March 20, 2017

Dear Secretary Price:

On behalf of the undersigned organizations, we are writing to request that you use your regulatory authority to minimize the 2018 penalties to be imposed on physicians pursuant to the Value Modifier (VM), Meaningful Use (MU) and Physician Quality Reporting System (PQRS) programs. Taken together, these programs have the potential to reduce Medicare payment for the services provided by some physicians by up to 9% in 2018 while increasing the payment provided to a select few by over 30%.

We provide our views and legal analysis to argue that both the broad reductions and windfall increases that would result from application of the VM, MU, and PQRS programs as currently configured are not defensible, and urge that you take quick action to minimize the potential redistributive impact of these programs. Creating regulatory relief for physicians in these complicated reporting systems is not only well within the purview of HHS, but also would also enable physicians to continue to deliver high quality care without onerous, unfair, and illogical regulations getting between them and the patients they serve.

CMS Should Establish a VM Adjustment of Zero for 2018.

Authorized by Section 3007 of the Affordable Care Act ("ACA"), the purpose of the VM program is to provide for upward or downward payment adjustments to a physician or group of physicians "based upon the quality of care furnished compared to cost."

Because the VM program was enacted as part of the ACA, the program is subject to President Trump's first Executive Order issued on January 20, 2017, which directs HHS to "exercise all authority and discretion" available to it to "waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that imposes a penalty or regulatory burden on healthcare providers." The 2018 VM program imposes a significant regulatory burden on physicians and the VM adjustment of up to 4% authorized by the current regulations constitutes a considerable penalty.

Further, for the reasons set forth in the attached legal analysis, HHS has the authority under the governing statute to refrain from implementing the VM in 2018 (or, stated differently, to establish a VM adjustment of zero percent).

In fact, the governing statute specifically exhorts the Secretary to "coordinate" the VM with "other similar provisions of [the Medicare Program]". In final rules implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS agreed to "zero out" the impact of the resource use component of the Merit Based Incentive Payment System (MIPS)—the successor to the VM program-- in 2019. The agency is according zero weight to the cost component of MIPS because the agency determined that physicians needed more time to understand the program. Yet, essentially the same (or similar) cost measures are used under the VM program. Certainly a program that physicians do not understand in the MIPS 2017 performance year would also not be understood in the VM 2016 performance program. Thus, establishing a "zero" VM adjustment for 2018 is consistent with governing statute's language mandate to coordinate between the VM program and other comparable programs.

Establishing a VM adjustment of zero is not only consistent with the governing statute and the President's first Executive Order, it is also consistent with sound public policy. The VM purports to compare physicians based on quality and resource use (costs). The statutory mandate

requires that the cost component of the program "take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals such as to recognize that less healthy individuals may require more intensive interventions)". Yet, these factors are not adequately taken into account under the current VM methodology, resulting in substantial geographic disparities that penalize physicians in population areas with poor health status as well as subspecialists who treat those with more advanced disease or chronic conditions. Likewise, the current attribution methodology is fatally flawed, resulting, for example, in the designation of an ophthalmologist as a patient's primary care physician simply because the patient has an ophthalmic condition (e.g. macular degeneration or glaucoma) that requires frequent physician visits. In such cases, under the current attribution methodology, the costs of the patient's hernia repair and cardiac hospital admissions may be credited to the ophthalmologist. Similar absurdities are not uncommon for other specialists.

Finally, the fundamental redistributive impact of the program is unjustifiable: Based on the most recent data available, in 2016, nearly 40% of physician groups (5,418 TINs) received an automatic 2% downward VM payment adjustment for failing to meet PQRS reporting criteria; while 128 groups received upward adjustments of either "+15.92%" or "+31.84%." We are aware of physician groups that have received nearly $1 million in additional payment as the result of application of the VM. We believe that such a skewed result utterly fails to reflect the relative value of physician care to Medicare beneficiaries.

CMS Should Adopt Broader MU "Hardship Exemptions" To Maintain Consistency With MIPS Exemptions and Exceptions.

The statutory authority for the MU program specifically provides the Secretary with the authority to provide hardship exemptions, an authority that the Secretary has implemented since the inception of the program. We believe that, in light of the enactment of the 21st Century Cures Act (Pub. L. 114-225), the MU program should be suspended pending the adoption and implementation of new interoperability standards. In the alternative, the hardship exemptions provided under the MU program should be substantially expanded to be consistent with comparable exemptions under MIPS.

Under the MU regulations currently in effect, in order to avoid penalties in 2018, a physician must use the 2014 or 2015 editions of CEHRT. However, in the 21st Century Cures Act (Pub. L. 114-225), Congress amended the certification requirements to provide that, on and after January 1, 2018, an EHR system cannot be certified if it has not met new interoperability standards, and these standards have not yet been developed. Under Section 1848(o)(2)(A) of the Medicare Act, for the purpose of the MU payment adjustment, a meaningful user of CEHRT is defined as an eligible professional who, for the applicable EHR reporting period (i.e. 2016, in the case of the 2018 MU adjustment) meets the following requirement, among others:

(i) INFORMATION EXCHANGE.—The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that *during [the performance] period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.* [Emphasis added]

It was the lack of "law and standards applicable to the exchange of information" that resulted in enactment of the interoperability provisions of the 21st Century Cures Act. In other words, the

MU penalties appear to presume a level of interoperability that has not yet been achieved and that cannot be achieved until the new interoperability standards are implemented.

As a practical matter, what sense does it make to penalize physicians for failing to install or make "meaningful use" of CEHRT that, based on a Congressional mandate, will be outdated by the time the penalty is imposed? Under these circumstances, we believe that the Secretary should determine that the 2018 edition of CEHRT is required for the purposes of the MU program and that application of the MU adjustments are suspended pending implementation of the new interoperability standards.

Barring this type of relief, we strongly urge the expansion of the hardship exemptions to at least be consistent with the various exemptions and exceptions provided to low volume physicians[1], small practices, and hospital-based physicians under MIPS. MACRA regulations exempt from MIPS physicians and practices that meet the "low volume threshold" from the Advancing Care Information (ACI) and other MIPS requirements, because the agency found that compliance would constitute a hardship for these practices. The ACI requirements are the successor to today's MU program requirements, but are considerably less onerous. It is within the authority of the Secretary to determine that the same "low volume" threshold should be used to identify those physicians for whom compliance with the MU requirements would be a hardship. A similar rationale supports providing a hardship exemption for any physician who is in a "small practice" as defined by the MACRA regulations (a practice of 15 or fewer physicians and other clinicians. [2]

We note that, while MU exemptions historically have been based on individual hardship exemption applications, the statute does not require an application process, but only that determinations be made on a "case-by-case" basis. A physician's eligibility for a hardship exemption as a low volume physician, member of a small practice or MIPS eligible hospital-based physician can be determined by CMS based on the physician's claims history in 2016. Therefore, we believe that the expanded hardship exemptions described above could be implemented by CMS in 2018.

CMS has the Authority to Make PQRS More Rationale and Fair

[1] The final MIPS regulations substantially expanded the availability of the MIPS low volume exception as compared with the proposed rule, such that those physicians and other eligible professionals with less than or equal to $30,000 in Medicare Part B annual allowed charges or less than or equal to 100 Medicare patients per year are exempt from MIPS.

[2] Under the final MACRA regulations, such small practices are subject to less stringent scoring under the Clinical Practice Improvement Activity (CPIA) category of MIPS. In finalizing these more relaxed CPIA requirements for small practices, the agency states:

> Our rationale for small practices and practices located in rural areas and in HPSAs is grounded in the resource constraints that these MIPS eligible clinicians face. This rationale is especially compelling given that each activity requires at least 90 days and may not necessarily be conducted in parallel, with time allocated to pre-planning and post-planning, which would impact the practice's limited resources

Federal Register /Vol. 81, No. 214 at 77317 (November 4, 2016). Substantially greater resources are necessary to install CEHRT and implement a program that meets MU requirements than to meet the MIPS CPIA requirements. Therefore, a practice that meets the MIPS small practice definition (15 physicians or fewer) should be entitled to a MU hardship exemption.

The statutory authority for the PQRS payment adjustments specifies the percentage adjustment to be applied to a physician's payments if that physician fails to meet PQRS reporting requirements. For 2018, the statute states that the Secretary "shall" apply a payment adjustment of 2% to the payments of physicians who fail to meet PQRS reporting requirements.

CMS has the flexibility to make PQRS reporting considerably less onerous and to thereby minimize the number of physicians who are subject to PQRS penalties. For example, the current regulations require physicians to report on nine quality measures in three "domains" in order to avoid negative PQRS payment adjustments. This nine measure/three domain requirement has created a number of hardships for physicians, especially for specialists, who often lack clinically appropriate quality measures. In part as the result of the nine-measure/three domain reporting requirement, almost half of all physicians were subject to the PQRS payment adjustment in 2016.[3] And because those who do not meet PQRS reporting requirements are also subject to a 2% VM adjustment, the impact of the nine-measure/three domain requirement is essentially doubled.

The governing statute does not specify the number of measures required to be reported. The successor to the PQRS program – the quality component of MIPS – reduces the quality reporting requirement from nine measures to six. In the first year of MIPS, reporting on even one measure allows a physician to avoid the penalties. We strongly urge you to adopt a similar relief for the purpose of the PQRS adjustment for 2018.

We would appreciate the opportunity to meet with you and your staff regarding the 2018 payment adjustments, and will be contacting your office to arrange a mutually convenient time and date. In the interim, if you have any questions regarding this request, please do not hesitate to contact Catherine Cohen, Vice President, Governmental Affairs at (202) 737-6662.

Sincerely yours,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Neurology
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
American College of Rheumatology
American Glaucoma Society
American Society of Clinical Oncology
American Urological Association
Society for Vascular Surgery
The Macula Society
The Retina Society
The Society for Post-Acute and Long-Term Care Medicine

[3] See 2014 Reporting Experience Including Trends, 2007-2015 (April 15, 2016). https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Experience_Rpt.pdf