Sound Policy. Quality Care.

September 6, 2016

Andrew M. Slavitt
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
Submitted electronically via http://www.regulations.gov

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from 13 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy. In line with our mission, we are pleased to provide you with our comments on CMS's proposals in the CY 2017 Medicare Physician Fee Schedule Proposed Rule.

Valuation of Specific Codes

The Alliance is very concerned with CMS's proposals that do not accept a number of the RUC-recommended values. The AMA/Specialty Society Relative Value Scale Update Committee (RUC) represents the entire medical profession, with 21 of its 31 members appointed by major national medical specialty societies including those recognized by the American Board of Medical Specialties, those with a large percentage of physicians in patient care, and those that account for high percentages of Medicare expenditures. As we believe that the RUC undergoes a rigorous and informed analysis of values CMS should strongly consider accepting RUC-recommended values unless there is good reason not to accept the RUC's recommendations. We believe it is critical that values are determined based on sound analysis, particularly as we move towards the use of bundled payments.

Importance of Intensity in Valuation

We note that in the proposed rule, CMS is seeking comment on "…whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services." We believe the question goes straight to the heart of the RBRVS system, which must consider both time and intensity. There is no magic bullet formula that will allow the agency to fairly reduce values in a direct relationship to a reduction in the time required for a procedure. Often when time is reduced, the intensity of a procedure increases, and the overall work does not decrease commeasurably.

The RUC process is robust and thorough in its consideration of reduction in time for procedures it reviews. New and revalued codes receive comprehensive and appropriate scrutiny for time and intensity. The establishment of a formulaic "time test" will not be accurate. Treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and creates inherent payment disparities in a payment system which is based on relative valuation. **We are eager to work with the agency to assure fair valuation for procedures that accounts for both time and intensity, as is required statutorily for the RBRVS fee schedule.**

Refinement Panel

In the CY 2016 NPRM, CMS proposed to permanently eliminate its Refinement Panel process. In the CY 2016 Final Rule, instead of finalizing the exact language of that proposal, CMS announced they would "…retain the ability to convene Refinement Panels for codes with interim final values" and that "…CY 2016 is the final year for which we anticipate establishing interim final values for existing services." We object to CMS's intention to make this vital process obsolete. We strongly urge CMS to open Refinement Panel review to all procedures and services that are under CMS review during the current rulemaking process. The original Refinement Panel process, coupled with the input from the RUC, would provide the best mechanism to utilize the expertise from physicians and other health care professionals to determine the resources utilized in the provision of a service to a Medicare beneficiary. We urge CMS to review the role of the Refinement Panel within the current process in order to make its input more valuable to CMS.

Below, we provide specific examples of RUC-recommended values that CMS should accept:

Insertion of Spinal Stability Distractive Devices

The RUC recommended work RVUs of 15.00 for 228X1, 4.00 for 228X2, 7.39 for 228X4, and 2.34 for 228X5. CMS is proposing to reduce the values to 13.50 for 228X1 and 7.03 for 228X4 based on crosswalks to codes 36832 and 29881, respectively. These proposed cuts are significant and are not supported by the survey times accepted by both the RUC and CMS. Additionally, codes 228X1 and 228X4 are part of a family that also includes add-on codes 228X2 and 228X5, for which CMS is proposing to accept the RUC recommended values. This decision to reduce the values for 228X1 and 228X4 will impact relativity. The Alliance urges CMS to implement the RUC recommended values for the entire family of codes based on the survey data.

Biomechanical Device Insertion

For new add-on codes for biomechanical device insertion, the RUC recommended work RVUs of 4.88 for 22X81, 5.50 for 22X82, and 6.00 for 22X83. CMS is proposing to reduce the values to 4.25 for 22X81 and 5.50 for 22X83. CMS's rationale for the reduction to 22X81 is a belief that the work is overestimated compared to the other codes in the family and are proposing to crosswalk the code to 37237. Likewise, CMS proposed identical values for 22X82 and 22X83 based on their belief that the procedures have enough clinical similarities so as to render them identical to each other in spite of differing procedure times accepted from the RUC surveys. CMS's willingness to disregard survey data for two codes in the family is deeply concerning and again contradicts the theory of relativity that underpins the entire Resource-based relative value scale (RBRVS).

Endoscopic Decompression of the Spinal Cord

For code 630X1 used to report endoscopic decompression of the spinal cord, the RUC recommended a value of 10.47 RVUs based on a crosswalk to code 47562. CMS is proposing to reduce the value to 9.09 RVUs based on a crosswalk to code 49507 out of a belief that the original crosswalk overestimated the work involved. Once again, CMS is ignoring valid RUC survey data and proposing to significantly reduce a code's value.

Cystourethroscopy and Biopsy, Prostate (CPT codes 52000 and 55700)

With respect to urology codes 52000 (Cystourethroscopy (separate procedure)) and 55700 (Biopsy, prostate; needle or punch, single or multiple, any approach), we note that CMS is not accepted to RUC recommended values for these codes and recommend that CMS finalize values recommended by the RUC. With respect to CPT code 52000, CMS must recognize that cystourethroscopy is an essential diagnostic tool in the urologists' armamentarium. Without it, a major spectrum of urologic conditions, such as bladder cancer, urinary tract stones, hyperplasia of the prostate, and other urethra and urinary tract disorders, cannot be properly diagnosed.

Closure of Left Atrial Appendage with Endocardial Implant (CPT code 333X3)

CMS is proposing a reduction to the RUC recommended work value for the new code created to report left atrial appendage occlusion with endocardial implant (LAAO) procedures.

> 333X3 *Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*
>
> RUC Recommended work RVU 14.00; CMS proposed work RVU 13.00

CMS is incorrectly asserting that the RUC recommended value was based on the 25th percentile RUC survey result. The 25th percentile RUC survey result was actually 19.88 work RVUs. Based on this incorrect information, CMS is now proposing that the value should be based on the minimum survey result, claiming based on their "clinical judgment and that the key reference codes discussed in the RUC recommendations have higher intraservice and total service times than the median survey results for new LAAO, CPT code 333X3, [CMS] believe[s] a work RVU of 13.00 more accurately represents the work value for this service".

While the RUC certainly took into consideration the comparison of the new LAAO code to the key reference codes from the RUC survey, it was found that the key reference codes were describing services more commonly performed on a pediatric population. The new LAAO procedures will be performed on an elderly patient population that is sicker and has more co-morbidities than that of the RUC survey reference service codes CMS considered. Additionally, these key reference codes were valued back in 2002 and there has been significant, continual improvement and refinement to the RUC process since that time including the adoption of pre - and post-service packages.

Rather, than merely relying on a cursory comparison of the new LAAO code to the survey reference services codes, the RUC elected to subject the new code to the more intensive RUC facilitation process that involves a significantly deeper review of the new code's value. The RUC Facilitation Committee compared the new LAAO code, 333X3 to codes that have more recently gone through the valuation process including CPT code 93583 [*Percutaneous transcatheter septal reduction therapy (e.g., alcohol septal ablation) including temporary pacemaker insertion when performed*], which has a work RVU of 14.00 and intra-service time of 90 minutes. The RUC Facilitation Committee found that this value, with identical intra-service time, accurately accounted for the physician work involved in the new LAAO code, 333X3. For additional support, the Facilitation Committee also reviewed another code believed to be more clinically similar that has also more recently gone through the valuation process, code 37244 [*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation*], which also has a work RVU of 14.00 and intra-service time of 90 minutes. Based on this in depth, thorough review and analysis, the RUC has recommended a work RVU of 14.00 for CPT code 333X3.

The Alliance opposes CMS's proposed reduction in physician work values for the new Left Atrial Appendage Occlusion code, 333X3, finding that CMS did not conduct as in depth of an analysis and consideration of the proposed value for this new code, as that performed by the RUC. The RUC recommended work value of 14.00 RVUs for the new LAAO code was based on a thoughtful, deeper analysis with comparison to more recently valued codes which are performed on a fairly comparable patient population, unlike CMS's analysis.

Closure of Paravalvular Leak (CPT codes 935X1, 935X2, and 935X3)

CMS is proposing a reduction to the RUC recommended values for the three new codes created to report aortic and mitral Paravalvular Leak Closure (PVL) procedures.

935X1 - *Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve*

RUC Recommended Value 21.70; CMS proposed value 18.23

935X2 - *Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve*

RUC Recommended Value17.97; CMS proposed value 14.50

935X3 - *Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service)*

RUC recommended value 8.0; CMS proposed value 6.81

CMS is proposing to reduce the RUC recommended value for the aortic PVL code (935X2) from 17.97 work RVUs to 14.50 work RVUs, based on the false assumption that aortic PVL is fairly comparable in time and intensity to CPT code 37227 [*Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed*].

The Alliance opposes CMS's assertion that a cardiovascular intervention performed in an immobile leg is comparable in intensity and patient risk to an intervention performed in a beating, moving heart. Further speaking to the difference in intensity and risk, Lower Extremity Revascularization (LER) procedures (such as that represented by 37227) are safely performed in the non-hospital, non-facility, office setting. As a matter of fact, more than half of the procedures reported using code 37227 are performed in the office setting. Whereas, structural heart disease (SHD) procedures, such as PVL cannot be performed in the office setting. Due to the intensity and risks associated with these procedures, they **MUST** be performed in a facility setting and most typically are performed in special hybrid suites, in collaboration with imaging (e.g. TEE) and cardiac anesthesia expertise, needed to accommodate the special imaging needs above and beyond traditional angiography.

SHD procedures are more intense than cardiovascular LER procedures. Unlike LER procedures, which are most commonly performed under moderate sedation, SHD procedures, like PVL, are most typically performed under general anesthesia, involving greater intensity and supporting the need for greater coordination amongst the Heart Care Team (interventional cardiologist, cardiac anesthesiologist, imaging specialist, heart failure specialist). Frequently, the approach to paramitral defects includes a complex antegrade transseptal procedural expertise.

In addition to the unique cardiac anesthesia needs and coordination, SHD procedures also have unique imaging needs as compared to LER, requiring intraoperative transesophageal echocardiography (TEE) or real-time 3-

dimensional TEE guidance be provided, in addition to standard angiography techniques, with TEE being performed by yet another physician member of the Heart Care Team, leading to even more coordination amongst providers with greater intensity and patient risk. Some procedures (e.g. for paramitral defects) require collaboration of a cardiothoracic surgeon, with alternative approaches including retrograde transaortic cannulation or transapical access and retrograde cannulation.

The basis for CMS's proposed reduction in work value for the mitral PVL code 935X2, from the RUC recommended work RVU of 21.70 to the CMS proposed value of only 18.23 RVUs, is based on the same flawed rationale CMS presented for reduction of value for the aortic PVL code, 935X1. As the CMS proposed reduction in value for the 935X1 code is believed to be inappropriate, as explained above, so is the proposed reduction in value for code 935X2.

CMS also is proposing a reduction to the work value for the new PVL add-on code (935X3) that will be used to report the placement of additional PVL occlusion devices. CMS is again rejecting the RUC recommended value of 8.00 work RVUs, proposing a reduced work value of 6.81 RVUs. CMS is again proposing to use the value of a procedure, performed on an immobilized leg, 35572 [*Harvest of femoropopliteal vein, 1 segment, for vascular reconstruction procedure (eg, aortic, vena caval, coronary, peripheral artery) (List separately in addition to code for primary procedure*)] as the proxy for the intensity of an intervention performed in a continually moving, beating heart. This comparison is just clearly inappropriate and does not recognize the intensity and skill level needed to place a PVL device in a moving, beating heart, frequently in the setting of heart failure. In contrast, harvesting a vein from the leg, alone, may be performed by a non-physician (i.e., PAs) assistant-at-surgery provider; does not require intensive general anesthesia nor does it require coordination with the Heart Care Team to provide intraoperative transesophageal echocardiography (TEE) guidance and optimal multidisciplinary care.

The Alliance opposes the proposed reduction in physician work values for the new PVL Codes (codes 935X1, 935X2, and 935X3) finding CMS's proposed use of cardiovascular codes for procedures performed in or on a leg as a proxy for the intensity of SHD, PVL procedures performed on a heart requiring a Heart Care Team approach, typically involving general anesthesia and intraoperative transesophageal echocardiography (TEE) guidance, and with greater risk to the patient to be inappropriate.

Intracranial Endovascular Intervention Codes (CPT Codes 61645, 61650, 61651)

In April of 2015, the RUC recommended values for 61645, 61650 and 61651 of 17.00, 12.00 and 5.50 respectively. CMS proposed values for CY 2016 of 15.00, 10.00 and 4.25 respectively with the rationale that these procedures would be performed in the outpatient setting. As a result, CMS recommended CPT 37231 as a direct crosswalk for 61645, 37221 as the crosswalk for 61650 and 37223 resulting in the CY 2016 values. Medicare 2014 data demonstrated that 37231, was performed in the inpatient setting only 21.3% of the time. CPT codes 37221 and 37223 are performed in the outpatient setting 53.23% and 50% and in the office setting 12.81% and 11% of the time respectively. Additionally, based on the erroneous rationale that 61645, 61650 and 61651 are performed in the outpatient setting, CMS removed the 55 minutes associated with CPT code 99233 (level 3 subsequent hospital care, per day). The 30 minutes of intra-service time associated with 99233 was added to the immediate post service time. Although the post service time was now increased from 53 minutes to 83 minutes, this artificially and inappropriately reduced the total work time from 266 minutes to 241 minutes.

CPT code 61645 is always performed as a highly time sensitive emergent procedure for acute stroke patients with large vessel occlusions and will never be performed in the outpatient setting. CPT codes 61650 and 61651are typically performed in the setting of subarachnoid hemorrhage and cerebral vasospasm in patients with impending strokes that are in an intensive care unit. The survey results noted that these procedures were

100% performed in the inpatient setting. A multi-specialty letter outlining this erroneous rationale and requesting refinement. Evidence these patients are treated in the inpatient setting was clearly noted by the RUC, which, therefore, made no direct practice input recommendations.

A Refinement Conference call with CMS was conducted with the AANS, CNS, Society of Interventional Radiology (SIR), American College of Radiology (ACR), Society of Vascular Surgeons (SVS) and American College of Cardiology (ACC) on March 2, 2016 outlining the erroneous rationale, however CMS maintained the interim CY2016 values for CY 2017. We are astonished by the casual dismissal of the careful analysis provide by specialty societies for these codes, clearly outlining why the CMS-recommended comparator codes were inappropriate for valuation.

Evaluating the actual physician work performed in the inpatient setting is much more accurate than the applying a crosswalk to a CPT code that is performed predominantly in the outpatient setting. We implore CMS to review data provided by in the AANS, CNS, the RUC, and other specialty comments over the last two years. In addition, we urge CMS to more fairly characterize the refinement panel call for these codes and publish the vote of the refinement panel. We trust that after thorough review and consideration of the flaws in the CMS analysis that used outpatient and office codes to value these intense inpatient procedures, the agency will accept the RUC recommended work values for 61645, 61650 and 61651 of 17.00, 12.00 and 5.50 respectively.

CPT Code 43210

In the CY 2016 MPFS Final Rule, CMS rejected the RUC's recommended physician work RVU of 9.00 for CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed) and, instead, implemented the survey 25th percentile of 7.75 RVUs. Consideration by the Refinement Panel was granted and, upon review, the Refinement Panel supported the RUC's recommendation. However, in the 2017 PFS proposed rule, CMS rejected the Refinement Panel's recommendation and simply reiterated its previous rationale for maintaining the survey 25th percentile wRVU. We are puzzled why CMS rejected the expertise of the specialty societies, the RUC and the Refinement Panel after additional data and analyses were presented through the Refinement Panel. We would appreciate CMS's input regarding what else needs to be provided to demonstrate that 43210, which includes the performance of three separate endoscopic procedures, is undervalued.

Medicare Telehealth Services

CMS acknowledges the potential benefits of critical care consultation services furnished remotely and the need to distinguish such services from telehealth consultations for other hospital patients. We believe the creation of new codes for consultations of critically ill patients via telehealth would allow CMS to adequately identify resource cost, time and intensity involved in furnishing these services remotely. While we commend CMS for promoting use of telehealth services by continuing to expand the list of covered Medicare services, we urge CMS to work with the AMA Current Procedural Terminology (CPT) Editorial Panel Telehealth Services Workgroup. The Telehealth Services Workgroup was established in September 2015 to recommend solutions for reporting of current non-telehealth services when using remote telehealth technology, address the accuracy of telehealth data, recommend whether any other telehealth service codes should be developed based upon services currently being provided, and develop new introductory language or modify existing introductory language to guide coding of telehealth services.

Potentially Misvalued Services under the Physician Fee Schedule

CY 2017 Identification and Review of Potentially Misvalued Services

0-Day Global Services Typically Billed with an E/M Service with Modifier 25: CMS identified as potentially misvalued 83 0-day global codes (that have not been reviewed in the last 5 years and with greater than 20,000 allowed services) billed with an E/M 50 percent of the time or more, on the same day of service, with the same physician and same beneficiary. **The Alliance opposes CMS's proposal to identify these 83 0-day global codes as misvalued.** We disagree with stakeholders concern and believe that billers are appropriately using Modifier 25 when billing a significant, separately identifiable E/M service, and the practice of using the Modifier 25 is consistent with educational documents and guidelines provided by Medicare. In addition, the Alliance specifically requests that CMS remove the STEMI PCI code (92941) from the list of potentially misvalued 0-day global codes, as this code does not even meet CMS's own criteria for inclusion in this listing with same day E&M being RARELY reported (only 5% of the time) and the code HAS been valued in the last 5-years.

Collecting Data on Resource Used in Furnishing Global Surgery Services

To collect needed data to accurately value the 4,200 codes with a 10- or 90-day global surgery period, CMS is proposing a three-pronged approach to collect timely and accurate data on the frequency of, and inputs involved in furnishing, global surgery services — including the procedure and the pre-operative visits, post-operative visits, and other services — for which payment is included in the global surgical payment. Specifically, the effort would include:

(1) Claims Reporting: CMS is proposing to collect data on furnishing global surgery services via comprehensive claims-based reporting about the number and level of pre- and postoperative visits furnished for 10- and 90-day global services. Specifically, CMS is proposing to require all practitioners who furnish a 10- or 90-day global service to submit a claim(s) providing information on all services furnished within the relevant global service period, beginning with surgical or procedural services furnished on or after January 1, 2017. CMS is proposing that practitioners would furnish this information via reporting new G-codes, classified under three settings (in patient, office or other outpatient, or via phone or internet).

The Alliance strongly opposes this proposal. First and foremost, CMS's proposal to require all practitioners providing 10- and 90-day global services report these G-codes is overly burdensome and goes well beyond the requirements of the statute. CMS can meet its requirements by implementing prongs two and three of the proposed global surgery data collection effort, making the claims-based approach totally unnecessary.

There are two fundamental problems with the claims-based plan. First, requiring all physicians to report data on all 10- and 90-day global surgery services is excessive. Section 523 of MACRA only requires CMS to collect data from a "representative sample of physicians" and we believe using a representative sample should be sufficient for purposes of collecting additional information on how global services are furnished.

Second, the Alliance believes that the proposed method of using new G-codes, rather than, for example, using CPT code 99024, is also overly burdensome. The use of new G-codes would require billing staff to undergo significant training and education to learn how to appropriately bill these new G-codes. In addition, we note that the proposed requirement to report these newly proposed G-codes in 10 minute increments is overly burdensome, as physicians typically do not monitor or deliver care based on timed increments. If CMS intends to implement a claims-based approach to data collection, we strongly recommend that CMS adopt a process that

uses CPT code 99024 rather than establishing new G-codes. Information on the level of visit can be assessed in another manner (for example, via survey).

As an aside, we note that these proposed changes come at a time when practitioners are already facing new challenges in 2017, particularly with respect to the implementation of Alternative Payment Models (APMs) and the Merit-based Incentive Payment System (MIPS). Furthermore, the Alliance is concerned that these changes will certainly lead to physicians taking on an increasing role in a practice's administrative tasks, thereby taking away valuable time that would normally be used to see and treat patients. In addition, this increased administrative burden makes it less likely for smaller practices to comply thoroughly and accurately, which will then result in CMS receiving flawed data. Larger practices with more resources and technology will be better able to comply, even though they are not a representative sample of all practices, directly contravening the law and CMS's intent with this proposal.

Given all these concerns, the Alliance strongly requests that CMS not implement its proposal to require all practitioners who furnish a 10- or 90-day global service to submit information via newly established G-codes on all services furnished within the relevant global service period, beginning with surgical or procedural services furnished on or after January 1, 2017.

(2) Pre- and Post-Op Services Survey: CMS is proposing to survey a large, representative sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre-operative and post-operative visits and other global services like care coordination and patient training. **The Alliance believes the use of a survey is significantly less burdensome than requiring collection of data through the reporting of new G-codes. When conducting the survey, we urge CMS to consider minimizing as much as possible the potential reporting burden on providers**. At a minimum, the agency needs to provide sufficient guidance to providers to ensure they can be prepared to successfully participate in the billing of post-operative care prior to January 1, 2017.

We would like to remind the agency that most specialty society-driven data registries can and do collect "episode of care" information that reflects the actual post-operative care provided and would encourage the agency to work with interested specialty societies to evaluate the number and types of visits and other services furnished by a surgeon during the post-operative period.

(3) Data Collection from Accountable Care Organizations (ACOs): CMS is proposing to collect primary data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs (Pioneer and Next Generation ACOs). The Alliance is concerned with CMS's intention to use data collected from ACOs to determine values for global services. We believe that participants in ACOs are typically high performing, and, as such, collecting data from ACOs may skew data collected on how to appropriately value global services. Furthermore, we note that ACO participants typically are typically larger practices and therefore would not provide a representative sample of smaller and solo practitioners. **As ACOs would not provide a representative sample of how global services should be valued, the Alliance is concerned about the use of data from ACOs to determine values for global services, particularly if the information gleaned from this effort would be extrapolated to value global surgery services that are provided outside of the ACO setting**.

Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

CMS continues to emphasize its commitment to supporting primary care services, and for prioritizing the development and implementation of initiatives designed to improve the accuracy of payment for, and

encourage long-term investment in care management services. For CY 2017, CMS is proposing a number of coding and payment changes to better identify and value primary care, care management, and cognitive services.

CMS's proposals for improving payment accuracy for primary care and care management services are thoughtful towards addressing challenges in providing primary care and care management services. While we encourage CMS to appropriately incentivize the provision of these important services, it must not be at the detriment of specialty medicine.

As the population continues to age and as more beneficiaries are diagnosed with complex specialty medical conditions, including rheumatoid arthritis, Parkinson's disease, osteoarthritis, heart disease, diabetes and dementia, the demand for specialty medical care will increase tremendously. In fact, a recent study[1] in *Health Affairs* found the demand for adult primary care services would only grow by approximately 14 percent between 2013 and 2025, whereas the projected demand growth for cardiology and neurological surgery was much higher, at 20 percent and 18 percent, respectively. Study authors state that "the current supply of many specialists throughout the United States is inadequate to meet the current demand" and "[f]ailure to train sufficient numbers and the correct mix of specialists could exacerbate already long wait times for appointments, reduce access to care for some of the nation's most vulnerable patients, and reduce patients' quality of life."

In addition, we are concerned about the inclusion of these new codes in the PFS without the infusion of new funding. Payment for these services will come from other providers paid under the PFS given the budget-neutral nature of the system. In the interim, we urge CMS to ensure these new codes are not limited to traditional primary care specialties. Specialty physicians routinely provide the same types of services described, particularly for their patients that have multiple chronic health conditions, whether they have a primary care provider or not.

In addition, we urge CMS to consider additional proposals for new and add-on codes that address unique circumstances where specialty physicians are providing primary care and care management services. In most instances, traditional primary care providers, such as internists and family practitioners, do not have the requisite knowledge, clinical training, and expertise in many complex specialty medical conditions facing beneficiaries. As a result, many patients who present with positive symptoms for complex medical conditions are not referred to a specialist in a timely manner. Late referrals to specialty care add significant cost to the Medicare program, as the treatment options for these beneficiaries narrow and become more expensive as disease progression worsens. This is frequently the case for beneficiaries with complex rheumatologic conditions, such as rheumatoid arthritis. CMS should look at ways to emphasize the provision of specialty care in the Medicare program, moving forward.

As the comment window is too narrow for us to elaborate on the types of collaborative care models that our specialties would like to offer, we urge CMS to issue a Request for Information (RFI) to solicit additional proposals and public comment on this topic in advance of making any more formalized proposals in next year's rule.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 establishes a new program under the statute for fee for service Medicare to promote the use of appropriate use criteria (AUC) for advanced

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[1] THE CARE SPAN: An Aging Population And Growing Disease Burden Will Require A Large And Specialized Health Care Workforce By 2025, Health Aff November 2013 32:112013-2020;

diagnostic imaging services. In this proposed rule, CMS proposes to continue to establish requirements for this program. Specifically, CMS provides proposals for priority clinical areas, clinical decision support mechanism (CDSM) requirements, the CDSM application process, and exceptions for ordering professionals for whom consultation with AUC would pose a significant hardship.

Appropriate Use Criteria (AUC) are well-intended efforts on the part of physicians to make sure the profession is doing the right things for the right reasons. We believe the best approach to implementing AUC is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and clinical decision support mechanism developers (i.e., Apps, other). It is for these reasons that the agency should proceed using a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program.

The Alliance continues to strongly oppose using AUC for withholding payment for services provided. AUC are designed to help ensure that the best information is available for clinical decision making and to help support appropriate choices by physicians and their patients, in the context of good clinical judgment and patient preferences. AUC are developed to identify common clinical scenarios but they cannot possibly include every patient presentation, clinical scenario, or set of patient preferences.

Also, under the Protecting Access to Medicare Act of 2014 (PAMA), starting in January 1, 2020, outlier ordering professionals – defined as those who have low adherence to AUC criteria when ordering imaging studies for certain priority conditions -- will be required to obtain prior authorization from CMS. **We urge CMS to be prudent in implementing the prior authorization program so that it does not hinder timely access to care and place a significant administrative burden on physician practices.** Medical necessity should be the primary driver behind this program rather than reduction of cost and resource utilization.

In addition, regarding the clinical priorities, CMS intends to base outlier identification on a narrow set of conditions where there is wide agreement on clinically appropriate care. While the proposed clinical priority areas reflect the most prevalent and costly conditions in the Medicare population, some of these areas have limited evidence bases to develop guidelines or appropriateness criteria. In selecting clinical priority areas, we urge CMS to also place some weight on conditions with existing appropriateness criteria or evidence-based recommendations with strong support.

In addition, we note that the implementation of the Medicare AUC program adds an additional burden on providers, who are already faced with many changes ahead, particularly with the implementation of MACRA. We urge CMS to consider the additional burdens these changes have overall on physician practices.

CDSM Qualifications and Requirements: CMS proposes to establish requirements for qualified CDSMs. Specifically, CMS is proposing to require CDSMs to:

- Make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas.
- Incorporate specified applicable AUC from more than one qualified provider-led entity (PLE).
- Make available within the qualified CDSM specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered.
- Identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.
- Provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of "not applicable" when the mechanism does not contain a criterion that would apply to the consultation.

- Generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered.
- Include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional.
- Update the specified applicable AUC content within qualified CDSMs at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion.
- Make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS.
- Meet privacy and security standards under applicable provisions of law.

The Alliance supports the proposed definition of CDSMs, specifically the proposed requirements requiring the CDSM to update its content at least every 12 months. We believe it is important for CDSMs to routinely update AUC content as changes in practice standards occur. Nevertheless, we have concerns about the burden this new reporting requirement could impose on practicing clinicians. The Alliance requests that CMS carefully monitor the level of burden these mechanisms impose and ensure that the required alerts and updates impose minimal disruptions to practice.

Ideally, CDSMs would be integrated within or seamlessly interoperable with existing HIT systems and would automatically receive patient data from the EHR or through an API or other connection. The Alliance appreciates CMS's recognition of the fact that a CDSM may be a module within or available through CEHRT or a private sector mechanism independent from CEHRT since some physicians continue to face real barriers to CEHRT adoption. In addition, the Alliance encourages continued efforts toward interoperability between EHRs and other modules, as issues with interoperability continue to be a barrier to seamless use of health information.

Consultation by Ordering Professional and Reporting by Furnishing Professional: Although CMS continues to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult qualified CDSMs by January 1, 2017. Instead, CMS anticipates that furnishing professionals may begin reporting as early as January 1, 2018. **We appreciate CMS's acknowledgement that more time may be needed to implement the provisions of the Medicare AUC program and support the delay in ordering professionals to begin consulting AUC**.

Exceptions to Consulting and Reporting Requirements: CMS proposes to provide for exceptions to the AUC consultation and reporting requirements for (1) an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act, (2) applicable imaging services for an inpatient and for which payment is made under Medicare Part A, and (3) applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. **The Alliance supports these proposed exceptions. However, we note that the EHR Incentive Program provides additional situations that may constitute a hardship, such as lack of sufficient patient interactions, EPs practicing at multiple locations and who lack control over CEHRT availability. In addition, the EHR Incentive Program also exempts certain specialties (based on their designation in PECOS), such as anesthesiologists. To streamline these proposed exceptions with the EHR Incentive Program, as CMS intends per its comments in the proposed rule, the Alliance requests that CMS include these additional exceptions.**

Value-Based Payment Modifier and the Physician Feedback Program

CMS proposes updates to the VM informal review policies and establishes how the quality and cost composites under the VM would be affected if unanticipated issues arise under four scenarios. **The Alliance supports holding eligible professionals who encounter data issues through no fault of their own harmless by assigning these eligible professionals average quality and/or cost composites and encourage CMS to continue investing in efforts to ensure these errors do not occur**.

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American Academy of Facial Plastic and Reconstructive Surgery
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions