August 24, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS– 1656–P
P.O. Box 8013
Baltimore, MD 21244–1850

Dear Acting Administrator Slavitt:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,900 family physicians and medical students across the country, I write in response to the proposed rule published by CMS in the July 14, 2016, *Federal Register* that would, among several other policy changes, revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for 2017. In addition and of particular interest to family physicians, this proposed rule would:

- Implement section 603 of the *Bipartisan Budget Act* of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider;
- Make changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs; and
- Remove the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program.

X.A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off Campus Departments of a Provider

Summary

The proposed rule discusses that research literature and popular press have recently documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting.

When a Medicare beneficiary receives services in an off-campus department of a hospital, the total payment amount for the services made by Medicare is generally higher than the total payment amount made by Medicare when the beneficiary receives those same services in a physician's office. Medicare pays a higher amount because it generally pays two separate

claims for these services—one under the OPPS for the institutional services and one under the Medicare Physician Fee Schedule for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims; often resulting in significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician's office.

Section 603 of the *Bipartisan Budget Act* of 2015 amended the Medicare statute as it relates to OPPS by requiring that applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered covered outpatient department services for purposes of payment under the OPPS. Instead, such applicable items and services will be paid ''under the applicable payment system'' under Medicare Part B. The law specifies some exceptions to this change with respect to both the departments and items and services affected.

Under the proposed rule, all excepted off-campus provider-based departments (PBDs) may continue to bill for excepted items and services under the OPPS. These excepted items and services include those furnished in an emergency department, in an on-campus PBD, or within 250 yards from a remote location of a hospital facility. In addition, excepted items and services include those furnished by an off-campus PBD that was billing Medicare for covered outpatient department services furnished prior to November 2, 2015, for all services within a clinical family of services, provided that those services continue to be furnished at the same physical address of the PBD as of November 2, 2015. CMS also proposes the clinical families of services for this purpose. Items and services furnished in a new off-campus PBD or new lines of service furnished in an excepted off-campus PBD would not be excepted items and services. An excepted off-campus PBD would lose its status as excepted if it changes location or changes ownership, unless the new owners also acquire the main hospital and adopt the existing Medicare provider agreement.

For 2017, CMS proposes that non-excepted, off-campus PBDs or excepted off-campus PBDs that provide non-excepted items and services must bill and be paid for non-excepted items and services under the Medicare physician fee schedule at the non-facility rate instead of the facility rate. For CY 2018, CMS is soliciting public comments on regulatory and operational changes that it could make to allow an off-campus PBD to bill and be paid for its services under an applicable payment system. CMS will take comments into consideration in developing a new payment policy proposal for CY 2018.

AAFP Response
In general, the AAFP fully supports CMS implementing these proposals that better align payment policies for physicians in independent practice with those owned by hospitals since these changes, if finalized, would lead to a more level economic playing field for independent practices while also being more equitable for Medicare patients. The AAFP encourages CMS also to consider site-of-service payment parity polices from a broader perspective. Namely, CMS should not pay significantly more for the same services in the inpatient, outpatient, or ambulatory surgical center setting than in the physician office setting. From a global cost perspective, and as further discussed in the AAFP's August 29, 2012, letter to CMS sent in response to the solicitation of comments regarding outpatient status, the AAFP encourages CMS to create incentives for services to be performed in the most cost-effective location, such as a physician's office. The AAFP considers the artificial distinction between "inpatient," "outpatient," and other sites of service as a product of the equally artificial distinction between

Part A and Part B. The AAFP calls for policies that progress beyond this silo mentality and instead pay for healthcare services in a more consistent and equitable manner.

With respect to the specifics of CMS's proposals, we believe that the agency has done a reasonable job of defining applicable items and services and an off-campus outpatient department of a provider consistent with the statute. We also believe that CMS's proposals regarding exceptions to the policy are also consistent with the statute.

We support CMS's proposal to void the excepted status of off-campus PBDs that move or relocate. Like CMS, we believe that the intent of section 603 of the *Bipartisan Budget Act of 2015* is to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services. Failure to void the excepted status of off-campus PBDs that move or relocate would allow hospitals to circumvent the law's intent, as CMS notes. That said, we do think that CMS should develop a clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital Value-Based Purchasing program for hospitals struck by a natural disaster or experiencing extraordinary circumstances. Like physicians, hospitals should not be penalized by CMS for circumstances outside their control.

For similar reasons, we also support CMS's proposal to limit the excepted status of items and services furnished in excepted off-campus PBDs to the items and services (defined as clinical families of services) such department was billing for under the OPPS and were furnished prior to November 2, 2015. We understand that this proposal would not limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish. It does not appear that the statute anticipates such a limit on volume, and CMS's other proposals should effectively prevent circumvention of the statute's intent without adding such a limit. In response to CMS's question about whether it should adopt a specific timeframe for which the billing had to occur (e.g. CY 2013 through November 1, 2015), we think adopting a timeframe would be reasonable and defer to CMS and the hospital community regarding what length of time makes the most sense in this regard.

The rationale behind CMS's proposal that excepted status for an off-campus PBD would transfer to new ownership only if ownership of the main provider is also transferred and the new owner accepts the Medicare provider agreement is not clear. Under this proposal, an individual excepted off-campus PBD cannot be transferred from one hospital to another and maintain excepted status. Since transfer of ownership does not expand hospital ownership of physician practices, which is what section 603 is intended to curb, it is unclear how this proposal supports the intent of the law. We encourage CMS to better justify this proposal if it decides to finalize it.

We were troubled by CMS's admission that it is "unable to automate a process by which we could link hospital enrollment information to claims processing information to identify items and services to specific off-campus PBDs of a hospital." Absent an audit of hospital billing, it does not appear that CMS or its contractors are capable of ensuring that off-campus PBDs are billing under the proper billing system. With this in mind, we support CMS's inclination to require hospitals to self-report certain information to CMS to implement this provision of the law, including separately identifying all individual excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing, and the clinical families of services that were provided by the excepted off-campus PBD prior to the November 2, 2015, date of enactment. We recognize that such a requirement would add to the administrative reporting burden of hospitals. However, those hospitals already benefit from the additional Medicare payments

attributed to excepted items and services, so they are, in some sense, compensated for this reporting burden, a luxury not enjoyed by physician practices that often have to report things to CMS without any financial incentive.

Finally, we support CMS's proposal to pay non-excepted, off-campus PBDs or excepted off-campus PBDs that provide non-excepted items and services under the Medicare physician fee schedule at the non-facility rate for 2017. We believe this is a reasonable short-term response until CMS and the hospital community can develop a long-term solution for 2018 and beyond.

XVII.D. Proposed Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs

Summary

CMS proposes to allow physicians, hospitals, and critical access hospitals (CAHs) to use a 90-day reporting period in 2016, down from a required full calendar year reporting period for returning participants.

AAFP Response

The AAFP fully supports the agency's proposal to change the EHR reporting periods in 2016 for returning participants from the full 2016 to any continuous 90-day period within 2016. We applaud the agency for being responsive to stakeholder feedback, including feedback from the AAFP, which requested that CMS allow a 90-day EHR reporting period for eligible professionals (EPs), eligible hospitals and CAHs in 2016 in order to reduce the reporting burden and increase flexibility in the program.

Regarding clinical quality measurement (CQM), CMS proposes that providers may:

- Report CQM data by attestation for any continuous 90-day period during calendar year 2016 through the Medicare EHR Incentive Program registration and attestation site; or
- Electronically report CQM data in accordance with the requirements established in prior rulemaking. We note that, for EPs, eligible hospitals and CAHs, CQM data submitted via attestation can be submitted for a different 90-day period than the EHR reporting period for the meaningful use objectives and measures.

The AAFP supports this change in reporting period for CQMs under Meaningful Use (MU). We support the dual tracks of reporting which allow those wanting to report electronically for the year to continue on that track, whereas those choosing to report via attestation may do so for any continuous 90-day period within the calendar year.

XVII.E. Proposal to Require Modified Stage 2 for New Participants in 2017

Summary

This proposed rule discusses that CMS, after the publication of the 2015 EHR Incentive Programs Final Rule, the agency determined that:

> *…due to cost and time limitation concerns related specifically to 2015 Edition CEHRT updates in the EHR Incentive Program Registration and Attestation System, it is not technically feasible for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in 2017 in the EHR Incentive Program Registration and Attestation System. For this reason, we are proposing that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation system, or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program*

Registration and Attestation System, would be required to attest to the Modified Stage 2 objectives and measures. This proposal does not apply to EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants) attesting for an EHR reporting period in 2017.

AAFP Response
The AAFP struggles to understand this change with the given rationale. It appears to the AAFP that the proposed change only provides needed, more realistic requirements for EPs new to the program in 2017. The AAFP understands that under current regulation, an EP that first attests to MU in 2017 has the option to either attest to Modified Stage 2 or Stage 3. However the newly proposed rule would eliminate the option for new attesters to attest to Stage 3 due to the impracticality of achieving Stage 3 as a new attester (which we recognize). With existing meaningful users moving to the Merit-Based Incentive Payment System (MIPS) reporting in 2017, and new EP attesters only able to attest to Modified Stage 2, this in essence eliminates Stage 3 for the Medicare EHR Incentive Program. For purposes of clarity, simplicity, and as an expressly obvious indicator to clinicians that their feedback is being heard, the AAFP urges CMS to simply propose to eliminate Stage 3, which the proposed rule appears to do anyway.

XVII.F. Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017
Summary
In the *Medicare Access & CHIP Reauthorization Act* (MACRA) proposed rule, CMS proposed 2017 as the first MIPS performance period. As established in the 2015 EHR Incentive Programs final rule, 2017 is also the last year in which new participants may attest to meaningful use (for a 90-day EHR reporting period in 2017) to avoid the 2018 payment adjustment. Therefore an EP could use a 90-day reporting period from June through August 2017 to report under the Medicare EHR Incentive Program and, in the same time period, collect data for reporting under the Advancing Care Information (ACI) performance category in MIPS.

CMS discusses the agency's understanding that this overlap of reporting and performance periods in 2017 could be confusing to EPs who are new participants in the EHR Incentive Program and are also making the transition to MIPS because although both programs require the use of certified EHR technology, the measures and other requirements for meaningfully using that technology under the EHR Incentive Program are different from the measures and other requirements proposed under the ACI performance category of the MIPS. In addition, there are also different systems in which participants will have to register and attest and that new participants may be actively working with EHR vendors to build out their EHR technology and day-to-day EHR functions to align with the various and different requirements of the EHR Incentive Program and MIPS.

For these reasons, CMS proposes to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment. CMS proposes to limit this proposal only to EPs who have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017 to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the ACI performance category under the MIPS in 2017.

CMS makes this proposed significant hardship exception based upon the proposal in the *MACRA* proposed rule to establish 2017 as the first performance period of the MIPS. In the event CMS decides not to finalize that proposal, and instead adopt a different performance

period for the MIPS which does not coincide with the final year for EPs to attest to MU under the Medicare EHR Incentive Program, CMS may determine that this proposed significant hardship exception is not necessary. Finally, CMS discusses that this new category of significant hardship exception would allow the EPs who are new to certified EHR technology to focus on their transition to MIPS, and allow them to work with their EHR vendor to build out an EHR system focused on the goals of patient engagement and interoperability, which are important pillars of patient-centered care and expected to be highly emphasized under the *MACRA* proposed rule.

AAFP Response
As proposed, the significant hardship exception would only be an available option to new EP attesters and would be unavailable to existing and returning meaningful users who successfully attested in prior year(s). The AAFP rejects that as inadequate and recommends CMS make this new category of significant hardship exception available to all EPs, so that existing/returning and new meaningful users may apply for it.

The proposed rule notes the newly proposed significant hardship exception is based upon finalization of proposals within the *MACRA* proposed rule to establish 2017 as the first performance period of MIPS and that if, instead, an initial performance period other than 2017 be adopted as the first performance period (which would then not coincide with the last year for new attestations under MU), then this significant hardship exception is deemed not to be necessary. The AAFP does not share the agency's assumption that significant hardship exceptions may only be needed by new EP attesters, nor do we agree that the very need for the existence of a significant hardship exception is based upon the contingency that the first performance period in MIPS actually becomes finalized as 2017, as proposed.

Many of the AAFP's reasons for disagreement can be found within the proposed rule's justification of the need for this exception for new attesters. The proposed rule notes new attesters need flexibility and additional time to enable them to implement updates of 2015 CEHRT and put into place functionality increasingly required to succeed within MIPS and APMs reimbursement models. The same is true for EP's who successfully attested in prior year(s). In addition, other hardships can be experienced by any EP, without regard to whether they are a new attester or existing/returning meaningful user. Examples of such challenges can include experiencing failure of currently implemented EHR systems to meet clinician needs and requiring time and resource investments into selecting and implementing a new system. EPs are increasingly changing EHR systems at the point when upgrading to new 2015 CEHRT is necessary rather than expending additional resources and funding into continuing partnerships with CEHRT vendors that are not meeting their needs. The time and resource investments involved when changing EHR systems cannot be overstated. Issues, such as substantial changes to workflow or establishing new workflows, can also be encountered during upgrades to new 2015 edition CEHRT with the same vendor. This can be especially true with new functionalities, such as with registries and third-party intermediaries contracted to assist with reporting, added for 2015 edition certification. EPs are increasingly becoming frustrated with existing technology that fails to meet their needs, and in some occasions fails to produce reliable performance metrics. Clinicians are increasingly burdened by time spent working with health IT vendors to build or acquire technology functionality that meets not only Advancing Care Information (ACI) and new value-based payment model requirements, but also clinician needs as well.

The AAFP urges CMS to also extend eligibility for a hardship exception or significant hardship exception not only to new attesters, but to all EP's who encounter challenges with compliance and reporting due to valid issues.

Regardless of whether the adopted year for the first performance year under MIPS ends up being 2017 or some other period, EPs can encounter significant challenges with implementation of new technologies needed in order to be successful within new value-based reimbursement models at any point in time. The AAFP requests that the final rule be comprehensive and inclusive of this possibility and extend eligibility of hardship exception or significant hardship exception to all EPs.

XVII.G. Proposed Modification to Measure Calculations for Actions Outside the EHR Reporting Period

Summary

CMS discusses that an open-ended timeframe could be confusing to providers and could vary widely among providers as their date of attestation could fall anywhere from January 1 through February 28 (or other date specified by CMS) after the year in which their EHR reporting period occurs. For these reasons, and to be consistent with incorporation of data from one EHR reporting period, CMS proposes that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs.

AAFP Response

While the AAFP recognizes that this may cause some confusion and challenges for implementing within a CEHRT, we are supportive of this proposed change to allow for numerator to *optionally* be counted from within the full year of a 90-day reporting period.

XIX.B. Proposed Removal of the HCAHPS Pain Management Dimension From the Hospital VBP Program

Summary

CMS discusses how some stakeholders expressed concern about the Pain Management dimension questions being used in a program where there is any link between scoring well on the questions and higher hospital payments due to the possibility that linkage of the Pain Management dimension questions to the Hospital VBP Program payment incentives creates pressure on hospital staff to prescribe more opioids in order to achieve higher scores on this dimension. Due to some potential confusion about the appropriate use of the Pain Management dimension questions in the Hospital VBP Program and the public health concern about the ongoing prescription opioid overdose epidemic, while we await the results of CMS's ongoing research and the modifications to the Pain Management dimension questions, CMS proposes to remove the Pain Management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey in the Patient- and Caregiver Centered Experience of Care/Care Coordination domain beginning with the 2018 program year.

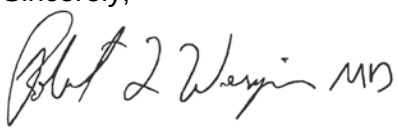
AAFP Response

The AAFP is encouraged that CMS acknowledges that many clinicians report feeling pressure to overprescribe opioids because scores on the HCAHPS survey pain management questions are tied to Medicare payments to hospitals. To mitigate the perception that there is financial pressure to overprescribe opioids, we fully support the proposal to remove the HCAHPS survey

pain management questions from the hospital payment scoring calculation. The AAFP believes this is laudable policy that should be extended to all patient experience measures.

We appreciate the opportunity to comment on this proposed rule and make ourselves available for any questions you might have. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,



Robert L. Wergin, MD, FAAFP
Board Chair