June 20, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201
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Re: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P)

Dear Administrator Slavitt:

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies and the Puerto Rico Society of Interventional Pain Physicians, as well as the entire membership, societies that represent the vast majority of practicing and future interventional pain management physicians who provide medical services every day to hundreds of thousands of patients suffering with chronic intractable pain, we would like to express our concerns and also provide information on a number of proposed provisions affecting the medical community, independent practitioners, and interventional pain management practitioners in particular.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain-related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09, www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf). ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain management physicians and other practitioners who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

ASIPP was engaged with Congress, specifically the Energy and Commerce Committee, during the drafting of the Medicare Access and CHIP Reauthorization Act (MACRA) legislation. We supported and also wanted to be participants supporting the elimination of the sustained growth rate (SGR) formula and the potential for significant improvement over the previous incentive programs, hoping that it would increase patient care quality and reduce costs and bureaucracy. However, the proposed rule, a 962 page document published on May 9, 2016, took almost 13 months to prepare. It was obviously prepared by nonmedical or non-practicing individuals. Further, it will be another 4 to 5 months before a final rule on Merit-based Incentive Payment System (MIPS) is released, which would leave physicians with only 2 months to prepare a response. The following comments seek to:

- Exempt or exclude interventional pain management from the proposed MIPS program due to its independent speciality status without an anchor specialty.
- Repeal MIPS replace MIPS with a better system or delay the implementation of MIPS for 2 years so that pilot programs can be started in order to evaluate the value and

validity of the various measures and regulations introduced, as well as its value and validity in improving quality and reducing costs.

- Clarify multiple misleading proposals in the MIPS program to ensure that it facilitates meaningful opportunities for performance improvement and decreases administrative and compliance burdens.
- Accommodate the needs of interventional pain management physicians in solo and small practices in order to enhance their opportunities for success and avoid unintended consequences.
- Provide a guarantee to the physician community that the Centers for Medicare and Medicaid Services (CMS) will depart from its path of destruction of independent practices and instead assist them to progress into the future. Further, assurance is needed that the program is only for improving quality initiatives, rather than balancing the budget and improving the pockets of a few by changing regulations as they fit the needs of CMS and also misinterpreting or misconstruing the intent of the law.

Exemption of Interventional Pain Management

As shown above, interventional pain management is a small specialty with a specialty designation provided in 2002. Since then, this specialty has grown significantly, with a significant proportion of expenditures, with its own special practice expense and membership in Carrier Advisory Committees (CAC). However, this specialty has been ignored substantially by CMS due to the political nature of multiple organizations, specifically the American Society of Anesthesiologists (ASA), which claims ownership of interventional pain management. Interventional pain management includes physicians from multiple specialties as approved by the American Board of Medical Specialties (ABMS) including physical medicine and rehabilitation, neurology and psychiatry, interventional radiology, emergency and sports medicine, and finally general practice/family medicine. The specialty is expanding, attracting physicians from multiple other specialties also. All the primary specialties have exerted undue influence in Current Procedural Terminology (CPT) coding and the Relative Value Update Committee (RUC), in collaboration with American Medical Association's (AMA) bureaucratic and rather unethical approaches. But, when it comes to meaningful use, the Physician Quality Reporting System (PQRS) and value-based modifier, and now, MIPS, have ignored interventional pain management and have told us that they were only interested in their primary specialities.

Consequently, interventional pain management is left without an anchor specialty. Unfortunately, CMS, also in its proposed rule, has not provided any specialty specific measures for interventional pain management. However, interventional pain management physicians can adapt multiple measures from various other specialties including physical medicine and rehabilitation, internal medicine, radiology, orthopedic surgery, mental/behavioral health, neurology, and preventive medicine. In fact, the 7 specialty-specific measures provided for physical medicine are all related to interventional pain management or pain management rather than physical medicine.

In addition, previous experience with meaningful use and PQRS has taught us numerous lessons even though interventional pain management physicians have scrambled to identify measures to fit into interventional pain management and to comply with from various specialties and utilized them. PQRS reports have also stated that a value-based modifier will not apply to a majority of interventional pain physicians because either no physicians or less than 100 eligible professionals buibill in this category.

Additionally, cost comparison data has been extremely bizarre with inclusion of any patient who presents even for a single visit to interventional pain management for an initial evaluation and subsequent follow-ups or treatments. Some, which include minor expenses, have resulted in extensive expenditures based on hospitalizations and other expenses as CMS well knows that an interventional pain management

physician has no control over factors such as chronic disease management or other issues such as heart and liver transplant, heart failure, diabetes, hypertension, coronary artery disease, and stroke.

The major anomaly appears to be CMS's calculations and the contention of the physician community in general, and interventional pain management in particular, is that CMS changes its calculation of the composite score without any rhyme or reason. Composite scores in PQRS calculated by quality domain of one of the physicians showed 0.33 as an average, even though this physician achieved scores over 90, 7 of the 11, and others over 60% and as high as 87%. However, 2 of the 5 categories where data are available, the composite scores within the category were downgraded to 0.13 and 0.05 and finally, no score is available for efficiency and cost reduction because of the interventional pain management specialty, even though with all the bizarre calculations our costs were lower than the benchmark.

Finally, CMS has never included interventional pain management physicians from ASIPP, the largest society representing interventional pain management physicians, to participate in the preparation of any type of measures or sought our opinion.

Consequently, it is justifiable to exempt interventional pain management as a whole or exempt us from penalties and provide bonuses for those enthusiastic individuals who meet the criteria.

Repeal or Delay the Merit-Based Incentive Payment System (MIPS)
We propose that CMS should delay implementation of MIPS for at least 2 years so that CMS can a pilot program to test its efficacy concerning quality measures, improvement in quality of care, and reduction in costs. This will provide a scientific basis for utilization of such measures. The proposed rule at many places states that either there is no evidence or there is very little evidence on many aspects of this proposed rule.

As of now, there is no evidence for the efficacy or necessity to use any of the measures.

Multiple reasons for repeal or delay are:

- Quality measures have nothing to do with quality. The Medicare Payment Advisory Commission (MedPAC) agrees.
- MIPS penalizes small practices and solo physicians. While it is supposed to be based on quality initiatives, CMS has already announced how many will get bonuses and how many will get negative adjustments, which essentially shows that it is a pre-possession. The major issue here appears to be balancing the budget—not improving health care.
- Quality metrics only look at data points. They utilize numerous measures which are irrelevant to the particular specialty, to patient care, and finally to measures which are not controlled by that particular physician.
- At minimum, provide a one-year delay, followed by implementation of MIPS for only one of 4 quarters to qualify. This will provide opportunities to prepare appropriately over a period of one year, both for CMS and physicians; as well as if in fact this improves quality, it can be observed in a 3-month follow-up. In addition, if a person participating during the first or second 3 months fails to achieve the scores, that person may participate again in the third or fourth quarters.

While organized medicine, including the undersigned organization, was involved in MIPS development, the formulation of the proposed rule by CMS was conceivably created by non-practicing physicians and others who are non-physicians who seemingly did not ask for any input from physicians or relevant organizations.

Meaningful use has been given a fancy name as advanced care information, even through you have stated meaningful use was ending. Even though it is promoted that advancing care information is more flexible than meaningful use it appears to be questionable.

In fact, at the annual Healthcare Information and Management Systems Society (HIMSS) conference in March 2016, you, revealed the worst kept secret in health care: physicians are extremely frustrated with current electronic health record (EHR) systems. You shared findings from 8 focus groups CMS conducted with front line physicians on EHRs. The main theme was that EHRs were not intuitive and usable for a physician's work flow. One doctor interviewed by CMS complained that it took 8 clicks to order aspirin in the EHR, and it took 16 clicks to order full-strength aspirin. For interventional pain management physicians it takes a minimum of one minute to order one controlled substance with multiple clicks when a system is functioning appropriately. The dislike for EHR systems, especially in terms of usability, has been boiling for several years and continues to decline with its approvals. According to a survey conducted by the AMA and American EHR Partners, a research company which rates vendors in the space, satisfaction with EHR systems among physicians plummeted almost 30 percentage points from 62% in 2010 to 34% in 2014 – thanks to the advances and complicated regulations from CMS.

Essentially, current EHRs take too long to enter data, require a number of things that need to be entered that do not seem to be valuable for patient care, are designed to fulfill federal programs rather than the needs of the physicians and the patients using them, and they do not display information in a way that is usable and helpful to doctors as it should be as per Steven J. Stack, an emergency physician and President of AMA. This effect is much more exacerbated for practicing physicians, specifically in a chronic management setting such as interventional pain management.

In addition, EMRs do not talk to each other, the main reason EHRs were widely deployed to share information across different sites of care and clinicians, and they simply don't do that at any level at present and they increase the time required to acquire the data. A majority of the times, meaningful use requirements and PQRS requirements necessitate documentation of data that is neither applicable to the specialty nor to the treatment the patient is receiving.

Dr. Robert Wachter, a physician and professor and interim chairman of the Department of Medicine at the University of California, San Francisco, as well as the author of *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age* succinctly stated that the core problem is EHRs are not built with usability in mind or an appreciation for a physician's work flow. Moreover, Dr. Wachter does not think that it is a coincidence that higher rates of physician burnout have correlated with widespread EHR adoption.

In fact, assessment of burnout among pain management physicians showed that 61% of interventional pain management physicians suffer with emotional exhaustion, 43% suffer with a lack of personal satisfaction and accomplishments, and 36% reported depersonalization. Another recent survey on physician burnout showed EMRs increased their stress level substantially and the physicians reported stress levels of 80% to 90% and a significant proportion of them will be dropping out of practice sooner or later, while the majority of them choose to pay a penalty.

However, patient safety appears to be at the core of the issue. According to Dr. Wachter, EHR-related workflow issues can lead to bigger problems apart from burnout. He stated that, "the most disturbing thing (that can happen) are major medical mistakes . . . they happen all the time." Obviously these mistakes have been underreported as CMS and Congress only listen to the lobbyists from information technology and EHR and those benefiting with EHRs, ICD-10, and other programs. Even the AMA with vast income from CPT coding and ICD-10-CM coding does not reveal these issues. It has been

demonstrated beyond any reasonable doubt that Congress was listening only to information technology professionals in implementing ICD-10 with all positive comments benefiting information technology while the physician community was ignored.

The CMS data itself show that solo and small practices will get hit hardest under the new incentive payment system with 87% of solo practitioners likely to be penalized with inclusion of 103 eligible clinicians; whereas groups with 2 to 9 physicians comprising 124,000 eligible clinicians will be likely to be penalized at a 70% rate. The penalties start reducing at 60% for 10 to 24 physician groups, which incorporates only 81,000 physicians and 45% for 25 to 99 physician groups. The majority of the physicians have already flocked to hospitals and they constitute 100 or more physicians in a group with a total of 306,000 with only 18% likely to be penalized. Consequently, MIPS will send many physicians into hospital employment and many of them do not have such programs. Ironically, hospital settings are the most costly with the least cost effectiveness and present with low quality with entangled bureaucracy.

This is in total conflict with the philosophy of Congress to provide high quality care with reduced costs.

Further, CMS estimates that approximately $900 million will be provided in bonuses, which will be recouped from penalties. Essentially this states to any person with business experience or economists that if CMS is not able to achieve this goal with the present regulation, it will change it so that more and more will be penalized with the composite score being changed or the measures will be instituted so that they cannot be appropriately implemented. Consequently, CMS should delay MIPS for at least 2 years for all the reasons cited above, and Congress should repeal it on a bipartisan basis. This meaningless, valueless provision in the law which is affecting patients and physicians across the United States will increase costs and reduce quality.

Clarify Multiple Issues

Even with postponement of implementation, CMS must clarify the following 3 questions. These questions have been raised by the Ways and Means Committee to CMS. Even then, the Ways and Means Committee has not received a reply to clarify these questions.

1. Are the measures separate for each individual category such as quality, meaningful use, etc., or can one measure apply into more than one category?

    - It is extremely crucial that CMS provide an appropriate response and clarify these questions even with potential delay in implementation and repeal. As described in the proposed rule, there are multiple measures which can cut across all 3 categories, namely advancing care information, quality reporting, and clinical practice improvement activities.

      Overall, it appears to be prudent for CMS to incorporate multiple measures cutting through multiple parameters and be credited in each category towards calculation of the composite score.

      CMS has proposed that as an example, the category of quality will incorporate 50% of the composite score in 2019, which is reduced to 45% in 2020 and 30% in 2021. However, the resource use changes from 10% to 30% within 2 years. The proposed rule shows that clinical practice improvement activity stays at 15% and advancing care information also stays at 25%; however, this appears to be contradicting their own proposed rule. The proposed rule essentially states that with widespread penetration of EHRs, the proportion of advancing care information will be reduced or even eliminated.

2. While CMS has clearly provided in the past the included CPT codes for consideration for PQRS, it has not provided the type of CPT codes to be used for MIPS assessment.

   - The question is that are these limited to evaluation and management services only, or all services? If so, how do they receive implementation for what measures?
   - Are they different based on the type of service provided or the visit such as a procedure, surgery, or only a follow-up visit?

3. CMS also has not answered the question in reference to if the procedures are performed in a surgery center or hospital, is the physician still obligated to provide these measures or not?

It is essential to understand this aspect. As many as 60% of interventional pain management procedures are performed in either an ambulatory surgery setting or hospital outpatient departments, which are exempt from MIPS. Consequently, is a physician still responsible for collecting the data and submitting for these services as there will be a physician service bill on these patients apart from the facility bill?

Certain clinical improvement activities provide inclusion if a physician is participating in service conducted by JCAHO. However, it does not offer the same for other agencies approved by CMS such as AAAHC.

Thus, CMS must immediately respond to the above questions with clarifications so that participants can prepare, provided there is time to prepare and accommodate. Accommodation seems to be the essential ingredient lacking in this proposed rule. Accommodation can come in multiple ways. It is essential that CMS accommodate the needs of the most vulnerable physicians in solo and small practices and do not lead to the end of independent medical practices. It has been stated that the changes in MIPS have the potential to upend the way medicine is practiced today, accelerating the move towards hospital employment and making the small group practice a thing of the past. This is achieved at a high cost for physicians and to the public.

Accommodate the Needs of Independent Physicians

1. Repeal MIPS leaving intact other provisions of MACRA with SGR. As it is, SGR repeal has been problematic in future years. Physicians are already struggling with future prospect of major cuts. In addition, physicians have been burnt with onerous regulations from CMS over the years and most recently, ICD-10-CM, and, finally now, MIPS. Thus, repeal and do nothing after that is the number one option.
2. The number 2 option is repeal the present proposed MIPS and replace it with real quality improvements with appropriate delay.
3. Delay for 2 years with multiple pilot programs demonstrating efficacy and the value of this MIPS.
4. Change requirement to per quarter than yearly.
5. Only implement rewards, but not penalties. This essentially means CMS and Congress would need $900 million per year.
   - **Approximately $4 to $6 billion can be obtained by removing the site of service differentials with hospitals being paid at the same rate as ambulatory surgery centers for surgical services performed in the operating room and being paid at the same rate as 10% higher than the office expense rate.**

     This has been proposed by MedPAC as well as the Department of Health and Human Services/Office of Inspector General with no action from CMS. Congressional action would be good on this aspect; however, CMS with all the

powers with its fee schedule can implement the site of service equalization. This will be the most accountable activity ever performed by CMS.

Finally, we appreciate CMS for consideration of our comments. A copy of this is being sent to appropriate committee chairs and ranking members in both houses and all the members of Congress. If you have any questions, please feel free to contact us.

Thank you,

SIGNATURES