August 30, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW.,
Washington, DC 20201

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the proposed rule titled, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program" as published by the Centers for Medicare & Medicaid Services (CMS) in the July 21, 2017 *Federal Register*.

Detailed comments on these provisions are within this letter, but at a high level we appreciate that CMS included several AAFP-recommended provisions. We are pleased that CMS:

- Recognizes that the Evaluation and Management (E/M) 1995 and 1997 documentation guidelines are too complex and ambiguous. By calling for comments on E/M documentation guidelines, CMS recognizes that these guidelines, which were written 20 years ago, do not reflect the current use of electronic health records and team-based care to support clinical decision-making and patient centeredness.
- Has begun implementing site-neutral provisions to 'new' off-campus provider-based departments, policies the AAFP has strongly supported in regulatory and legislative letters.
- Proposes to delay until Jan. 1, 2019, the Appropriate Use Criteria (AUC) program for advanced diagnostic imaging services, which the AAFP has repeatedly expressed concern over due to the disproportional administrative burden this would place on primary care physicians.
- Lowered the maximum amount of risk under the 2018 value modifier program from 4.0 percent to 1.0 percent for practices of less than 10 physicians.

However, for the third year in a row, The AAFP is very disappointed and cannot understand why CMS has failed to achieve the required, minimum net expenditure reduction through identifying misvalued codes. Since these changes do not fully meet the misvalued code target required by law, physicians will not receive the full positive 0.5 percent update in 2018 called for in the *Medicare Access and CHIP Reauthorization Act* (MACRA). The proposed 2018 Medicare conversion factor will be $35.99, an increase of only $0.10 (0.31 percent) from the 2017 conversion factor.

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Family medicine plays a critical role in delivering care to patients in communities across the country. Family physicians are the most visited specialty—especially in underserved areas. Family physicians conduct approximately one in five of all office visits in the United States. This represents more than 192 million visits annually. Family physicians already operate on slim financial margins and the AAFP remains very disappointed that CMS was unwilling or unable to identify and reduce a sufficient amount of overly inflated codes. In its March 2017 Report to Congress, the Medicare Payment and Advisory Commission (MedPAC) raised concerns with the fee schedule and undervaluing of primary care services. The AAFP therefore continues to urge CMS to more aggressively address the payment inequities in the Medicare fee schedule, especially as it relates to the relative valuation across families of codes as mentioned later in this letter.

Since the agency did not reduce overvalued RVUs to the levels required by law, CMS should have taken steps to reduce the impact on primary care services which are known to be undervalued until the agency could meet its statutory requirement. The continuing undervaluation of primary care services in the fee schedule will be perpetuated in the new MACRA quality payment programs if the agency does not urgently act to mitigate and correct these longstanding imbalances.

As CMS moves to replace payment for individual procedures with payment for value and quality of care, we remind the agency that it's important to strengthen the primary medical care that supports the system-wide reforms taking place today and for years to come. In fact, the AAFP has developed an Advanced Primary Care Alternative Payment Model (APC-APM), which has been submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to help migrate our members away from the current inequitable FFS payment system. The APC-APM is a foundational model for delivering patient-centered, longitudinal, and coordinated care to Medicare beneficiaries – and establishes a payment structure that will begin to appropriately compensate family physicians for delivering this type of care

In summary, to improve the 2018 final Medicare physician fee schedule, the AAFP:

- Strongly supports CMS efforts to align payment policies for physicians in independent practice with those owned by hospitals. The AAFP encourages CMS to create incentives for services to be performed in the most cost-effective location, such as a physician's office.
- Is deeply disappointed in CMS' new approach to valuing codes under the Medicare physician fee schedule. As CMS states in this part of the proposed rule, its obligation is "to ensure that the RVUs reflect relative resource use." CMS needs to live up to this obligation, not kowtow to the Relative Value Scale Update Committee (RUC).
- Strongly agrees with CMS that "it would be appropriate to remove our documentation requirements for the history and physical exam for all E/M visits at all levels." We ideally believe that the documentation guidelines should be eliminated for primary care physicians for all three domains: history, physical exam, and medical decision making.
- Fully agrees with CMS that Appropriate Use Criteria (AUC) requirements will place more burden on primary care physicians than on other providers. The AAFP, therefore, strongly urges CMS to fully align the AUC with the MIPS program's cost or quality performance categories. In fact, we would prefer that the AUC program and regulatory burden be discontinued completely, and we will work with Congress to achieve this goal legislatively and would hope that CMS would do likewise.

- Appreciates that CMS recognizes there will be a learning curve in using patient relationship categories and codes and is therefore proposing an initial period for voluntary reporting while physicians gain experience in using the modifiers.

B. Determination of Practice Expense Relative Value Units (PE RVUs)
2. Practice Expense Methodology
Summary
As part of the methodology where CMS creates indirect PE RVUs, CMS proposes to make a change related to low-volume services (fewer than 100 Medicare allowed services). CMS currently uses an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. For 2018, CMS proposes to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the clinicians reporting the services in the claims data, CMS is proposing to instead use the expected specialty that CMS identifies on a list. For 2018, CMS is proposing to use a list that was developed based on its medical review of the list most recently recommended by the RUC, in addition to its own proposed expected specialty for certain other low-volume codes for which CMS has historically used expected specialty assignments. CMS proposes to consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis.

CMS is also proposing to apply these service-level overrides for both PE and malpractice (MP) RVUs, rather than one or the other category. CMS believes that this would simplify the implementation of service-level overrides for PE and MP and address stakeholder concerns about the year-to-year variability for low volume services. CMS solicits public comment on the proposal to use service-level overrides to determine the specialty mix for low volume procedures, as well as on the proposed list of expected specialty overrides itself, which is largely based on the recommendations submitted by the RUC last year.

AAFP Response
The AAFP supports CMS' proposal to use service-level overrides to determine the specialty mix for low volume procedures for both PE and malpractice (MP) RVUs. We have reviewed the proposed list of expected specialty overrides and focused on those codes where 2016 estimated claims data show "Family Practice" as the top specialty. In each case, we agree with the alternate specialty proposed by CMS. Furthermore, the AAFP urges CMS to use the phrase "Family Medicine" rather than the more outdated term "Family Practice".

3. Changes to Direct PE Inputs for Specific Services
Summary
Several years ago, the RUC's PE Subcommittee reviewed the preservice clinical labor times for CPT codes with 0-day and 10-day global periods. The RUC concluded that these codes are assumed to have no preservice clinical staff time (standard time of 0 minutes) unless the specialty can provide evidence that the preservice time is appropriate. In other words, for minor procedures, it is assumed that there is no clinical staff time typically spent preparing for the specific procedure prior to the patient's arrival. However, CMS notes that, for 2018, 41 of the 53 reviewed codes with 0-day or 10-day global periods include preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for the procedure prior to the patient's arrival. As it reviews misvalued codes, CMS believes that the general adherence to values that it has established as standards supports relativity within the PFS. Because 77 percent of the reviewed codes for the current calendar year deviate from the "standard," CMS

seeks comment on the value and appropriate application of the standard in its review of RUC recommendations in future rulemaking. In reviewing the inputs included in the direct PE inputs database, CMS found that for the 1,142 total 0-day global codes, 741 of them had preservice clinical labor of some kind (65 percent). CMS also noticed a general correlation between preservice clinical labor time and the recent review. CMS seeks comment specifically on whether the standard preservice clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.

AAFP Response
The AAFP supports the RUC and CMS in continuing to use a standard of 0 minutes for preservice clinical labor time for 0-day and 10-day global codes, especially when the global service is done on the same date as an evaluation and management (E/M) service. In family medicine, 0-day and 10-day global codes are typically initiated because of an E/M encounter, such that there is no clinical staff time typically spent preparing for the specific procedure prior to the patient's arrival. We believe this to be true in many other specialties, too. Thus, we encourage CMS to consistently apply the standard in future rulemaking as it reviews recommendations from the RUC and give extra scrutiny to any 0-day or 10-day global code for which preservice clinical labor time is recommended.

That said, like the RUC, we acknowledge there may be exceptions to this standard. If the specialty that typically provides the service can provide evidence to CMS' satisfaction that preservice clinical labor time is appropriate, we would support CMS' decision to allocate preservice clinical labor time to the code, despite the standard to the contrary. However, as noted, this should be an exception, and we support and applaud CMS' apparent questioning of application of the standard by the RUC in its recent recommendations to CMS.

b. Obtain Vital Signs Clinical Labor
Summary
To preserve relativity among codes on the fee schedule, CMS is proposing to assign 5 minutes of clinical labor time for all codes that include the "Obtain vital signs" task, regardless of the date of last review. CMS is proposing to assign this 5 minutes of clinical labor time for all codes that include at least 1 minute previously assigned to this task. CMS is also proposing to generally update the equipment times of the codes with this clinical labor task accordingly to match the changes in clinical labor time.

CMS has traditionally assigned a clinical labor time of 3 minutes for the "Obtain vital signs" clinical labor activity, based on the amount of time typically required to check a patient's vitals. Over time, that number of minutes has increased as codes are reviewed. Many of the reviewed codes for the current 2018 rulemaking cycle have a recommended clinical labor time of 5 minutes for "Obtain vital signs," based on the understanding that these services are measuring two additional vital signs: the patient's height and weight. CMS does not have any reason to believe that measuring a patient's height and weight is only typical for services described by recently reviewed codes. Instead, CMS believes that the review standards have changed, perhaps in conjunction with changes in medical practice, and that the change in the minutes assigned for the "Obtain vital signs" task for newer-reviewed services is detrimental to relativity among physician fee schedule services.

AAFP Response
The AAFP supports CMS' proposal for the reasons outlined by CMS in the proposed rule.

C. Determination of Malpractice Relative Value Units (MRVUs)
Summary
CMS proposes to use the most recent data for the proposed MP RVUs for 2018 and to align the update of MP premium data and MP GPCIs to once every 3 years. Historically, CMS has done a 5-year review of MP RVUs. CMS seeks comment on these proposals and on methodologies and sources that CMS might use to improve the next update of MP premium data.

For most physician specialties, including family medicine, CMS proposes to update MP RVUs using actual premium data. For some physician specialties for which there was insufficient premium data and for most, if not all, non-physician provider types, CMS proposes crosswalks from physician specialties for which there is sufficient premium data. In particular, regarding non-physician provider types, CMS has again proposed to crosswalk such provider types to the lowest physician risk factor specialty, Allergy Immunology (risk factor = 1), for which the CMS contractor collects premium rates.

In this section, CMS repeats its proposal from the PE RVU section of the NPRM to use a list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services. CMS solicits comments on the proposal to use service-level overrides to determine the specialty for low volume procedures, as well as on the list of overrides itself.

AAFP Response
The AAFP reviewed the proposed crosswalks, as shown in Table 6 in the proposed rule. For the physician specialties in question, the crosswalks appear to be appropriate. Regarding the crosswalks for non-physician provider types, we note that even a risk factor of 1 may still be too high. Data collected by the RUC and shared previously with CMS suggests that crosswalking non-physician provider types to even the lowest physician specialty in many cases overstates the associated PLI premiums and risks with these non-physician services. We are unclear why the CMS contractor who collects the physician malpractice premium data can't collect the same thing for non-physicians. We encourage CMS, through its contractor, to more diligently seek out and use actual premium information for non-physician provider types rather than continuing to assign them a risk factor equal to that of the lowest physician specialty.

As noted elsewhere, the AAFP supports CMS' proposal to use service-level overrides to determine the specialty mix for low volume procedures for both PE and malpractice (MP) RVUs. We have reviewed the proposed list of expected specialty overrides and focused on those codes where 2016 estimated claims data show "Family Practice" as the top specialty. In each case, we agree with the alternate specialty proposed by CMS. Furthermore, the AAFP urges CMS to use the phrase "Family Medicine" rather than the more outdated term "Family Practice".

E. Potentially Misvalued Services under the PFS
Summary
CMS proposes the following CPT codes as potentially misvalued:

- 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device)
- 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker

- 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)),

Also, CMS seeks additional comment and continues to request robust data regarding the potentially misvalued work RVUs for CPT codes 36901 through 36909 (Dialysis vascular access). Finally, CMS seeks comment on whether CPT codes 99281-99285 (Emergency department visits for the evaluation and management of a patient) should be reviewed under the misvalued code initiative.

CMS is not proposing a new screen for potentially misvalued codes for 2018. However, CMS continues to believe it is important to prioritize codes for review under the misvalued code initiative. Thus, CMS is seeking public comment on the best approach for developing screens, as well as what new screens CMS might consider. CMS will consider these comments for future rulemaking.

AAFP Response
The AAFP appreciates the effort CMS and the RUC have expended to identify and review potentially misvalued codes, as described in the proposed rule. As noted in the proposed rule, since 2009, CMS has reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. These results are commendable. However, given there are several thousand codes in the fee schedule with more being added each year, much work remains to be done.

We have no objection to review of any of the specific codes that CMS proposes as potentially misvalued in this proposed rule, including CPT codes 99281-99285 (Emergency department visits for the evaluation and management of a patient). Like other stakeholders, we are concerned that the work RVUs for the emergency department E/M services, like most other E/M services, have been undervalued.

Like CMS, the AAFP continues to believe it is important to prioritize codes for review under the misvalued code initiative. In the context of CMS efforts to identify and review potentially misvalued services, we were surprised and disappointed CMS failed to reference two recent efforts. First, CMS funded a pilot project by the Urban Institute to develop a validation process for the work relative value units (RVUs) used in the fee schedule for both new and existing services. The project focused on the physician service times used in establishing physician work RVUs and included two distinct elements: developing empirical measures of physician service times and considering the implications of these estimates for physician work RVUs. Table 3 (attached) in the final report from the project showed a significant difference in 2016 physician fee schedule intra-service time for some services and the median empirical intra-service time from the study. For most codes, the physician fee schedule intra-service time was greater than the median empirical intra-service time. We would strongly suggest that any code in this table whose 2016 physician fee schedule intra-service time was at least 10% more or less than median empirical intra-service time from the Urban Institute study is worthy of review, unless it has already been reviewed in the interim.

The other effort not mentioned was a CMS-funded project by RAND to develop a model to validate the physician work values using external data sources. The final report from that study offered findings similar to those of the Urban Institute project referenced above. For instance, the RAND estimates of intra-service time, which are based on data in independent datasets, are typically shorter than the current CMS estimates. As detailed in Chapter 4 of the RAND project

report, for 83 percent of the procedures, the RAND time is shorter than the CMS estimates. This difference in time is a critical issue because intra-service time is highly correlated with total work RVUs. Table 4.3 in the RAND report (also attached) compares CMS and RAND intra-service time estimates for the "Top 20" procedures used by RAND. Again, we suggest that any code in this table whose CMS intra-service time was at least 10% more or less than the average intra-service time from the RAND models is worthy of review, unless it has already been reviewed in the interim. We note that 12 of the 20 codes on RAND's list are also on the Urban Institute list referenced above.

We note that the RAND report is full of other comparisons between its models and what CMS uses to set fees under the Medicare physician fee schedule. Given CMS is seeking public comment on the best approach for developing screens to identify misvalued codes, as well as what new screens CMS might consider, we suggest the RAND report, which CMS funded, would be a good place to start. RAND believes CMS could use the model, the individual components that go into the building block model, and the overall work RVUs RAND generates in two key ways to validate codes:

- CMS could use the RAND model estimates as another means of identifying potentially misvalued codes.
- CMS could use the RAND model estimates as an independent estimate of the work RVUs to consider when assessing a RUC recommendation.

We would like to know what CMS believes and how, if at all, it intends to use the results of the Urban Institute and RAND projects. We acknowledge that neither study is without limitations. However, neither is the RUC process on which CMS currently relies.

II.G. Proposed Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

Summary

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. In the 2017 OPPS/ASC final rule with comment period, CMS finalized the PFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus provider-based departments (PBDs). In the current proposed rule, CMS proposes the payment policies under the PFS for nonexcepted items and services furnished during 2018.

For 2017, CMS established site-specific rates under the PFS for the technical component of the broad range of nonexcepted items and services furnished by nonexcepted off-campus PBDs to be paid under the PFS that was based on the OPPS payment amount for the same items and services, scaled downward by 50 percent. CMS called this adjustment the "PFS Relativity Adjuster." CMS considered the 2017 50 percent PFS Relativity Adjuster to be a transitional policy and has previously stated its concern that the adjuster for 2017 might be too small. For 2018, CMS proposes to revise the PFS Relativity Adjuster for nonexcepted items and services furnished by nonexcepted off-campus PBDs to be 25 percent of the OPPS payment rate.

For 2018, CMS is proposing to continue using its authority under section 1848 (e)(1)(B) of the *Social Security Act* to maintain a class-specific set of GPCIs for these site-specific technical component rates that are based both on the hospital wage index areas and the hospital wage

index value themselves. For purposes of payment to hospitals, this means that the geographic adjustments used under the OPPS continue to apply.

CMS continues to believe it is necessary to incorporate the OPPS payment policies for comprehensive APCs, packaged items and services, and the multiple procedure payment reduction to maintain the integrity of the PFS Relativity Adjuster, because the adjuster is intended in part to account for the methodological differences between the OPPS and the PFS rates that would otherwise apply. CMS is interested in comments regarding the applicability of particular prospective OPPS adjustments to nonexcepted items and services. To apply these OPPS payment policies and adjustments to non-excepted items and services, CMS proposes that hospitals continue to bill on an institutional claim form that will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment.

For 2019 and for future years, CMS intends to examine the claims data in order to determine not only the appropriate PFS Relativity Adjuster(s), but also to determine whether additional adjustments to the methodology are appropriate – especially with the goal of attaining site neutral payments to promote a level playing field under Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs. CMS solicits comments on potential changes to its methodology that would better account for these specialty-specific patterns.

AAFP Response
In general, **the AAFP strongly supports CMS efforts to align payment policies for physicians in independent practice with those owned by hospitals. The AAFP continues to encourage CMS to also consider site-of-service payment parity polices from a broader perspective. Namely, CMS should <u>not</u> pay more for the same services in the inpatient, outpatient, or ambulatory surgical center setting than in the physician office setting.**

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.

Like CMS, we believe that the intent of section 603 of the *Bipartisan Budget Act* of 2015 (BBA) is to curb the practice of hospital acquisition of physician practices that then results in receiving additional Medicare payment for similar services. The AAFP supported CMS' original proposal, made in 2016, 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 continue to believe that this was a reasonable response consistent with section 603 of the BBA.

Accordingly, we remain disappointed that, for 2017 and now proposed for 2018, CMS will continue to pay non-excepted, off-campus PBDs or excepted off-campus PBDs that provide non-excepted items and services under what, in essence, remains the OPPS, albeit at a discounted rate. Nominally, the payment rates are under the MPFS, but as CMS noted in the interim final rule with comment, these rates are "specific to and can only be reported by hospitals reporting nonexcepted items and services on the institution claim form," which acknowledges explicitly that payments to all hospital outpatient departments—excepted or non-excepted—will maintain an enhanced status.

The reality that payment rates continue to be based on OPPS rather than the MPFS is evidenced by the fact that, for 2018, CMS is proposing to continue to maintain a class-specific set of GPCIs for these site-specific technical component rates that are based both on the hospital wage index areas and the hospital wage index value themselves. As noted in the proposed rule, this means that the geographic adjustments used under the OPPS, rather than those used under the MPFS, continue to apply. The necessity to incorporate the OPPS payment policies for comprehensive APCs, packaged items and services, and the multiple procedure payment reductions is further evidence that the proposed payment methodology is really just a stealth version of OPPS rather than the MPFS, even though CMS finalized the PFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus provider-based departments (PBDs).

The only "positive" in what CMS is proposing for 2018 is the proposal to revise the PFS Relativity Adjuster from 50% to 25%, meaning CMS will pay 25% of the OPPS amount for these services, rather than 50% as is the case in 2017. CMS remains concerned that the current 50% adjustment is too small. However, as CMS notes, its payment methodology for 2018 will not assure equal payments for the same service regardless of site of service, any more than its 2017 payment methodology does. That means hospitals may still be incentivized to buy physician practices based on the mix of services they provide and bill for them as PBDs at Medicare rates higher than would have been paid had the practice not been bought by the hospital, which is contrary to the intent of section 603. Equalizing payments "in the aggregate" still encourages hospitals to make business decisions that run counter to the public interest and the goals of the Medicare program.

Thus, for calendar year 2019, if not 2018, we support an approach like the approach that CMS initially proposed for 2017. Under this approach, CMS would pay non-excepted off-campus PBDs for their non-excepted items and services at a true MPFS-based rate that would reflect the relative resources involved in furnishing the services. For most services, this MPFS-based rate would equal the non-facility payment rate under the MPFS minus the facility payment rate under the MPFS for the service in question. For other services for which CMS does not provide separate payment under the MPFS, if payment is made under OPPS, this MPFS-based rate would equal the MPFS non-facility rate. For still other services, the technical component rate under the MPFS would serve as the MPFS-based rate. Such an approach would, in fact, equalize payment rates between physician offices and non-excepted off-campus PBDs on a procedure-by-procedure basis which is consistent with the AAFP's vision for how Medicare payment should be designed.

H. Proposed Valuation of Specific Codes
2. Methodology for Proposing Work RVUs
Summary
In this section of the proposed rule, CMS observes that, for many codes reviewed by the Relative Value Scale Update Committee (RUC), recommended work RVUs have appeared incongruous with recommended assumptions about the resource costs in time. This has been true for a significant portion of codes for which CMS has recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When CMS has adjusted work RVUs to account for significant changes in time, CMS has begun by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs have not appeared to account for significant changes in time, CMS has used different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values.

In the 2017 PFS proposed rule, CMS requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, CMS did not receive any specific potential alternatives as requested. Despite this lack of alternative approaches, CMS has shifted its approach to reviewing RUC recommendations, because it believes most practitioners paid under the PFS would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the PFS. Thus, for 2018, CMS has generally proposed RUC-recommended work RVUs for new, revised, and potentially misvalued codes, as evidenced in Table 10, which shows only one code where CMS did not accept the RUC-recommended work RVUs. To the extent CMS has identified some concerns similar to those it has recognized in prior years during its review of these RUC-recommended values, CMS has included descriptions of potential approaches it might have taken in developing work RVUs that differ from the RUC recommended values. CMS seeks comment on both the RUC-recommended values as well as the alternatives considered.

AAFP Response
Like CMS, the AAFP has observed that, for many codes reviewed by the RUC, recommended work RVUs are incongruous with recommended assumptions regarding the resource costs in time. We have called out these incongruities during deliberations at the RUC, and we have supported CMS in its subsequent adjustment of work RVUs to account for significant changes in time.

Despite the fact no one offered any alternative to the approach that CMS has been taking in this regard, CMS has changed its approach. For 2018, CMS has proposed RUC-recommended work RVUs for all but one new, revised, and potentially misvalued codes, even when CMS has identified concerns similar to those it has recognized in prior years.

We are deeply disappointed in CMS' new approach to valuing codes under the Medicare physician fee schedule. Section 1848 of the *Social Security Act* charges CMS, not the RUC, with the responsibility to set work RVUs under the Medicare physician schedule. From our perspective, CMS is abandoning that responsibility by wantonly accepting the RUC's recommendations, even where it recognizes those recommendations are inconsistent with the time and intensity paradigm of physician work.

In defense of its new approach, CMS cites its belief that most clinicians paid under the PFS would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the PFS. If that belief is true, it is driven in large part by the facts that the RUC methodology and process favor procedural services and most clinicians paid under the PFS are procedurally-oriented. CMS does not have an obligation to bend to the perceived will of the majority in this regard. **As CMS states in this part of the proposed rule, its obligation is "to ensure that the RVUs reflect relative resource use." CMS needs to live up to this obligation, not kowtow to the RUC. The RUC is not infallible, and CMS should not act as if the RUC is.**

Accordingly, for each code reviewed by CMS for which the agency has identified some concerns similar to those it has recognized in prior years, we urge CMS to act on those concerns and make appropriate refinements using potential approaches described in the proposed rule.

4. Proposed Valuation of Specific Codes for CY 2018

Parent, Caregiver-Focused Health Risk Assessment (CPT codes 96160 and 96161)

Summary

For these two practice-expense-only codes, the RUC recommended seven total minutes of clinical staff time, and CMS is proposing to adopt this number of minutes in valuing the services. However, whereas the PE worksheet submitted by the RUC included several distinct tasks with minutes for each, CMS is proposing to designate all seven minutes under "administration, scoring, and documenting results of completed standardized instrument" rather than dividing the minutes into the four categories as shown in the RUC recommendations.

AAFP Response

The AAFP supports CMS designating all seven minutes of clinical labor time as "administration, scoring, and documenting results of completed standardized instrument."

Psychiatric Collaborative Care Management Services (CPT codes 994X1, 994X2, 994X3, and HCPCS code G0507)

Summary

In 2017, CMS established separate payment for three services (HCPCS codes G0502, G0503, and G0504) under the psychiatric collaborative care model that paralleled CPT codes that were being created to report these services as well as a G-code for general behavioral health integration (BHI) services (HCPCS code G0507). For 2018, the CPT Editorial Panel is creating CPT codes 994X1, 994X2, 994X3, and 99XX5 to describe these services.

CMS is proposing the RUC-recommended work RVUs for each of these services, which are identical to the current values for HCPCS codes G0502, G0503, G0504, and G0507. CMS is also proposing the RUC-recommended PE inputs, with two refinements. First, CMS is proposing to delete one couch and two chairs from among the equipment for 994X1, 994X2, and 994X3 in the facility setting. Second, the RUC recommended values included clinical labor inputs in the facility setting, but CMS is not proposing to include these minutes in developing the facility PE RVUs.

In the proposed rule, CMS states that the reason for the second refinement is that, if CMS were to develop facility PE RVUs for these services that included clinical staff time and a practitioner working in a provider-based department of a hospital was furnishing these services, both the professional and the hospital would be paid for the same clinical labor costs.

CMS acknowledges that this aspect of the RUC's recommendation likely reflects the circumstance where the patient receiving the services spends significant time in a facility setting, but the billing practitioner is nonetheless incurring the cost associated with the non-face-to-face clinical staff time over the course of a month. CMS also acknowledges that the binary site of service differential may not recognize the different models of this kind of care and may not be appropriate in some cases. CMS seeks comments on how to best address this valuation issue for these and other monthly care management services and offers the possibility of considering a range of options for future rulemaking, including allowing separate billing for the professional, technical, and global components of these services to allow practitioners to bill the component of the service they furnish.

Regarding the general BHI code (99XX5), CMS remains interested in how this code is being used and looks forward to hearing from stakeholders regarding its use in reporting different models of BHI services. Additionally, CMS has received inquiries from stakeholders about whether professionals who cannot report E/M services to Medicare might nonetheless serve as

a primary hub for BHI services. For purposes of future rulemaking, CMS seeks comment on the circumstances under which this model of care is happening and whether additional coding would be needed to accurately describe and value other models of care.

AAFP Response
The AAFP agrees with the CMS proposal to delete one couch and two chairs from among the equipment for 994X1, 994X2, and 994X3 in the facility setting. We agree that it would not be typical for the billing provider to need such equipment when the services are provided to a patient in the facility setting.

We disagree with CMS' proposal to not include the minutes of clinical staff time when these services are done in a facility setting. As CMS notes, the RUC's recommendation to include clinical labor time for these codes in the facility setting reflects what we believe is a typical circumstance in which the patient receiving the services spends significant time in a facility setting, but the billing clinician is nonetheless incurring the cost associated with the non-face-to-face clinical staff time over the course of a month.

We appreciate CMS' willingness to consider other means to address the appropriate valuation of these services in the facility setting. Like CMS, we are open to separate billing for the professional, technical, and global components of these services to allow clinicians to appropriately bill the component of the service they furnish. We believe that option is preferable to simply not including clinical staff time in the facility setting.

Another option may be to reconsider how place of service (POS) codes are used with such services. In section 10.6 of chapter 26 of the Medicare Claims Processing Manual, CMs instructs Medicare administrative contractors and, by extension, physicians, "For purposes of payment under the Medicare Physician Fee Schedule (MPFS), the POS code is generally used to reflect the actual setting where the beneficiary receives the face-to-face service." CMS goes on to state:

However, there are two exceptions to this general rule – these are for a service rendered to a patient who is a registered inpatient or an outpatient of a hospital. In these cases, the correct POS code -- regardless of where the face-to-face service occurs -- is that of the appropriate inpatient POS code (at a minimum POS code 21) or that of the appropriate outpatient hospital POS code (at a minimum POS code 19 or 22, for outpatient services performed off campus or on campus) as discussed in section 10.5 of this chapter.

We note that both instructions refer to "face-to-face" services. However, psychiatric collaborative care management and other monthly care management services are often non-face-to-face services, in which the practice expenses are driven by where the physician is rather than where the patient is located. If CMS were to adjust its place of service instructions for these services to have physicians report their place of service (rather than the patient's location), then CMS could safely not include the minutes of clinical staff time when these services are done in a facility setting. Thus, a physician providing these services from his office would report POS 11, regardless of the patient's location, be paid at the non-facility rate, and thus be compensated for the clinical staff time involved. Meanwhile, a physician in a clinician-based department of a hospital would report POS 19 or 22, be paid at the facility rate, and thus not be compensated for the clinical staff time, which is otherwise captured by the facility fee paid to the hospital. Adjustment to the POS instructions for these services might also reflect who employs the clinical staff supporting the billing physician.

In sum, we believe there are multiple ways in which CMS could address the identified dilemma besides simply not including clinical staff time in the facility setting. We look forward to working with CMS to identify a mutually agreeable solution before the final rule on the 2018 fee schedule is adopted.

Regarding the general BHI code (99XX5), 2017 is the first year in which physicians may report it, so we do not have any information yet on how physicians are using this code. Consequently, we do not know whether additional coding is needed.

Physician Coding for Insertion and Removal of Subdermal Drug Implants for the Treatment of Opioid Addiction (HCPCS codes GDDD1, GDDD2, and GDDD3)

Summary

For 2018, CMS proposes to make separate payment for the insertion, removal, and removal with reinsertion of Buprenorphine subdermal implants using HCPCS G codes:

- HCPCS code GDDD1: Insertion, non-biodegradable drug delivery implants, 4 or more.
- HCPCS code GDDD2: Removal, non-biodegradable drug delivery implants, 4 or more.
- HCPCS code GDDD3: Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more.

Based on recommendations from the American Society of Addiction Medicine (ASAM), CMS proposes to set the work RVUs for these codes as follows:

- GDDD1: 1.82 (crosswalk to CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles))
- GDDD2: 2.10 (crosswalk to CPT code 96922 (Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm))
- GDDD3: 3.55 (crosswalk to CPT code 31628 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe))

CMS proposes direct practice expense inputs for each code to include an RN/LPN/MTA blend of clinical staff time, various medical supplies, and the following medical equipment: mobile instrument table, power table, basic instrument pack, and exam light. CMS invites comments on its proposal to create these codes as well as the appropriateness and accuracy of its proposed work RVUs and PE inputs.

AAFP Response

The AAFP supports CMS' proposal to create these codes. As noted in the proposed rule, ASAM unsuccessfully applied to have similar CPT codes created. The AAFP supported ASAM's application to the CPT Editorial Panel. We believe family physicians provide a significant number of these services as they deal with the current opioid epidemic in this country. Having specific codes to describe these services will be helpful.

Regarding the proposed work RVUs and PE inputs, we have no specific comments about their accuracy or appropriateness now. If CMS finalizes its proposal to create these codes, we anticipate that the RUC will review them with respect to both work and PE. If appropriate, we will participate in that review.

Payment Accuracy for Prolonged Preventive Services (HCPCS codes GYYY1 and GYYY2)

Summary

To more accurately reflect the differential resource costs when additional time is required to furnish a Medicare-covered preventive service, CMS is proposing to make payment for prolonged preventive services using two new HCPCS G codes that could be billed along with the Medicare-covered preventive service codes, when a clinician provides a prolonged Medicare-covered preventive service:

- GYYY1: Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (List separately in addition to code for preventive service))
- GYYY2: Prolonged preventive service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for preventive service)).

These proposed services are only permitted to be billed with Medicare-covered preventive services. Beneficiary coinsurance and deductible would not be applicable.

For purposes of valuation for both initial and additional 30 minute codes, CMS is proposing to use one half of the current work RVUs and direct PE inputs for CPT code 99354 (Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)). CPT code 99354 has a total time of 60 minutes and a work RVU of 2.33. Therefore, CMS is proposing a work RVU of 1.17 and 30 minutes of total work time for HCPCS codes GYYY1 and GYYY2. CMS is proposing to use one half of the direct PE inputs for CPT code 99354, which results in a proposal of 7 minutes of clinical labor type L037D (RN/LPN/MTA) and 15 minutes for equipment type EF031 (table, power).

For preventive services with both physician work and practice expense, CMS is considering the typical service time of the primary procedure to be the intra-service work time used for the purposes of rate setting. For Medicare-covered preventive services with no face-to-face physician work, the typical time is the service period clinical staff time that best represents the face-to-face time with the patient.

AAFP Response

The AAFP supports CMS' proposal to create these codes. As CMS notes in the proposed rule, like E/M visit codes, many of the Medicare-covered preventive services codes describe a service that has an atypically broad range of potential resource costs, including differential amounts of time required to furnish services. However, unlike for most E/M visit codes, there are not prolonged services codes that apply to Medicare-covered preventive services. CMS' proposal would correct this deficiency.

CMS' proposed valuation of these codes assumes that prolonged preventive services are equivalent in intensity to other prolonged E/M services represented by CPT code 99354. That code currently has an intensity as represented by intra-service work per unit of time (IWPUT) of 0.0388, which is only slightly higher than the current IWPUT of 99212 (0.0346). Given this

intensity and the relative amount of time involved, we support CMS' proposal to value these new codes at one half of the current work RVUs and direct PE inputs for CPT code 99354.

If CMS finalizes its proposal to create these codes, we anticipate that the RUC will review them with respect to both work and PE. If appropriate, we will participate in that review.

Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular (CPT code 96372)

Summary

CMS proposes to reduce the clinical labor time for this code by three minutes for the following reasons and then adjust the equipment times accordingly:

- Complete medical record documentation – reduce from 1 minute to zero, because it's an Indirect Practice Expense input and/or not individually allocable to a patient for a particular service
- Document lot number and expiration date – reduce from 1 minute to zero to conform with clinical labor activity in other codes in family
- Clean room/equipment – reduce from 1 minute to zero because this code is typically done with an E/M

AAFP Response

The AAFP agrees with CMS' proposal to reduce the clinical staff time to clean room/equipment from one minute to zero, because, according to Medicare claims data, this code is typically done in conjunction an E/M code, for which there is already time to clean room/equipment. Admittedly, it does not take much, if any, extra time to dispose of supplies for the injection when cleaning the room after the visit.

That said, we note that code 96372 can and often is performed for recurrent injections with a defined plan of care. In such cases, there is no associated E/M when not evaluated for a separate reason by a physician, and code 99211 is bundled into 96372 and is not separately billable with a -25 modifier. In that case, one minute of clinical staff time to clean room/equipment as part of 96372 is appropriate, and CMS should add this clinical staff time back to the inputs for 96372 when or if Medicare claims data ever show it is not typically done in conjunction with an E/M code.

The AAFP disagrees with the other proposed reductions in clinical staff time associated with this code. Completing medical record documentation for a procedure such as therapeutic injection involves clinical staff, which makes it a direct expense allocable to that procedure. We fail to grasp why CMS perceives it as an indirect practice expense or not individually allocable to a patient for a particular service. Likewise, it takes clinical staff time to document the lot number and expiration date of the substance injected; clinical staff are required to do the documentation, and it is a great liability, possibly, if the practice cannot track back any injections given based on lot number.

Accordingly, we recommend that CMS only adjust the clinical staff time and corresponding equipment time for code 96372 by one minute to reflect the reduced clinical staff time to clean room/equipment.

Immunization administration (90460, 90471, and 90473)

Summary

CMS uses CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) as a crosswalk for valuing the Immunization Administration (IA) codes (90460, 90471, and 90473). Accordingly, CMS proposes to apply the same refinement of the direct practice expense (PE) inputs for crosswalk code 96372 to each of the IA codes (90460, 90471, and 90473).

AAFP Response

Beyond our objections to the refinement of the direct practice expense (PE) inputs for code 96372, noted above, we also we do not believe that similar refinements need to be made for the IA codes.

The current IA direct PE inputs are accurate and in no need of refinement. Additionally, if refinement were to occur as a result of the 96372 crosswalk, there would be no rationale for the resulting decrease in PE RVUs for codes 90460, 90471, and 90473. Furthermore, it would contradict CMS' position that espouses the value of vaccines and the critical role they play in disease prevention. The administration of vaccines has been shown to reduce the cost of the health care burden.

The Academy regards the current IA inputs as appropriate and, as such, suggests an alternative crosswalk code, if CMS needs one: 36000 (Introduction of needle or intracatheter, vein).

I. Evaluation & Management (E/M) Guidelines and Care Management Services

Summary

CMS notes the work it has done with the CPT Editorial Panel in recent years to develop and value (or revalue) the following codes:

- Transitional care management (TCM) services (2013).
- Chronic care management services (CCM) (2015, 2017).
- Behavioral health integration (BHI) services (2017).
- Assessment/care planning services for cognitive impairment (2017).
- Prolonged E/M services without direct patient contact (2017).

CMS solicits public comments on ways it might further reduce administrative burden for these and similar services under the PFS.

Regarding E/M guidelines, CMS agrees that there may be unnecessary burden with these guidelines and that they are potentially outdated, since they have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity. CMS believes this is especially true for the requirements for the history and the physical exam.

Thus, CMS agrees with stakeholders that the E/M documentation guidelines should be substantially revised. CMS believes that a comprehensive reform of E/M documentation guidelines would require a multi-year, collaborative effort among stakeholders. CMS also believes that achieving the goal of reduced clinician burden and improved, meaningful documentation for patient care will require both updated E/M guidelines, as well as changes in technology, clinician documentation practices and workflow. CMS seeks input on the specific changes it should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine. CMS is specifically

seeking comment on how it might focus on initial changes to the guidelines for the history and physical exam, because differences in medical decision making and time are likely the most important factors in distinctions between visits of different levels. CMS is also specifically seeking comment on whether it would be appropriate to remove the documentation requirements for the history and physical exam for all E/M visits at all levels and allow medical decision making and/or time to serve as the key determinant of E/M visit level.

CMS is additionally seeking comment on whether it should leave it largely to the discretion of individual clinicians to what degree they should perform and document the history and physical exam. CMS also welcomes comments on specific ideas that stakeholders may have on how to update medical decision making guidelines to foster appropriate documentation for patient care commensurate with the level of patient complexity, while avoiding burdensome documentation requirements and/or inappropriate miscoding.

CMS notes that many stakeholders think the E/M code set itself is outdated and needs to be revised. CMS acknowledges the limitations of the current E/M code set and agrees that the structure of the underlying code set and its valuation relative to other PFS services are also important issues that CMS expects to continue to explore, though CMS is immediately focused on revision of the current E/M guidelines to reduce unnecessary administrative burden.

Lastly, CMS seeks comment on ways it might further reduce burden on reporting practitioners for care management services, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes.

AAFP Response
The AAFP applauds CMS' leadership in recognizing the need to review and revise the 1995 and 1997 documentation guidelines (Guidelines) for evaluation and management (E/M) services. Family physicians rely on the E/M code set to capture the essence of their work. Accordingly, no specialty has more of a stake in improving the Guidelines than family medicine. The AAFP thanks CMS for this acknowledgement and looks forward to working with the agency in its effort to reform the Guidelines and the burden that they impose on family medicine practices.

In general, the AAFP views the Guidelines as a burden on family medicine—a burden that lacks an offsetting benefit to clinical care. Indeed, the Guidelines are not about patient care; they are about coding, and justifying payment. In the broadest sense, the Guidelines detract from the work of family physicians, and can even serve as a barrier between physician and patient. They are among the contributing factors to the current lowering of morale among physicians, impeding some physicians from achieving the "Quadruple Aim"—which includes professional growth and satisfaction. In a letter to President Trump sent earlier this year, the AAFP listed the Guidelines as one of the two most onerous examples of the various burdensome regulations on the work of family physicians. The following are some justifications for this position:

- First—and most importantly—the Guidelines consume an inordinate amount of physician time, one of the family physician's most vital resources. The focus of family medicine should always be on a continuous, caring relationship with the patient—not on justifying the level of billing. Trying to make sure that all qualifiers are met or that enough buttons are clicked adds time and frustration to many patient encounters. A 2016 study published in the *Annals of Internal Medicine* found that, while in the examination room with patients, physicians spent 37.0% of the time on EHR and desk work, much of which we suspect is driven by the E/M documentation guidelines.

- Second, the Guidelines are not designed to support the workflow of the family physician. The Guidelines are both overbroad and under-inclusive—overbroad because, as CMS notes in the proposed rule, they include detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved) without respect to the nature of the patient's visit; under-inclusive especially for primary care because they do not adequately support the documentation of the management of multiple chronic conditions—which is common in family medicine. The Guidelines are set up for single-problem visits—not the complex multi-problem visits most family physicians see today. As physician payment under Medicare becomes more value-based, the role of primary care practices as care managers and care coordinators for both acute and chronic conditions will become even more important. This role is not well represented in the current guidelines. Meanwhile, the Guidelines contain multiple ambiguities; even coding experts cannot always agree on how to interpret them, which can lead to audit uncertainty and miscoding.
- Third, in the case of primary care and family medicine, many patient-physician relationships are bonds that are formed over years and even decades. We know our patients, and our patients know us. It is detrimental to these relationships for the physician to be chained to a system as needlessly rigid as the current Guidelines. They promote evaluation in terms of itemized bullets in various categories that can often displace critical thinking.
- Fourth, as CMS acknowledges, the Guidelines are outdated. They were designed before the widespread adoption of electronic health records (EHR), and as such negatively impact the usability and interoperability of EHR tools. The clinically relevant documentation leads to more clicking, and physicians are being asked to perform additional data capture for quality measurement and for recording the key clinical data needed for care delivery. Any subsequent physician now must wade through the extra documentation to find the key clinical data, as EHRs are not currently smart enough to discriminate between clinically relevant and non-clinically relevant components of the record. Additionally, the Guidelines dictate who can and should record data within the medical record. This stilts the advance of team-based care. Clinical staff are fully capable of obtaining a history on a patient for the physician to review before an encounter begins. It should be relevant to the presenting problem; a physician can elaborate on the history and exam as needed from that initial interview. As the Guidelines stand now, a physician is to be the one to obtain the history of present illness. Additionally, the components of medical decision making are outdated and should be updated to reflect current models of care and technology. Even though Section 4001(a)(1)(c) of the 21st Century Cures Law prohibits restricting recording documentation to only a physician, this is only for CMS regulations and does not bind private payers to the same. As discussed elsewhere below, we also think it's important for CMS to reconsider restrictions in the Guidelines on capturing data for documentation. Further guidance is needed to make this provision of the 21st Century Cures Law clear to physicians and practice/hospital administrators.
- Finally, the Guidelines are costly. An entire industry related to coding has emerged to help physicians comply with these and other related administrative tasks. Absolutely none of this adds value to the patient experience; it is merely an additional cost for the practice of medicine.

In response to CMS' question about whether the "it would be appropriate to remove our documentation requirements for the history and physical exam for all E/M visits at all levels," the AAFP strongly agrees. **Indeed, the AAFP has previously called for the**

documentation guidelines to be eliminated for primary care physicians for all three domains: history, physical exam, and medical decision making.

We presume that removal of the documentation requirements for the history and physical exam for all E/M visits at all levels would still leave in place a modified version of the Guidelines for medical decision making. Indeed, the guidelines to support medical decision making-driven E/M documentation need to be in place before the documentation requirements for the history and physical exam are eliminated, lest physicians find themselves without any guidance or protection from subjective audits of medical decision making.

In general, medical decision making should make up the essence of a rational documentation system and could guide the coding of E/M in most instances, although the history and exam can sometimes be very important to a visit (e.g., when one must pay close attention to patient and family history for genetic issues). The Assessment and Plan is the best way to capture the patient encounter; in fact, a well-prepared Assessment and Plan is often all that is needed to fully describe the management of patients with chronic illnesses. The organization and utility of the medical decision making documentation guidelines could be updated and improved—including to reflect the EHR environment—in a manner to allow physicians to document their work in a much more rational and patient-centered manner, whether the visit focuses on medical decision making, history, or exam.
As noted, we ideally believe that the documentation guidelines should be eliminated for primary care physicians for all three domains: history, physical exam, and medical decision making. This approach is consistent with our proposal, pending with the Physician-focused Payment Model Technical Advisory Committee, that face-to-face E/M services in advanced primary care practices should be paid via a prospective, risk-adjusted, per patient per month primary care global payment. Such a payment model eliminates the necessity for documentation guidelines grounded in a fee-for-service payment world.

Whatever the proposed solution CMS considers, it must not be one that merely replaces the current complex and administrative burden laden solution with another yet different administratively burdensome solution. Further, as CMS alludes, the failures of the current Guidelines are also due to limitations of the current E/M code set. **Thus, we are happy that CMS agrees the structure of the underlying code set and its valuation relative to other PFS services are also important issues that CMS expects to continue to explore. The AAFP continues to believe that the current E/M code set is inadequate to describe the range of E/M services provided by different specialties. We believe its structure and valuation particularly disadvantage primary care, which rely most heavily on E/M codes. CMS currently undervalues E/M codes and other primary care services. Without remedying this flaw, payments under MIPS and future actuarial calculations for APMs will not adequately compensate primary care for the complexity of care provided – and could undermine broader goals to improve care, improve health, and reduce costs.**

We agree with CMS that comprehensive reform of E/M documentation guidelines, and the E/M code set, should occur and be a collaborative effort among stakeholders. We appreciate that CMS has agreed to initiate that effort now, and we stand ready to do whatever we can to help CMS achieve the twin goals of reduced clinician burden and improved, meaningful documentation for patient care. However, we disagree that this requires a prolonged multi-year effort. These codes have been undervalued for decades and the documentation guidelines are archaic in the delivery of current day primary care. The result has been disastrous for primary care becoming foundational to a reformed health care system and delivering on the Triple Aim of better care, better health and smarter spending. The time for action is now and this effort

demands that appropriate resources be allocated by CMS so this can be accomplished as rapidly as possible.

In the meantime, there is something that CMS can do immediately to make the Guidelines more consistent with team-based primary care as practiced today. Specifically, we believe that all the elements of team-based care that are part of the patient office visit, if reviewed by and finalized by a physician or other qualified health care professional, should be considered part of the E/M service and supporting documentation for the coding that follows the information entered. Accordingly, we advocate that CMS revise its Documentation Guidelines for E/M Services, so the guideline that currently reads, "The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others," reads instead as follows:

> *The medical record may be recorded by any staff involved in the patient's care or by the patient, as appropriate. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.*

Additionally, we advocate that section 3.3.2.1.1(B) of chapter 3 of the Medicare Program Integrity Manual be revised to instruct review contractors to consider all medical record entries made by physicians and "other staff involved in the care of the patient, along with the patients themselves." With these changes, we believe Medicare's guidelines and instructions would more appropriately be in line with the kind of team-based care practiced and advocated by CMS today. **We call on CMS to make this change immediately.**

III. Other Provisions of the Proposed Rule

A. New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Summary

CMS proposes revisions to the CCM payment for RHCs and FQHCs, and proposes requirements and payment for general BHI and psychiatric CoCM services furnished in RHCs and FQHCs, beginning on January 1, 2018. Specifically, effective January 1, 2018, CMS proposes the establishment of two new G codes for use by RHCs and FQHCs:

- GCCC1, would be a General Care Management code for RHCs and FQHCs, with the payment amount set at the average of the national non-facility PFS payment rates for CCM codes 99490 and 99487 and general BHI code G0507.
- GCCC2, would be a Psychiatric CoCM code, with the payment amount set at the average of the national non-facility PFS payment rates for psychiatric CoCM codes G0502 and G0503.

RHCs and FQHCs could bill the new General Care Management code, GCCC1, when the requirements for any of these 3 codes (CPT codes 99490, 99487, or HCPCS code G0507) are met. The General Care Management code could be billed alone or in addition to other services furnished during the RHC or FQHC visit. This code could only be billed once per month per beneficiary, and could not be billed if other care management services (such as TCM or home health care supervision) are billed for the same time period.

CMS proposes the following requirements for RHCs and FQHCs furnishing BHI services:

- Initiating Visit: An E/M, AWV, or IPPE visit with an RHC or FQHC primary care practitioner (physician, NP, PA, or CNM) occurring no more than one-year prior to commencing BHI services. This could be the same initiating visit that is used for initiating

CCM services, and would be billed separately as an RHC or FQHC visit (if the RHC or FQHC has not already billed for this visit).

- Beneficiary Consent: Documentation in the medical record that the beneficiary has consented to receive BHI services, given permission to consult with relevant specialists as needed, and been informed that there may be beneficiary cost-sharing, including deductible and coinsurance amounts as applicable, for both in-person and non-face-to-face services that are provided. The beneficiary consent process would also include informing the patient that only one practitioner/facility can furnish and be paid for these services during a calendar month, and that the patient can stop care coordination services at any time (effective at the end of the calendar month). This could be obtained at the same time that beneficiary consent is obtained for CCM services.
- Billing Requirements: At least 20 minutes of care management services per calendar month, furnished under the direction of the RHC or FQHC primary care physician, NP, PA, or CNM, and furnished by an RHC or FQHC practitioner, or by clinical personnel under general supervision. These are the same billing requirements as for CCM services. If both CCM and BHI services are furnished in the same month, the time would be combined and billed as one under the new care coordination code.
- Patient Eligibility: One or more new or pre-existing behavioral health or psychiatric conditions being treated by the RHC or FQHC primary care practitioner, including substance use disorders, that, in the clinical judgment of the RHC or FQHC primary care practitioner, warrants BHI services.
- Required Service Elements: An initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.

RHCs and FQHCs could bill the new psychiatric CoCM code when the requirements for any of these 2 codes (G0502 or G0503) are met. The psychiatric CoCM code could be billed alone or in addition to other services furnished during the RHC or FQHC visit. To prevent duplication of payment, this code could only be billed once per month per beneficiary, and could not be billed if other care management services, including the proposed General Care Management code, are billed for the same time period.
CMS had considered allowing RHCs and FQHCs to bill for the complex CCM codes, the BHI code, and the psychiatric CoCM codes by allowing the individual CPT or HCPCS codes to be added to an RHC or FQHC claim, but the agency does not believe this approach is in the best interest of RHCs and FQHCs. CMS believes bundling the CCM and BHI codes and the psychiatric CoCM codes into 2 G codes:

- Is more consistent with the RHC and FQHC payment methodology of averaging actual costs to determine a payment rate and not paying for services based on time increments.
- Would require less record keeping, monitoring, and coding expertise, while maintaining the same quality of care standards.

AAFP Response
On behalf of its family physician members in RHCs and FQHCs, the AAFP fully supports CMS' proposals to add these services to ensure that RHC and FQHC patients have access to new care management services. We encourage CMS to finalize this in the final rule this fall and be effective for services with dates of service on or after January 1, 2018.

However, by our calculations, the proposed payment amount of GCCC1, set at the average of the national, non-facility, PFS payment rates for CCM codes 99490 and 99487 and general BHI code G0507, would, at current rates, be $61.37. Meanwhile, office-based practices billing Medicare Part B for CPT 99490, the most common chronic care management code, receive approximately $42.71. Though we support RHCs and FQHCs offering these important services, the AAFP does not understand why CMS proposes to provide a $18.66 increase to RHCs and FQHCs over what office-based practices would receive for the same work. We therefore demand that CMS revalue CPT 99490 and related codes to reflect this level of payment for these important codes in primary care. This is consistent with our comments about the importance of site-neutral payment.

C. Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

Background

In a June 23, 2016, in a final rule on the "Medicare Clinical Diagnostic Laboratory Tests Payment System," CMS implemented a statutory provision that requires extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS).

Under the CLFS final rule, reporting entities must report to CMS certain applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to CMS during a data reporting period.

In the CLFS final rule, CMS established a data collection period from January 1 through June 30 and a related data reporting period from January 1 through March 31 of the following year. The first data collection period was January 1, 2016, through June 30, 2016. The first data reporting period was January 1, 2017, through March 31, 2017. This data collection period and data reporting will be repeated every 3 years for CDLTs that are not advanced diagnostic laboratory tests (ADLTs), and every year for ADLTS that are not new ADLTs.

For the first data reporting period, industry feedback suggested that many reporting entities would not be able to submit a complete set of applicable information to CMS by the March 31, 2017 deadline, and that entities required additional time to review collected data, address any issues identified during such review, and compile the data into CMS' required reporting format. Consequently, on March 30, 2017, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period.

Proposed changes

To better understand the applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods, CMS is interested in public comments from applicable laboratories and reporting entities on the following questions:

- Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity

and/or any problems the reporting entity experienced with submitting applicable information to us.

- Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) use the sub-regulatory guidance on data reporting provided on the CMS CLFS website?2 If so, was the information presented useful?
- Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?
- Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?
- If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?
- How much time (hours) was required to assemble and report applicable information to CMS?
- Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

AAFP Response
CMS has previously estimated that only 5% of physician office laboratories (POLs) qualified as "applicable laboratories" required to collect and report private payer data. As such, we don't have answers to the questions posed by CMS in the proposed rule and would be hard pressed to find family medicine POLs that could help us answer them based on their own experience.

Instead, we will take this opportunity to express our concern that Medicare beneficiary access to clinical laboratory testing will be substantially limited starting January 1, 2018, due to widely anticipated cuts to Medicare fees for clinical laboratory testing services. We believe the size of the projected cuts is due to problematic implementation of the new payment methodology established under the *Protecting Access to Medicare Act* (PAMA). We urge CMS to implement several measures to ensure that the payment rates are accurate and consistent with Congressional intent.

Among several pressing concerns, the most immediate is that the integrity of the data for calculating payment is not assured, since the data collection process has been hamstrung by the previous Administration's decision to impose a retrospective data collection period. Also, the regulation issued did not provide a clear mechanism for aggregation of each clinical test payment and a means for stakeholders to validate the accuracy of the final payment amount. Since the rates will be effective on January 1, 2018, CMS has very limited time to address deepening concern that the payment rate will not actually reflect the weighted median of private payer payments as Congress intended. The consequences for our members' patients will be pronounced.

Applicable laboratories have reported that the decision to establish a retrospective reporting period for data collection hindered their ability to capture or reconstruct the actual final payment for applicable clinical tests. Based on the CMS regulation (not the statute), clinical laboratories were expected to know nearly six months before they were informed what data should be

collected. Many clinical laboratories did not learn of the requirements until well after June 2016 (when the regulation was issued) and after the collection of accurate data became possible. Many clinical laboratories were not aware that they were subject to the reporting requirement, because CMS provided inadequate time to conduct outreach and education.

Physician organizations have previously recommended that the data collection period should be prospective to provide applicable laboratories an adequate amount of time to work with their vendors to prepare their systems to collect the required information. Instead, the final regulation provided for a retrospective data collection period. Not surprisingly, reports have emerged that some clinical laboratories submitted inaccurate data. For instance, there are reports that partial payments have, in some instances, been reported as a total payment, particularly for paper transactions where co-pays, co-insurance, and primary/secondary payer payments could not be reconciled to generate an accurate total payment amount. There are reports of other difficulties that even large clinical laboratories have encountered. Also, given the difficulties with CMS' beta test for submission of data prior to the actual data submission period, we are concerned that the process for aggregating reported data for each clinical test and calculating the weighted median could be error prone, and CMS has not specified steps that it will take to provide transparency or validation.

For context, we note the significant irregularities and difficulties CMS encountered during the first year it rolled out another major program, the Open Payment Program. Implementation of that program was marked by disputes about whether correct data was submitted or if CMS handling of the data corrupted the accuracy. CMS had to withhold publication of large amounts of the data to address data integrity problems in the first year. The PAMA reporting involves an equally large data reporting undertaking (if not larger) with even less ability to ascertain whether (1) accurate data was submitted; and/or (2) the data processing has corrupted data accuracy. As such, there is no ability to assess whether the final payment amount reflects the data submitted. The foregoing underscores the need to validate data and to ensure that there is a transparent manner under PAMA to ascertain whether the payment calculation is correct, particularly for first cycle where data integrity remains a widely-shared concern

Based on the lack of data integrity, we have absolutely no confidence that the resulting Medicare payment rates set by CMS will reflect the resources needed to provide the tests in question. If they do not, many clinical laboratories will close, and testing in physician offices will be particularly hard hit. Consequently, Medicare patients will experience reduced access to clinical laboratory testing.

Laboratory testing furnished at the point-of-care, such as in a physician's office, enhances patient centered care and outcomes while also decreasing the costs of care coordination and administrative processes to the health care system. Point of care tests such as glucose and glycohemoglobin can be essential to assessing therapy compliance for patients with diabetes. Children presenting with flu like symptoms or sore throat are tested to determine if antibiotic treatment is necessary or if the child can return to school. The number of point of care tests is growing to meet the demands of patient centered care, and limiting the availability of such tests due to Medicare payment relative to cost will counter with increase costs of additional care coordination. For instance, patients will learn to seek care at urgent care or emergency departments, because they do not want to wait up to two days for antibiotics for a urinary bladder infection, simply because the medical office cannot afford to perform the test at a loss.

If left unchecked, the current implementation of PAMA will threaten the following important goals:

- Prevent spread of infectious diseases and pandemics - A strong, comprehensive network of clinical laboratories, including POLs, is needed to provide the first line of detection and defense against an infectious disease outbreak or pandemic in the interest of public health.
- Strengthen patient-centered care through point-of-care testing/near patient testing - Point-of-care testing is an important component of efforts to advance patient-centered care, because point-of-care testing ensures care is delivered near to patients. This is particularly important for Medicare beneficiaries who typically have more comorbidities, are more medically fragile, and face more barriers (e.g. cost and geographic) to accessing clinical care.
- Support delivery pathways that are consistent with MACRA Implementation - Point of care testing in the physician's office improves patient care continuity, optimizes care coordination, enhances efficient communication, and minimizes patient burdens associated with fragmented care. These outcomes, in turn, facilitate and advance new payment and delivery models envisioned under the *Medicare Access and CHIP Reauthorization Act* of 2015.

Because CMS did not promulgate the PAMA regulation to reasonably effect Congressional intent—namely, obtain accurate data in order to establish the correct weighted median for each test on the Medicare clinical laboratory fee schedule—we urge CMS to implement a number of steps.

1. Promptly publish preliminary information concerning the number of clinical laboratories that have reported based on market segment and geographic locations.
2. Publish preliminary clinical laboratory fee schedule rates for 2018 in early September 2017 to provide physicians and their patients time to prepare for any potential disruptions to care delivery resulting from potential significant cuts.
3. Issue an interim final rule to:
    a. Modify existing regulation and provide that CMS will conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital community laboratories) to validate and adjust the final amount calculated based on the current data collection to ensure Congressional intent achieved that payments reflect private market payments.
    b. Allow pricing to proceed as planned on January 1, 2018, based on data collection and submission under existing rule only for:
        i. Sole source clinical tests, since the data submissions are reasonably expected to be accurate given the limited test menus and since the final amount calculated can be easily validated by the sole source clinical laboratory.
        ii. Any additional clinical tests where factors establish high data integrity and transparency of private payer payment calculation.
    c. Delay pricing changes for all other clinical tests until market segment surveys are complete and final amounts calculated based on the current data collection are either validated or adjusted based on the market segment surveys.

At a time when relief from overly burdensome regulation has become a top priority of the Trump Administration, we urge CMS to ensure that implementation of PAMA results in as little administrative burden and disruption as possible. We look forward to ongoing communication and dialogue with CMS as implementation continues to ensure that Medicare beneficiaries have access to medically necessary clinical testing.

III.E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Background

The *Protecting Access to Medicare Act* of 2014 established a program that, effective January 1, 2017, would have denied payment for advanced imaging services unless the physician ordering the service had consulted appropriate use criteria (AUC). The intent of this policy is to promote the use of AUC for advanced diagnostic imaging services. This policy requires physicians ordering certain imaging services (ex. magnetic resonance imaging, computer tomography, or positron emission tomography) for Medicare beneficiaries to consult with AUC applicable to the imaging modality.

CMS began implementation of the AUC program in the 2016 Medicare PFS, in which CMS stated that AUC "crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast." This sentiment is repeated within the 2018 proposed MPFS. In 2016, CMS established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify, or endorse AUC. CMS published the first list of qualified PLEs online at the end of June 2016.

In the 2017 final Medicare PFS, CMS delayed full AUC implementation until 2018. CMS then continued to implement the program by specifying and defining the qualified clinical decision support mechanisms (CDSMs). CMS also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirements that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

Proposed Changes

In the 2018 proposed Medicare PFS and due to significant concerns regarding implementation from the AAFP and other stakeholders, CMS proposes to further delay the AUC requirement until January 1, 2019. CMS characterizes 2019, the first year of reporting, as an opportunity for testing and education that would not impact payments to furnishing professionals (i.e. imaging providers). CMS discusses including an optional, voluntary reporting period expected to begin in July 2018 for those desiring to begin testing earlier.

Regarding coding and to operationalize the AUC requirements, CMS proposes to establish a series of HCPCS level 3 codes to describe specific CDSM used by the ordering professional. CMS suggests that one G-code would be available for every qualified CDSM but that the CMS claims processing systems can only recognize new codes quarterly, such that CMS would establish a generic G-code that would be used to report that a qualified CDSM was consulted. Ordering professionals would only be permitted to use this code if a more specific named code did not yet exist for that clinician's CDSM. CMS also proposes to establish a G-code to identify circumstances where there was no AUC consultation through a qualified CDSM. CMS also proposes to develop a series of modifiers to provide necessary information as to whether and when a CDSM is used to consult AUC and whether the imaging service does or does not adhere to the applicable AUC. Furthermore, CMS would develop additional modifiers to describe exception situations, such as when the imaging service was ordered for a patient with an emergency medical condition or the ordering professional has a significant hardship exception.

This proposed rule then discusses that after *PAMA* passed into law in 2014, Congress subsequently passed the *Medicare Access and CHIP Reauthorization Act* of 2015 (MACRA),

which creates the Merit-based Incentive Payment System (MIPS), part of the Quality Payment Program (QPP). Within a separate proposed rule, the 2018 proposed QPP regulation, CMS proposed to develop a direct tie between MIPS and the AUC programs by giving MIPS credit to ordering professionals for consulting AUC using a qualified CDSM as a high-weight improvement activity for the 2018 performance year. Within the 2018 proposed MPS, CMS requests comments on how the AUC program could serve to support a quality measure under the MIPS quality performance category.

CMS had finalized in 2017 that AUC significant hardship exceptions included:

- Insufficient internet connectivity;
- Practicing for less than 2 years;
- Extreme and uncontrollable circumstances;
- Lack of control over the availability of CEHRT, and
- Lack of face-to-face patient interaction.

For operational reasons connected to the MIPS advancing care information performance category and since newly enrolled physicians are not MIPS eligible, CMS proposes to remove as a criterion for a significant hardship exception for the AUC program the criterion for those practicing for less than 2 years. Finally, in conjunction with the 2018 proposed Medicare PFS, CMS posted on their AUC website the first lists of newly qualified PLE (17 total) and CDSMs (seven qualified and nine with "preliminary qualification").

AAFP Response
As the AAFP has communicated to CMS in multiple meetings and communications, we have unending, substantial concerns about the disproportional burden primary care physicians will face when trying to comply with AUC requirements. We believe the AUC requirements run counter to the Administration's goal of reducing regulatory and administrative burden in healthcare – and we urge alignment with both MACRA and this broader goal. We are therefore pleased that, for now, CMS has:

- Further delayed AUC requirements until January 1, 2019.
- Encouraged optional AUC use in the 2018 MIPS performance year by proposing to recognize AUC as a high-weight improvement activity.
- Offered optional testing of the AUC program starting in July 2018.
- Continued to seek public feedback on how to operationalize this unfortunate statutory requirement that is separate from and predating MACRA.
- Recognized the impact of this program as extensive and with a particular impact on primary care physicians since their scope of practice is broad.

To the last point, we fully agree with CMS that AUC requirements will place more burden on primary care physicians than on other providers. As made entirely evident by the abundant G-codes and modifiers in this proposed rule, complying with the AUC for primary care physicians will add a substantial level of complexity to the already complex Medicare system that severely overtaxes our members. All physicians will be impacted by the extraordinary administrative burden associated with duplicative data entry into stand-alone CDSMs, but ultimately, this will impact primary care physicians to a disproportionate degree.

We are equally concerned that this substantial addition of administrative burden remains an unproven benefit to quality or cost reduction and that current policies and proposals in this regulation are not yet tied to the MIPS quality or cost categories. Now that value-based payment is required under *MACRA*, CMS must limit additional requirements that are not tied specifically to value. Primary care physicians have enough on their plates complying with *MACRA*.

The AAFP, therefore, strongly urges CMS to fully align the AUC with the MIPS program's cost or quality performance categories. In fact, we would prefer that the AUC program and regulatory burden be discontinued completely, and we will work with Congress to achieve this goal legislatively and would hope that CMS would do likewise. With the passage and implementation of *MACRA*, which begins to align payment with value, the need for AUC requirements has been supplanted, and those requirements will now likely divert resources from patient care in the interest of unproven efficacy.

In summary, the AAFP strongly urges CMS to discontinue the AUC program. If not discontinued, delay implementation of the AUC provision in the law until such time as all the following conditions are met:

- There is evidence to demonstrate that AUC improves quality of care.
- MACRA is fully implemented for a minimum of three years.
- Any AUC requirements are fully aligned with MACRA.
- Sets of AUC for the same diagnostic imaging modality, developed by different provider led entities, are standardized.
- CDSMs are fully interoperable with electronic health records.
- At least one CDSM with a comprehensive set of AUC, which is fully interoperable with CEHRT, is freely available.
- CDSM communicate AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition in an automated manner and do not require any separate action or use by a physician.

F. Physician Quality Reporting System Criteria for Satisfactory Reporting for Individual EPs and Group Practices for the 2018 PQRS Payment Adjustment

Summary

CMS reviewed the requirements for the final PQRS reporting period, which ended in 2016 and which will impact 2018 payments to eligible professionals for Medicare Part B covered professional services. EPs that failed to successfully report PQRS in 2016 are subject to a 2.0% downward payment adjustment in 2018. CMS proposes to retroactively modify criteria that would be applied to data already collected for determination of satisfactory reporting in 2016. Specifically, CMS proposes to lower the reporting requirement to six measures with no domain, cross-cutting, or outcome/high-priority measure requirements, to better align with MIPS. This change would not affect 2017 payments (2015 reporting period), except for those reporting using the ACO Secondary Reporting Period. The MAV process would still be applied to EPs that report fewer than 6 measures.

Individual EPs and groups who bill under the TIN of an ACO may report separately from the ACO if the ACO failed to report during the 2016 reporting period for the purposes of the 2017 and 2018 payment adjustments. The modified criteria would apply to such individual EPs and groups for the purpose of both the 2017 and 2018 payment adjustment.

CMS believes these changes will result in fewer individual EPs and groups being subject to 2018 payment adjustments with no additional burden. CMS requests comment on these proposals.

AAFP Response

The AAFP supports retroactive modification of the 2016 reporting criteria as proposed. Since there are no 2018 upward payment adjustments associated with 2016 PQRS reporting (only

downward payment adjustments), there will be no negative impact as a result of these changes, and additional physicians may avoid 2018 downward adjustments.

5. Physician Compare Downloadable Database – Addition of Value Modifier Data

Summary

Three data points for the value modifier were scheduled to be posted on Physician Compare in late 2017 based on 2016 data: quality tiers (high, med, low) for cost and quality; payment adjustment (upward, downward, neutral); and an indication if a physician or group was eligible but did not report quality measures. CMS proposes not to report this data in light of the proposal to hold all physicians and groups who meet minimum quality reporting requirement harmless from downward payment adjustments. CMS also proposes to not move forward with public reporting of Value Modifiers data in Public Use Files and Research Identifiable Files for 2016 data. All other policies related to 2016 PQRS public reporting will remain unchanged and all data required by law will remain available.

AAFP Response

The AAFP agrees Value Modifier data as described above would not be useful given the proposed policy changes and should not be made publicly available. The AAFP agrees that all other PQRS data should be made publicly available as mandated by policy and law.

G. Medicare EHR Incentive Program

Summary

In earlier regulations, CMS had finalized reporting requirements for clinical quality measurement for physicians participating in the Electronic Health Record (EHR) Incentive Program. In this proposed rule, CMS recognized that stakeholders have found the previously finalized reporting criteria for the 2016 reporting period to be complex and had difficulty in understanding the requirements to be a satisfactory reporter. Therefore, while CMS is not proposing to collect any additional data for 2016, CMS proposes to change the reporting criteria for EPs and groups who chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare EHR Incentive Program. Specifically, CMS proposes to change the reporting criteria from 9 CQMs covering at least 3 NQS domains to 6 CQMs with no domain requirement.

AAFP Response

We agree that the complexity of the CQM reporting requirements makes it very difficult to be a successful reporter and creates an unnecessary level of administrative burden for EPs (and EC under QPP). We therefore support CMS' change to 6 CQMs and dropping the domain requirement.

H. Medicare Shared Savings Program

Summary

For performance year 2019 and subsequent performance years, CMS proposes to:

- Eliminate the requirement for ACOs that include an RHC or FQHC as an ACO participant to provide attestation identifying physicians who directly provide primary care services in each RHC or FQHC that is an ACO participant and/or ACO provider/supplier in the ACO and make confirming changes to the definition of primary care;
- Use all claims submitted by the RHC and FQHC in the pre-step assignment methodology to determine whether the beneficiary is eligible for assignment to an ACO participating in the Shared Savings Program, treat a service reported on an RHC or FQHC claim as if it were a primary care service performed by a primary care physician, and remove revenue center codes from the definition of primary care services.

Additionally, CMS proposes to revise the definition of primary care services to include three additional CCM service codes (99487,99489, and G0506) and four behavioral health integration service codes (G0502, G0503, G0504, and G0507) beginning in 2018 for performance year 2019 and subsequent performance years and to include these codes when performing beneficiary assignment.

AAFP Response
We applaud CMS for recognizing the unique challenges that rural and underserved communities pose for physicians and non-physician clinicians serving in RHCs and FQHCs. The removal of the additional step of attestation process for submitting physician identifiers for purposes of beneficiary assignment would decrease administrative burden.

The AAFP would only support attributing these patients if the plurality of the services is provided by RHC or FQHC. This action would prevent inappropriate attribution for patients that receive the plurality of care through another source.

We encourage CMS to continue to promote that Medicare beneficiaries attest to one primary care physician or clinician. The beneficiary's direct attestation of a primary care physician is a significant step to promote quality and cost efficient care in any setting. Consistent with our response to the 2017 proposed rule, the AAFP advocates for CMS to standardized a term to define the beneficiary's primary care clinician across all members of the care team between settings, as this is imperative to promote effective communication between patients and clinicians. Further education from CMS is necessary to make this successful.

The AAFP appreciates that CMS created additional codes in the PFS 2017 for CCM and BHI. These codes support care management and behavioral health integration into primary care. These additional codes help sustain access to high quality, cost-effective care. It would stand to reason the inclusion of the mentioned codes identify primary care services used in the assignment of Medicare beneficiaries in the Shared Savings Program. We encourage CMS to continue to monitor and consider making changes to the definition of primary care services. Advanced Care Planning codes 99497 and 99498 are two such examples that would further define primary care services in Medicare beneficiary assignment.

2. Medicare proposal to ACO Quality Reporting
Summary
CMS proposes to include the right to re-designate a measure as pay for reporting when a substantive change to a CMS web interface measure is made under the Quality Payment Program (QPP). Such measures would not necessarily be automatically re-designated as pay for reporting when substantive changes occur. When a measure results in an issue with sampling, calculating performance, or calculating the quality benchmark, it may make it inappropriate to hold an ACO accountable for performance on the measure for the time needed for CMS to obtain the information necessary to calculate a quality benchmark for the substantively changed measure in advance of a performance year and/or until ACOs gain experience reporting the measure is substantively changed.

CMS expects to conduct at least a preliminary assessment of any substantive changes to the CMS web interface measures as part of the annual PFS rulemaking to determine whether any change to the phase-in schedule for a measure is warranted. CMS cannot always anticipate the types of substantive changes that may be finalized under the QPP or the effect of those changes on its ability to calculate performance measure. The proposal would give CMS the

flexibility to re-designate existing measures undergoing a substantive change as pay for reporting on a measure by measure basis.

Because the substantive changes that are proposed in the 2018 QPP proposed rule do not appear to change the information that must be collected for measures, CMS does not believe any changes to the measures as phase in schedules are necessary.

In analysis of the 2016 quality measure validation audit results, consideration is being made to the 90 percent match rate adopted in 2017 PFS final rule, as this might be too high and could inappropriately penalize the ACO. CMS is proposing if an ACO has a match rate below 80 percent, absent unusual circumstances, adjustment would be made to the ACO's overall quality score proportional to the ACO's audit performance. The methodology under which the audit-adjusted quality score is calculated is proposed that for each percentage point difference between the ACO's match rate and match rate considered passing the audit, the overall quality score would be adjusted downward by one percent. An 80 percent match would be threshold to passing quality validation audit.

AAFP Response
While we realize that ACO web interface measures were developed prior to establishing the Core Measures, we encourage CMS to gravitate toward using core measures in all programs, including ACOs/APMs, medical home models, and within the MIPS program. Use of the core measure sets developed by the multi-stakeholder Core Quality Measures Collaborative, which included CMS, would ensure alignment, harmonization, and the avoidance of competing quality measures among programs and payers. We agree that measures with substantive changes may have to be re-designated as pay for reporting until new benchmarks can be set. We also encourage CMS to re-designate web interface measures as pay-for-reporting in the case that the measure becomes topped-out, to better align with MIPS quality measures. ACOs should not be given a relative advantage over MIPS reporters in their ability to score high on topped-out measures
.
We appreciate the analysis by CMS in reconsideration of the audit match rate of 90% to 80% along with the revision of how the audit-adjusted quality score is calculated. The lower rate is more in line with hospital quality reporting audit rates and is more reasonable, given the current state of documentation in clinic records. This will allow ACOs to become more experienced with quality reporting requirements without the negative impact of a lower quality score.

3.Reducing Shared Savings Program Application Burden
Summary
Based on initial experience in reviewing SNF 3-Day Rule Waiver applications, CMS believes there are two requirements that impose unnecessary burden on applicants without sufficient benefit to the administration of the SSP. CMS would retain all requirements related to ACO eligibility criteria and public reporting, as specified under the SSP. Instead of requiring submission of certain materials, narratives, or supporting documentation, ACOs would be required to certify that they meet the applicable eligibility and documentation requirements as specified under the program rules. CMS would retain the right to request submission of supporting materials and documentation in cases when such additional documentation is useful in making a determination in the ACOs application.

AAFP Response
The AAFP appreciates CMS reducing administration burden specific to this issue.

4. Addressing Compliance with ACO Participant TIN Exclusivity Requirement

Summary

Currently ACO participant TINs are not required to be exclusive to one Shared Savings Program ACO unless the TIN submits claims for primary care services used to determine beneficiary assignment. Due to increased participation, CMS has concerns that TIN overlap situations are likely to become common. This would result in ACOs falling out of compliance with the exclusivity requirement. In the proposed rule, CMS would modify the program that if during the benchmark or performance year an ACO participant shows overlap to more than one Shared Savings Program ACO, CMS would not include any services billed from that TIN for beneficiary assignment.

Further, as part of this proposed modification, CMS would eliminate the references to "primary care" when describing the services used to determine the ACO's assigned beneficiary population in order to conform with the proposal to implement section 17007 of the 21st Century Cures Act, which would consider all services furnished in FQHCs and RHCs in the assignment methodology as primary care services starting in the 2019 performance year. ACOs in which an overlapping TIN is an ACO participant may be subject to a compliance action plan explaining how the ACO plans to work with the overlapping ACO participant to resolve the overlap for the next performance year.

AAFP Response

The AAFP would be supportive of the TIN exclusivity requirement proposal if the plurality of services is provided by the RHC or FQHC for an overlapping TIN. This action would prevent inappropriate attribution of patients that receive the plurality of care through another source.

5. Treatment of Individually Beneficiary Identifiable Payments Under a Demonstration, Pilot, or Time Limited Program

Summary

CMS proposes to clarify that only final non-claims-based made under a demonstration, pilot, or time limited program be included in financial calculations. This proposal would be applied to calculations that are necessary to determine ACO performance for the 2018 performance year and subsequent performance years.

For ACOs that are in the middle of an agreement period, CMS would adjust benchmarks at the start of the 2018 performance year and each subsequent performance year, so the benchmark reflects the use of the same payment information that would apply in expenditure calculation for the performance year.

The new provisions indicate that: (1) when establishing benchmarks for agreement periods in 2018, CMS will include all individual beneficiary identifiable payments, including interim payments made under a demonstration, pilot, or time limited program; (2) for agreement periods beginning in 2018 and subsequent years, CMS would only include individually beneficiary identifiable payments made under a demonstrations, pilot or time limited program that are final and not subject to further reconciliation; and (3) for performance year 2018 and subsequent performance years in agreement periods beginning in 2015, 2016, and 2017, the benchmark would be adjusted to reflect only individually beneficiary identifiable payment not subject to further reconciliation made under a demonstration, pilot, or limited program.

AAFP Response

The AAFP feels this is reasonable.

I. Value-Based Payment Modifier and Physician Feedback Program
b Payment Adjustment Amount
Summary
CMS proposes modifications to the Value Modifier policies for the 2018 payment adjustment period. CMS is proposing these changes to ensure a smooth transition from the VM to MIPS. The 2017 VM adjustment factor resulted in payment adjustments, for some groups and solo practitioners, significantly higher than the maximum positive payment adjustment under MIPS. This is largely due to the number of physician practices failing to satisfactorily report under PQRS. However, CMS believes many of these physician practices would be exempt from MIPS due to the low-volume threshold. CMS would expect the 2018 VM adjustment factor would be equal to or higher than the 2017 adjustment factor. CMS is proposing the following changes for the 2018 payment adjustment period:

- All groups and solo practitioners who satisfactorily reported to PQRS (Category 1) will be held harmless from downward payment adjustments under the quality-tiering methodology. These groups and practitioners will receive either a neutral or upward payment adjustment. CMS is proposing this in recognition of the changes to the 2016 PQRS reporting criteria. CMS understands some groups and solo practitioners may have reported differently, which could have resulted in a higher quality composite score, had the criteria been established prior to the 2016 reporting period.
- The maximum upward adjustment factor under quality-tiering for all groups and solo practitioners will be reduced to +2.0x for high quality/low cost and +1.0x for average quality/low cost or high quality/average cost. CMS is proposing this change to mitigate the effect of a high adjustment factor in 2018. CMS seeks comment on this proposal.
- For groups of 10 or more EPs, the maximum automatic downward payment adjustment for failure to satisfactorily report under PQRS (Category 2) will be reduced to -2.0 percent. CMS seeks comment on this proposal.
- For solo practitioners and groups with 2-9 EPs, the maximum automatic downward payment adjustment for failure to satisfactorily report under PQRS (Category 2) will be reduced to -1.0 percent. CMS seeks comment on this proposal.

CMS is not proposing any changes to the additional +1.0x adjustment factor for groups and solo practitioners with average beneficiary risk scores in the top 25th percent of all beneficiary risk scores. CMS is also not proposing any changes to the 2017 and 2018 payment adjustment policies for groups and solo practitioners who satisfactorily meet the PQRS reporting criteria outside of their Shared Savings Program ACO during the secondary PQRS reporting period.

AAFP Response
The AAFP is supportive of CMS' proposals.

J. MACRA Patient Relationship Categories and Codes
Summary
We appreciate that patient relationship codes were developed with physician stakeholder input, including that of the AAFP. These codes are designed to facilitate the attribution of patients and episodes to one or more physicians to improve resource use (cost) measurement. CMS seeks comment on the operational list of patient relationship categories that was finalized on May 17, 2017. The agency is required to revise the operational list annually. CMS proposes voluntary reporting of Level II HCPCS modifiers on claims submitted for items and services furnished by a physician on or after January 1, 2018, using the proposed list of patient relationship modifiers.

AAFP Response

The AAFP appreciates that CMS recognizes there will be a learning curve in using patient relationship categories and codes and is therefore proposing an initial period for voluntary reporting while physicians gain experience in using the modifiers.

Since CMS only needs physicians to code HCC diagnoses once a year and to reduce administrative burden, the AAFP suggests that a physician be allowed to record a patient relationship code once annually on the claim, if the patient relationship code and NPI are the same for all items on the claim, as opposed to requiring that the patient relationship code and NPI be attached to each line item on the claim.

The AAFP agrees the codes should be resubmitted annually to the AMA for future consideration into the CPT modifier code set. We are concerned that the 2018 proposed Medicare physician fee schedule erroneously states that the CPT Editorial Panel denied the modifiers and therefore will not be included as level I modifiers, when, in fact, the CPT Editorial Panel did accept them. Compounding this concern is that level II HCPCS modifiers as proposed are not accepted by all payers. We urge CMS to construct these modifiers in a way that facilitates use by all payers.

K. Proposed Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

Background

In the 2017 Medicare physician fee schedule, CMS proposed and subsequently finalized aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model. The aim of the MDPP expanded model is to continue to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes as defined by the MDPP beneficiary eligibility criteria. Services available through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health professionals. CMS designated services under the MDPP expanded model to be covered as additional preventive services under Medicare. In the 2017 PFS final rule, CMS finalized MDPP policies to enable CDC-recognized organizations to prepare for enrollment, including finalizing the framework for the MDPP expanded model, details of the MDPP expanded model, beneficiary eligibility criteria, supplier eligibility criteria, and supplier enrollment requirements. CMS and stakeholders also identified several issues that were deferred to future rulemaking.

In the 2017 PFS final rule, CMS finalized the structure of MDPP services. CMS provided that the MDPP core benefit consists of at least 16 weekly core sessions over months 1 through 6 and at least 6 monthly core maintenance sessions over months 7 through 12, furnished regardless of weight loss. CMS also finalized that Medicare will cover ongoing maintenance sessions after the 12-month core set of MDPP services, if beneficiaries achieve and maintain the required minimum weight loss of 5 percent. CMS intends to begin supplier enrollment before MDPP services become available, and CMS finalized an expanded model start date of January 1, 2018.

In response to the 2017 PFS, the AAFP fully supported the expansion of the MDPP and supported these services being furnished by both physician and non-physician, community based organizations that are recognized by the CDC to provide these services to Medicare beneficiaries diagnosed with pre-diabetes. The AAFP also supported CMS designating the MDPP as an “additional preventive service” available under Medicare Part B, meaning that Medicare beneficiaries can utilize this service without being subjected to beneficiary cost-sharing in the form of deductibles and co-insurance.

Proposed Changes
CMS proposes to revise the structure of MDPP services as a 3-year service period, generally contingent upon a beneficiary's attainment of two performance goals: achievement and maintenance of weight loss and attendance at a certain number of MDPP sessions. CMS also proposes a new start date for the furnishing of MDPP services within the expanded model of April 1, 2018. As proposed, the supplier enrollment and compliance policies will become effective on January 1, 2018, to allow time for organizations to enroll in Medicare before they begin furnishing and billing for MDPP services.

CMS discusses a proposed payment structure for MDPP services with a maximum payment per beneficiary of $810 over 3 years for the set of MDPP core and maintenance sessions. CMS also proposes payment policies for instances in which an MDPP beneficiary switches MDPP suppliers. CMS proposes an interim MDPP preliminary recognition standard and revisions to the supplier eligibility and enrollment requirements, including establishment of standards and implementation of appropriate program integrity safeguards. CMS proposes policies related to MDPP beneficiary engagement incentives furnished by MDPP suppliers.

AAFP Response
The AAFP continues to fully support the expansion of the MDPP since addressing pre-diabetes in patients is important to family physicians.

The AAFP supports revising the structure of MDPP to be a 3-year service period if the suppliers use CDC-approved curriculum that promotes and expands MDPP as an evidence-based intervention program targeted to individuals with pre-diabetes. We support the goals of a beneficiary attaining achievement and maintenance of weight loss and attendance of a certain number of MDPP sessions. However, as the AAFP responded in the 2017 rulemaking cycle, we remind the agency that evidence shows even a modest amount of weight loss can improve health outcomes and adopting healthier lifestyles (increased activity, better diet) alone, without significant weight loss, can have an impact. These efforts may not prevent diabetes, but they may reduce other risks, such as heart disease. Though we acknowledge that CMS must ensure the program is working for the beneficiary, we urge CMS to allow beneficiaries that previously failed the program to attempt the program again. Compared to policies finalized in 2017, we support steps CMS has proposed to provide needed flexibility to MDPP suppliers by not binding payment as closely to patient adherence in attendance and outcomes.

Regarding the proposed new start date of April 1, 2018, the AAFP ultimately recognizes that CMS and suppliers may need additional time to enroll and become compliant with the new MDPP. However, since the MDPP was first discussed in the 2017 rulemaking cycle and CMS had finalized a January 1, 2018, start date, CMS and suppliers alike have had ample time to plan, enroll, and prepare to operationalize this program. Obesity and diabetes in the United States is rampant, so we urge both CMS and suppliers to expeditiously enroll and participate in this program. Thus, we urge CMS to not finalize April 1, 2018, as a start date and instead work with speed and efficiency to make these services available on January 1, 2018, as the agency had previously finalized.

L. Request for Information on CMS Flexibilities and Efficiencies
Summary
Stating a commitment to transforming the health care delivery system by reducing burdens for hospitals, physicians, and patients, CMS invites commenters to submit recommendations regarding when and how CMS-issued regulations and policies can be simplified. CMS particularly requests ideas to address opioid use disorder and other substance use disorders.

AAFP Response
The AAFP very much appreciates that CMS included this request for recommendations, since administrative simplification represents an industry-wide commitment to reducing health care costs by removing unnecessary burdens throughout the compliance, claims, and billing processes. The AAFP is continuously working to alleviate demands placed on family physicians through entangling paperwork and needless regulatory complexities and is glad that CMS is likewise engaged in these important efforts.

The Medicare and Medicaid programs are evolving rapidly as policymakers and elected officials attempt to reduce costs and improve the quality of care. The AAFP has actively supported reform efforts, since primary care can improve both the efficiency and quality of care. **At the same time, primary care physicians must be adequately compensated for the services they provide without imposing excessive administrative burden**. Primary care – and particularly family medicine – is foundational to continued progress in reforming our nation's health care system. Family medicine and primary care are delivered by dedicated individual family physicians and their health care teams in urban and rural communities.

The complexity of care provided by family physicians is unparalleled in medicine. Data demonstrates that family physicians address more diagnoses and treatment plans per visit than any other medical specialty. Furthermore, the number and complexity of conditions, complaints, and diseases seen in primary care visits is far greater than those seen by any other physician specialty.

Many family medicine practices are small businesses, facing the challenges of complying with federal and state regulations as well as requirements imposed by private insurers, while focusing on providing the highest quality of care to patients. Most family physician practices have contractual relationships with seven or more payers. This means they must comply with disparate rules and regulations from seven or more payers daily, which distracts from the family physician's core purpose: caring for patients. The human and financial costs of regulatory compliance have become untenable, forcing far too many family physicians to consolidate or sell their practices.

The AAFP believes that independent physician practices and groups are important to our health care system, patients, and for the communities where they exist. Therefore, we are calling for a coordinated effort to preserve and promote these practices. At the forefront of this effort is our call for an immediate reduction in the regulatory and administrative requirements these physicians and practices must comply with daily.

In reaction to President Trump's Executive Order on "Reducing Regulation and Controlling Regulatory Costs" issued January 30, 2017, the AAFP created an agenda for regulatory and administrative reforms to promote better primary care by preserving independent primary care practices. We call on CMS to significantly reduce the regulatory and administrative burdens on physician practices by acting on the following priorities:

- Prior Authorizations (unfunded mandate) - The frequent phone calls, faxes, and forms physicians and their staffs must manage to obtain prior authorization for an item or service create enormous burden. A large part of that burden stems from these unfunded prior authorizations (PA) requirements. PAs are becoming increasingly common as employers and insurance companies struggle to control escalating pharmaceutical, radiological, and medical equipment costs. Since most family physician practices have contractual relationships with seven or more payers, they must often navigate seven or

more different prior authorization rules and forms. The AAFP believes PA must be justified in terms of financial recovery, cost of administration, and workflow burden. The AAFP further believes rules and criteria for PA determination must be transparent and available to the prescribing physician. If a service or medication is denied, the reviewing entity should provide the physician with the criteria for denial. For medications, it should provide alternative choices to eliminate a guessing game. Additionally, PA for imaging services should be eliminated for providers with aligned financial incentives (e.g. shared savings, etc.) and proven successful stewardship. **The AAFP asks CMS and Congress to eliminate the use of PAs in the Medicare program for generic drugs and durable medical equipment, create a single PA form that all Medicare Part D plans must use, and further limit or reduce the number of products and services requiring PAs. The AAFP suggests that CMS require Medicare Advantage (Part C) and Part D plans to pay physicians for PAs that exceed a specified number or that are not resolved within a set period; prohibit recurrent PA requirements for ongoing use of a drug by patients with chronic disease; prohibit PAs for standard and inexpensive drugs; and require that all plans (public and private) use a standard PA form and process.**

- Chart Documentation - Documentation burdens have escalated dramatically without relief from adoption of electronic records. Documentation for Advancing Care Information, PCMH recognition, CPC+, and other initiatives has reduced meaningful face time with patients. Additionally, guidelines for E/M Services were written almost 20 years ago and do not reflect the current use and further potential of Electronic Health Records (EHRs) to support clinical decision-making and patient-centeredness reflected in Medicare's Quality Payment Program. The AAFP believes 1) the primary purpose of medical record charting should be to document essential elements of the patient encounter and to communicate that information to other providers; 2) the use of templated data and checking boxes should be viewed as administrative work and not contributing to the care and wellbeing of the patient; 3) changes should be made to the outdated E/M guidelines and the Medicare Program Integrity Manual. The changes should support medical information entered by any care team member related to a patient's visit. This standard should be applied by all Medicare contractors, Medicaid, marketplace policies, and private payers; 4) as part of the Medicare Quality Payment Program, the AAFP recommends that all documentation guidelines for E/M codes 99211-99215 and 99201-99205 be eliminated for primary care physicians.
- Medicare Certification and Documentation - Physicians want to efficiently order what their patients need to manage their disease conditions in a way that maintains their health. Unfortunately, the current procedures surrounding coverage of medical supplies and services impede this goal and add no discernible value to the care of patients. The AAFP believes:
    - The physician's order should be sufficient. Physicians should not have to sign multiple forms from various outside entities for patients to receive needed physical therapy, home health, hospice, or Durable Medical Equipment (DME), including diabetic supplies;
    - Physicians should not be required to recertify DME supplies annually for patients with chronic conditions;
    - Authorization for supplies should be generic so that physicians are not required to fill out a new form every time a patient switches brands, including but not limited to diabetic supplies;
    - Authorization forms should be universal across payers. Data within the forms should be standardized to allow for automated EHR extraction and population of forms;

  - Physicians should not be required to attest to the patient's status when the service is provided by another licensed health professional as is the case with diabetic footwear.

- Electronic Health Record (EHR) Interoperability - Family medicine has been a leader in practice transformation, delivery system reform, and EHR adoption. However, to truly achieve improved quality and reduce the cost of care, it is critical to have appropriate technology and data infrastructure to support more efficient and effective health care delivery. Based on data from surveys the AAFP and others have conducted, the current health IT infrastructure and products are neither efficient nor effective in supporting practice transformation. Therefore, all physicians need the national health IT ecosystem to undergo more rapid transformation than has been the case to date. We need systems that provide interoperability to support continuity of care, care coordination, and the ability to switch and integrate different health IT solutions (such as EHRs) with minimal disruptions. Physicians also need population management and patient engagement functionalities that require broad interoperability. These new features, as well as the old, need to be developed with user-centered design and consider the transformed practice environment. **Furthermore, we call on CMS to place the burden of compliance on EHR vendors and not on physicians. EHR vendors, not the physicians who struggle to use EHRs in their practices, must be held accountable for the inadequate design and poor performance of their products.**
- Interpretation Service Costs (unfunded mandate) - Since 2000, physicians have been required to provide interpreters for Medicare and Medicaid patients with hearing impairments or limited English proficiency, and on October 17, 2016, new and costly limited English proficiency policies went into effect. Family physicians already operate on slim financial margins. **The AAFP strongly believes that Congress and HHS must procure the necessary funding to address and offset the estimated financial burden on physician practices.** We have significant concerns that primary care practices are already taking a financial loss for treating patients that require interpretive services because of the historical undervaluation of primary care services in the resource-based relative value scale. Medicare and Medicaid payment for essential primary care services are simply inadequate and interpretive services remain costly. If the patient reschedules or does not appear for the appointment, the practice must still pay the interpreter. **We believe that HHS must fund the increased costs practices will bear to comply with these requirements. If this cannot be accomplished, we call on HHS to eliminate this requirement.**
- Quality Measure Harmonization and Alignment - The AAFP believes more work must be done in quality and performance measure harmonization. This harmonization should focus on aligning measures across all public and private payers, including Medicaid. Physicians, especially family physicians, bear the brunt of quality and performance measures. A major part of this is the burden of multiple performance measures in quality improvement programs with no standardization or harmonization. The AAFP urges CMS to align quality measures as part of their overall approach to reducing administrative burden. **To accomplish this, the AAFP recommends that CMS, in all federal programs and demonstrations, use the core measure sets developed by the multi-stakeholder Core Quality Measures Collaborative to ensure parsimony, alignment, harmonization, and the avoidance of competing quality measures among all payers.**
- Inconsistent Claims Review - There are a multitude of post-claims review processes: ZPIC, RAC, CERT, Meaningful Use, etc. Within these audit programs, there are a multitude of requirements, appeals processes (if any), differing deadlines, and governing

agencies. Communications from these entities are not easily understood by busy physicians nor are their deadlines easy to meet. **Monitoring activity is recognized as necessary, however the AAFP strongly recommends that CMS streamline programs and utilize one set of criteria that is universal.**

- Chronic Care Management Documentation - The 2017 Medicare Physician Fee Schedule Final Rule made great strides to simplify the requirements of Chronic Care Management (CCM) regarding consent and access to the care plan. **The AAFP believes that the documentation requirements are still excessive and should be further reduced. We also support the elimination of the cost-sharing requirements associated with the service.**
- Appropriate Use Criteria (AUC) Alignment with MIPS (unfunded mandate) - As noted in our earlier comments specific to AUC, the AAFP has ongoing, significant concerns about the disproportionate burden primary care physicians will face when trying to comply with AUC requirements. Much like prior authorization requirements noted above, we believe that AUC requirements will place more burdens on primary care physicians than on other clinicians and add an unnecessary level of complexity to the already complex Medicare system that severely overtaxes our members. **The AAFP, therefore, strongly urges CMS to delay the implementation of this program until the AUC is fully aligned with the MIPS program.** In fact, we would prefer that this program and regulatory burden be discontinued completely. With the passage and implementation of MACRA, which begins to align payment with value, the need for AUC requirements has been supplanted, and those requirements will now likely hinder, rather than improve, effective care.
- Transitional Care Management Services - Communication and EHR interoperability barriers continue to hinder the uptake of transitional care management (TCM) services. The stringent and brief time frames for patient contact after hospital discharge in addition to the lack of open communication between hospitals and primary care physicians impedes family physicians' ability to provide these important services and bill these codes. Enhanced EHR and HIE (health information exchange) would reduce the burden on both physicians and hospitals and provide for reduced patient readmissions. These activities would, in turn, result in reduced cost for physicians, hospitals, health plans, and government payers.

Since the CMS request for information specifically requests suggestion on how to address opioid abuse disorder, per the AAFP's position paper titled, "Chronic Pain Management and Opioid Misuse: A Public Health Concern," we suggest that CMS, other payers, and policymakers consider policies that:

- Work for adjustments in payment models to enable physicians to provide patient-centered, compassionate care in the treatment of chronic pain and opioid dependence and to appropriately compensate them for providing such care.
- Expand governmental and private insurance coverage of medication-assisted treatment (MAT) in the primary care setting, with adequate payment for the increased time, staff, and regulatory commitments associated with MAT.
- Expand the role of advanced practice nurses (APNs) and physician assistants (PAs) in providing MAT as part of a team supervised by a DATA 2000-waivered primary care physician.
- In states that lack appropriate laws, advocate for better access to naloxone and appropriate Good Samaritan protections for prescribers and lay rescuers.

- Work with state and federal licensing boards, the Drug Enforcement Administration (DEA), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to destigmatize MAT, particularly in the setting of the community provider.
- Work with state and national partners to improve the functionality, utility, and interoperability of prescription drug monitoring programs, and develop best practices for their use and implementation.
- Expand governmental and private support of research into the management of chronic pain, as well as methods to better identify and manage opioid misuse. Particular attention should be paid to vulnerable populations who are at higher risk for undertreatment of pain and/or for opioid misuse.

We appreciate the opportunity to provide these comments and make ourselves available for your questions. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

Wanda D. Filer, MD, MBA, FAAFP
Board Chair