September 27, 2019

Via Electronic Mail
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-P)

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Proposed CY 2020 Physician Fee Schedule Rule.

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

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

Bringing innovation to patient care worldwide
I. Provisions of the Proposed Rule for PFS

CMS Advisory Committee on Coverage and Payment for Digital Technologies

Medical technology innovation is moving forward at an increasingly rapid pace, as witnessed by the number of technologies the FDA has designated as breakthrough technologies for its expedited approval process established by the 21st Century Cures Act. One area where innovation has been especially strong has been the development of digital medical technologies or technologies with digital components, with many of these technologies promising to transform the delivery of care and improve patient care outcomes. These digital technologies have created new capabilities for remote patient monitoring and connected care pathways, decision support for physicians, integrated hardware/software solutions for managing health care conditions and diseases, and data analytics applications.

In last year’s PFS proposed rule, AdvaMed commended CMS for taking a bold step in modernizing Medicare’s payment policies for physician services by proposing new CPT codes that would recognize communication technology-based services. These are important changes to the program and this year’s proposed rule builds on those policies. AdvaMed believes that we are at the very earliest stages of a long-term process of having to incorporate a broad array of digital technologies into Medicare’s coverage and payment policies. For beneficiaries to realize the benefits these technologies provide and for Medicare to capture savings from their deployment over the longer term, significant rethinking of regulatory policies across many benefit categories in the program will be required.

AdvaMed believes that work on this framework can and should begin immediately. In addition to using NPRMs for revising payment policies, we suggest that CMS convene an Advisory Committee of beneficiaries, providers, and other stakeholders, including digital technology manufacturers, together with CMS officials, who have direct experience with the impact existing regulatory and statutory policies have on access to health care services available through innovative digital technologies, and who also have a vision for how regulatory policies need to be revised to accommodate coverage and payment for these technologies under the program. As the Government Accountability Office (GAO) noted in a 2017 report on coverage and payment policies for innovative technologies, without a forward-looking process anticipating and planning for significant changes, CMS and other insurers that follow Medicare payment policy may not recognize advances in technology that may provide potential cost savings and better health outcomes (“CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment,” GAO Report 17-600, July 2017).
AdvaMed recommends that the Advisory Committee be charged specifically with:

- reviewing existing Medicare statutory and regulatory policies that define Medicare coverage and payment rules determining access to digital technologies, across benefit categories;
- identifying barriers in existing regulatory policies that limit access to digital technologies;
- making recommendations for changes to regulations, across Medicare benefit categories, necessary to provide coverage and payment for digital technologies; and
- making recommendations for new benefit categories in the Medicare statute to accommodate coverage and payment for digital technologies where needed.

AdvaMed also recommends that the Advisory Committee meet on a regular basis to address the broad regulatory and statutory challenges Medicare faces for coverage and payment for digital technologies as these technologies evolve over time, as well as for making recommendations on the specific challenges individual technologies face as they are approved for marketing by the FDA and become available for the delivery of care. Such meetings should be open, public meetings that provide an opportunity for input from other interested stakeholders not serving on the Advisory Committee.

**Payment for Medicare Telehealth Services (Section II. F. 1)**

**Requests to Add Services to the List of Telehealth Services for CY 2020**

(1) The proposed rule states that CMS did not receive any requests from the public for additions to the Medicare Telehealth List for CY 2020, and CMS concludes this must be an indication that the vast majority of services that can be appropriately furnished as Medicare telehealth services have already been added to the list. AdvaMed cautions against that assumption. As CMS describes in the proposed rule, the process for adding Category 2 services to the Telehealth List (those not similar to services already on the List) requires, among other things, submission of evidence from clinical studies demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury. This is a resource- and time-intensive process and AdvaMed requests that CMS reevaluate the requirements for Category 2 services to allow other types of evidence, from observational studies, for instance, to demonstrate impact on health.

We also note that the Bipartisan Budget Act of 2018 requires Centers for Medicare and Medicaid Innovation Office (CMMI) to conduct a study on utilization and spending for expanded telehealth services, which the Act authorizes accountable care organizations (ACOs) to provide, without waivers, both in the home and in urban areas. This is a potential source of valuable data on the effectiveness of telehealth services. AdvaMed recommends that this study, whose results must be reported by 2026, be designed in such a way as generate data about a broad range of specific telehealth services, including those not now included on the List. In the interim, AdvaMed recommends that CMMI use its experience with waivered telehealth services, which it has allowed ACO and bundled payment models to provide during the past several years, to produce studies on the impact these services have had on populations served.
(2) The proposed rule would add three HCPCS G-codes to the list of telehealth covered services related to treatment for opioid use disorder: HCPCS codes GYYY1, GYYY2, and GYYY3. We agree with CMS’s assessment that the face-to-face visit component of these services are sufficiently similar to psychotherapy services already on the list to allow them to be added to the Telehealth List and that the other components of these codes, such as care coordination, do not require the patient to be present in-person with the practitioner when furnished. AdvaMed supports the addition of **HCPCS codes GYYY1, GYYY2, and GYYY3 to the List.**

(3) AdvaMed has supported CMS’s various initiatives for addressing the opioid crisis and has advocated for improved coverage and payment policies for FDA-approved medical technology therapies that allow patients to more effectively manage and treat chronic pain without opioids. One such technology is spinal cord stimulation (SCS). Medicare currently requires that patients wanting to use SCS for controlling pain must first have an in-person psychological evaluation before the program will cover and pay for the technology. For beneficiaries in rural areas, where practitioners available to do this evaluation are in short supply, this requirement creates a significant barrier to access. AdvaMed recommends that services related to this evaluation be added to the Telehealth List. We note that these services are sufficiently similar to a psychology evaluation code, 90791, initial evaluation) already on the List. We specifically recommend that the following CPT codes be added to the List:

- 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).

**Chronic Care Remote Physiologic Monitoring (RPM) Services (Section II. K. 5)**

Last year, AdvaMed enthusiastically endorsed CMS’s proposal and finalization of three new remote physiologic monitoring codes: CPT 99453, 99454, and 99457. As a general comment, AdvaMed first notes that a number of our member companies have heard from physicians who have requested more clarity and guidance from CMS on billing, documentation, etc. under these codes. We expected that the proposed rule would have included some of this additional clarification, but since it does not, we request that it be provided in the near future without physicians having to wait until next year’s proposed rule for guidance.

The proposed rule explains that the CPT Editorial Panel has revised the CPT code structure for CPT code 99457 effective beginning in CY 2020. **The new code structure retains CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code, 994X0, to describe subsequent 20-minute intervals of the service.** AdvaMed believes these changes will more effectively support the care needs of the patient over the long term and encourage the continuous engagement of both the beneficiary and practitioner in meeting the patient’s care plan goals. **We also recommend that CMS clarify that the 20 minutes of service is inclusive of the remote physiologic monitoring, any related treatment management service, and the interactive communication with the patient or caregiver.** These three aspects of the descriptor should be considered as the collective service
provided by eligible practitioners and not be viewed as independent components that would independently have to meet the effort and time requirements for the code.

AdvaMed also supports CMS’s proposal to allow services furnished under CPT codes 99457 and 994X0 to be provided under the general supervision, rather than the currently required direct supervision, of a physician. We agree with CMS’s finding that care management services, such as establishing, revising, and monitoring a specific treatment plan that is monitored remotely, do not require the direct supervision of the physician.

AdvaMed, however, does not support CMS’s proposal to establish the work RVU for the new add-on CPT code 994X0 at 0.50, instead of the RUC-recommended value of 0.61. We are perplexed by CMS’s argument that the work RVU for the new chronic remote physiologic monitoring CPT code 994X0 is similar to CPT code 88381 (microdissection), with which remote physiologic monitoring seems to have nothing in common. We are also concerned that the proposed decrease in the work RVU will discourage the ongoing engagement of practitioners in managing the care of beneficiaries with chronic conditions, often multiple chronic conditions, and defeat the original purpose of the new code to be engaged with the patient over the longer term to improve patient care outcomes.

Transitional Care Management (TCM) Services (Section II. K. 2)
The proposed rule identifies services described in 14 HCPCS codes that may complement transitional care management (TCM) services rather than overlapping or duplicating them. CMS believes that by removing the billing restrictions associated with these codes that the program may see an increase in TCM services, which the agency believes are underutilized. AdvaMed supports this policy but is perplexed by CMS including CPT code 99091 among the 14 codes. It is our understanding from the CY 2018 Physician Fee Schedule final rule that CPT code 99091 is now separately payable alongside TCM. To eliminate any confusion in allowed billing going forward, AdvaMed recommends that CMS state in the final rule and manual that remote physiologic monitoring CPT codes 99091, 99457 and 99458 may be billed in conjunction with care management services, including TCM and chronic care management.

Principal Care Management (PCM) Services (Section II. K. 4)
The proposed rule discusses a gap CMS identified in coding and payment for care management services for patients with only one chronic condition. The current chronic care management (CCM) codes require patients to have two or more chronic conditions. CMS proposes to establish for CY 2020 two new principal care management (PCM) HCPCS codes to remedy this problem: GPPP1 and GPPP2. AdvaMed supports this change.

The proposed rule also solicits comment on whether the new PCM codes will duplicate payment for other existing codes, including remote physiologic monitoring CPT codes 99091, 99453, and 99457. AdvaMed believes that these named remote physiologic monitoring codes, and 99458, are distinctly different from the new PCM codes, are complementary to each other in the same way that CMS has found certain services complementary to TCM as discussed above. The new
codes CMS proposes to establish describe the more general management of the patient and his or her care plan on a day-to-day basis, and the remote physiologic codes a targeted and remote need for information about the patient in order to effectively manage the total care needs of the patient. As such we believe that the codes complement rather than duplicate each other.

Comment Solicitation on Consent for Communication Technology-Based Services (Section II. K. 6)

CMS states that the agency continues to receive comments from practitioners that the agency’s requirement to obtain consent from patients for each of the communication technology-based services under the several new codes finalized last year is difficult and burdensome for practitioners. AdvaMed agrees that the current requirement is burdensome and redundant. Instead, we recommend that CMS establish a single annual notice requirement for these services and that CMS offer several model examples that will satisfy an annual notice requirement through digital and paper-based versions.

Online Digital Evaluation Service (e-Visit) (Section II. N. 70)

AdvaMed supports CMS’s proposal to cover and pay for six new non-face-to-face codes to describe patient initiated digital communications that require a clinical decision that would otherwise typically have been provided in the office—three for online digital evaluation and management services performed by a physician or non-physician practitioner and three for qualified non-physician health care professional online assessments (HCPCS Codes GNPP1-GNPP3).

Self-Measured Blood Pressure Monitoring (CPT Codes 99X01, 99X02, 93784, 93786, 93788, and 93790) (Section II. N. 72)

AdvaMed supports CMS’s proposal to recognize the CPT Editorial Panel’s 2018 decision to establish two new codes and revise four other codes to describe self-measured blood pressure monitoring services and to differentiate self-measured blood pressure monitoring services from ambulatory blood pressure monitoring services. We believe these and other changes in this year’s proposed rule are important steps in recognizing how medical technologies can improve patient care outcomes and reduce the rate of growth in program spending.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs—Toxicology Testing

The proposed rule includes a discussion regarding implementation of The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act of 2018 [P.L. 115-271]. Section 2005 of the SUPPORT Act
allows opioid treatment programs (OTP) that meet eligibility criteria to enroll as Medicare providers and allows payment to be made under Part B for covered opioid use disorder (OUD) treatment services under a bundled payment methodology. The SUPPORT Act gives the Secretary authority to define the bundles of services that will be paid under this benefit. Per the proposed policy, CMS payments to OTPs will include toxicology testing. Under current law, payment for toxicology testing is made under the Medicare Clinical Laboratory Fee Schedule (CLFS). The 2019 rates for toxicology testing are shown in Table 1, below.

### Table 1

<table>
<thead>
<tr>
<th>CPT</th>
<th>Descriptor</th>
<th>2019 CLFS Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presumptive Drug Testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>80305</td>
<td>Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service</td>
<td>$12.60</td>
</tr>
<tr>
<td>80306</td>
<td>Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service</td>
<td>$12.60</td>
</tr>
<tr>
<td>80307</td>
<td>Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service</td>
<td>$64.65</td>
</tr>
<tr>
<td><strong>Definitive Drug Testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G0480</td>
<td>Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-7</td>
<td>$114.43</td>
</tr>
<tr>
<td>G0481</td>
<td>Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 8-14</td>
<td>$156.59</td>
</tr>
<tr>
<td>G0482</td>
<td>Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 15-21</td>
<td>$198.74</td>
</tr>
<tr>
<td>G0483</td>
<td>Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 22 or more</td>
<td>$246.92</td>
</tr>
</tbody>
</table>

AdvaMed is concerned that the proposed bundled payment for toxicology testing when provided by an OTP could have unintended consequences on patient access to the most appropriate testing for their unique needs.
Selecting the appropriate drug test is critical to patient care. Fentanyl kills over 70,000 people annually\(^1\) yet most basic drug tests will not detect it. The rule, as proposed, could encourage providers to test using the least expensive method, avoiding more complicated and costly tests for fentanyl, in order to operate within the financial constraints presented by the bundle. This could place patient lives at risk.

AdvaMed is also concerned that the proposed rates for the non-drug component bundles will not adequately reimburse for technology required to perform definitive drugs of abuse tests given their higher technology costs. We do not believe that Tricare is an appropriate reference for the proposed non-drug payment bundles—especially for definitive drugs of abuse tests (DAT).

- **AdvaMed recommends that CMS consider using the current CLFS rates for codes G0480-G0483 if the proposal is finalized.**

We note that CMS does discuss the fact that “medically necessary toxicology testing” is excluded from the bundle.\(^2\) The difference between OUD toxicology testing (bundled) and medically necessary toxicology testing (billed and paid under the CLFS) in this proposal is unclear. AdvaMed asks CMS to clarify how it is defining “medically necessary toxicology testing” and whether that definition includes or excludes definitive DATs.

- **Should the non-drug bundle exclude definitive DATs, AdvaMed recommends that CMS specifically clarify that these definitive DATs are excluded from the OUD non-drug component payment bundle and are, in fact, eligible for separate payment under the CLFS if finalized.**

**Valuation of Specific Codes**

**Negative Pressure Wound Therapy (NPWT)**

AdvaMed greatly appreciates the effort to assign an active status to CPT codes 97607 and 97608 for disposable NPWT\(^3\), which will allow office-based access to this proven wound care therapy for Medicare beneficiaries. We appreciate CMS’s shift toward greater care coordination. However, we are concerned that the proposed rule supply cost estimate for “kit, negative pressure wound therapy, disposable” of approximately $100, based on a search of publicly available commercial pricing data, is incorrect and could negatively impact access to this service by patients

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\(^2\) 84 Fed.Reg. 40,542

\(^3\) Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment, including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session
in the physician office setting. The proposed price for this service does not reflect the actual invoiced price of any manufacturer systems on the market today.

- **AdvaMed requests that CMS factor in additional paid invoices, which show the supply cost of the disposable NPWT deployed. This information should be used by CMS in making its final reimbursement determination regarding the PFS rates for disposable NPWT services.**

**Radiation Therapy Codes (G6001-G6015)**

In the 2015 PFS final rule, CMS rejected the RUC-recommended valuations for the radiation therapy conventional treatment delivery, Intensity Modulated Radiation Therapy (IMRT) and image guidance codes. CMS established G codes G6001 through G6015 to recognize the services and cross-walked the values back to the 2014 CPT codes that had been deleted. In December 2015, the Patient Access and Medicare Protection Act (PAMPA) effectively froze the definitions, work RVUs and direct practice expense inputs for the G codes at 2016 rates through the end of 2018. The Bipartisan Budget Act of 2018 extended this provision through 2019.

CMS is proposing to retain the G codes in the CY 2020 PFS to ensure payment stability. Additionally, the Agency is proposing to continue to include a 60 percent utilization rate assumption for equipment item: ER089: “IMRT Accelerator”.

AdvaMed appreciates and supports the CMS proposal to retain the G codes through 2020. As the Agency is aware, the Centers for Medicare and Medicaid Innovation Office (CMMI) introduced a proposed radiation oncology alternative payment model (RO Model) on July 10, 2019 that is expected to be implemented in 2020. The RO Model is inextricably linked to the payment stability of the radiation oncology treatment delivery and image guidance codes, which have been recognized by G codes in the PFS since 2015 and represent roughly half of what Medicare pays for radiation oncology services under the PFS. AdvaMed continues to support the CPT code revisions and RUC-recommended values associated with the conventional treatment delivery, IMRT and image guidance codes. We recognize that simultaneously moving to the RO Model while implementing the new code set for freestanding centers could be disruptive, particularly if some centers are required to participate in the alternative payment model.

- **AdvaMed urges CMS to finalize the proposal to retain the frozen payment rates for these G codes through CY 2020. AdvaMed also asks CMS to continue the freeze for the duration of the RO-APM which is tentatively scheduled to conclude on December 31, 2024.**

**Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299)**

CPT code 93299, which represents the technical portion of remote interrogation device services for subcutaneous implantable cardiovascular physiologic monitor systems, implantable loop recorder systems (ILR), and subcutaneous cardiac rhythm monitor systems (ICMs), has been deleted by the AMA CPT Editorial Panel effective January 1, 2020. Nevertheless, in the proposed rule, CMS has rejected the RUC-recommended direct practice expense (PE) inputs for
incorporation into the remote interrogation device evaluation CPT codes 93297 and 93298. Instead, CMS recommends the creation of the temporary code GTTT1.

AdvaMed is concerned that the designation of a G code to replace the existing CPT code may create confusion for providers and commercial insurers. Additionally, the proposed G code will not allow CMS to individually track costs for monitoring devices. Allocation of the practice expense into 93297 and 93298 will enable tracking of the technical costs of ILRs and ICMs separately from implantable cardiovascular physiologic monitor systems and ensure accuracy for future rate setting.

- **AdvaMed recommends that CMS only utilize the G code approach until such time as an appropriate valuation can be established for the technical portions of CPT codes 93297 and 93298.**

**Comment Solicitation on Opportunities for Bundled Payments Under the PFS**

CMS seeks public comments, via the proposed rule, on opportunities to expand the concept of bundling to recognize efficiencies among physicians’ services paid under the PFS and to better align Medicare payment policies with CMS’s broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system.

AdvaMed appreciates CMS’s desire to continue to update and modernize its payment systems with these goals in mind. However, we believe that CMS must do so within its existing statutory authorities, which currently do not authorize CMS to make bundled payments under the PFS.

The PFS requires payment be made for each individual service furnished to a beneficiary based on the relative resources involved in providing the service. [42 U.S.C. 1395w–4]. In recent years CMS has developed bundled payment approaches for some physician fee schedule services through targeted processes under the explicit authorities accorded to CMMI. CMMI was established by Section 1115A of the Social Security Act, in which Congress explicitly enumerated authority for the Secretary of Health and Human Services to test “innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care.” CMS does not have this same level of flexibility outside of the explicit waiver authorities granted to CMMI [42 U.S.C. 1315d] or outside of statutorily authorized prospective payment systems (PPS), like the Inpatient PPS and the Outpatient PPS.

We are also concerned that any attempts to bundle payment for clinical diagnostic laboratory tests into payment for physician visits would run counter to CMS’s explicit payment authorities for lab tests. Section 216 of the Protecting Access to Medicare Act (PAMA) [P.L. 113-93] requires CMS to pay for lab tests based on private payer information collected by certain laboratories (including physician office labs, independent labs and hospital-based labs) and subsequently reported to CMS. CMS determines national Medicare rates for lab services under PAMA based on the weighted median of those private payer rates.
Congress clearly contemplated that the PAMA reforms would continue a fee-for-service payment system for all laboratory services, whether provided by physicians in their offices, independent labs, or hospital-based labs – and CMS’s implementation of PAMA supports this. To attempt to bundle payment for lab services into payment for other physician services would run counter to the statutory authorities created by PAMA, far exceeding the intent of Congress to have a fee-for-service payment system.

- **AdvaMed recommends that CMS be cautious in any efforts related to the development of bundled payments for laboratory or other PFS services.**

II. CY 2020 Updates to the Quality Payment Program

Specialty Measure Set Changes

CMS proposes seven new specialty measure sets for addition, including Nutrition/Dietician specialty measure set.

AdvaMed urges CMS to prioritize adoption of malnutrition-focused quality measure(s) as part of the Quality Payment Program for all Merit-based Incentive Payment System (MIPS) eligible clinicians. We believe that addressing malnutrition aligns with CMS priorities around population health, simplicity, and alignment across care settings. Specifically, we urge CMS to adopt the currently available malnutrition electronic clinical quality measures (eCQMs) as part of the Quality Payment Program for all MIPS eligible clinicians. Four electronic clinical quality measures are currently available to address the screening, assessment, documentation and care planning of patients with or at-risk for malnutrition, including:

- NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission
- NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening
- NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis

We believe that these measures fit well with CMS’s interest in creating a new specialty measure set for Nutrition/Dietitian.

Promoting Interoperability Request for Information on Integration of Patient-Generated Health Data (PGHD) into EHRs Using Certified Electronic Health Record Technology (CEHRT)

CMS notes in the proposed rule that increased availability of patient-generated health data (PGHD) offers providers an opportunity to monitor and track a patient’s health-related data from
information that is provided by the patient and not the provider. Capturing important health information through devices and other tools between medical visits could help improve care management and patient outcomes, potentially resulting in increased cost savings. CMS notes that ONC had finalized in the 2015 Edition Health IT Certification Criteria a criterion that allowed a user to identify, record, and access information directly and electronically shared by a patient. In addition, CMS had finalized a PGHD measure requiring health care providers to incorporate PGHD or data from a nonclinical setting into CEHRT, but removed this measure in the CY 2019 PFS final rule, due to concerns that the measure was not fully health IT-based and could include paper-based actions, an approach that did not align with program priorities to advance the use of CEHRT.

AdvaMed recommends that CMS revisit its decision about allowing data from nonclinical settings to be incorporated into the CEHRT and specially consider allowing data obtained through remote patient monitoring and other digital technologies to be incorporated into the CEHRT. These new digital technologies are rapidly transforming the delivery of care and CMS is taking major steps forward in recognizing through the Physician Fee Schedule Rule the role these technologies can play in improving patient care outcomes. While activities related to PGHD would not necessarily have to be incorporated at these early stages into a quality measure, CMS should develop a broader range of approaches to reward practices that allow the capture of PGHD and that increase patient engagement with their providers and involvement and compliance with their care plans.

**Conclusion**

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2020 PFS rule and looks forward to working with CMS to address our concerns. We would be pleased to answer any questions regarding these comments. Please contact me or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can further assist you.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery Policy