performed and the care furnished to the patient in the hospital outpatient department.

Under this potential change, the hospital would have to bill for a test merely because it has the ability to perform the test, even if the patient was no longer a hospital patient and the results of the test would not impact the patient’s outpatient treatment. The potential for a hospital to perform a test is not a sufficient basis for changing the rule to limit the exception to ADLTs only.

- **CMS should not limit the existing DOS exception to ADLTs only in the final OPPS rule.**

**Administrative Procedures Act Concerns**
CMS did not explicitly propose any of the above three options but indicated it would “consider” finalizing any, or all, of these policies in the final rule. Generally, CMS explicitly proposes policies it is considering adopting, consistent with the Administrative Procedures Act, but the Agency did not do so in this case. AdvaMed recommends that CMS use the proposed rule to explicitly identify what it intends to do in the final rule (e.g. “propose to adopt one or more of the following policies”) rather than leave the public uncertain of CMS’s intentions. Making an explicit proposal(s) would be more consistent with the requirements and purposes of the Administrative Procedures Act.

- **CMS should use its proposed rulemaking to explicitly propose policies it is considering adopting, rather than discussing potential policy revisions and soliciting comments. This would be consistent with the Administrative Procedures Act and would allow the public to better understand CMS’s intentions with respect to changes in policy.**
Conclusion

AdvaMed appreciates the opportunity to comment on the CY 2020 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