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Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 [CMS-1612-P]

Dear Administrator Tavenner:

On behalf of approximately 6,000 physicians and physicians in training, the Connecticut State Medical Society (CSMS) appreciates the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Proposed Rule entitled *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015* [CMS-1612-P]. CSMS believes this Proposed Rule has some very significant implications for physicians and access to care for the patients they treat within the Medicare program.

This letter includes CSMS comments, questions, concerns, and recommendations regarding the following provisions of the Proposed Rule:

- Resource-Based Practice Expense Relative Value Units (RVUs)
- Potentially Misvalued Codes under the Physician Fee Schedule (Improving the Valuation and Coding of the Global Package)
- Professional Liability Insurance RVUs
- Medicare Telehealth Services
- Chronic Care Management
- Access to Identifiable Data for the Center for Medicare and Medicaid Models
- Private Contracting Opt-Out
- Reports of Payments or Other Transfers of Value to Covered Recipients
- Physician Compare Website
- Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System
- Medicare Shared Savings Program
- Value-Based Payment Modifier and Physician Feedback Program

I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

A. Practice Expense Relative Value Methodology

In 2010, CMS completed a transition to a “bottom-up” PE RVU methodology with the assertion that it was to conform to the budget neutrality requirements, which CSMS believes has resulted in CMS underpaying for the PE direct costs to provide a service. With PE often accounting for a large percentage of the overall cost of care, this underpayment over time has resulted in significant reductions in payment to physicians, especially in certain specialties. Further, it appears with the current methodology, the direct PE costs covered has fluctuated from about 50% to the proposed 59% percent in 2015, while in 2009 the direct costs covered were 62.5%. This instability in direct PE costs covered does not reflect, either generally or specifically, any specific changes in a physician practice or practice in general over this period of time. This variability is simply the result of the methodology established by CME to adjust PE direct costs. As a result, and to maintain more consistency year to year and in order to more accurately reflect the actual practice expense in providing medical services, **we believe that CMS should revise its methodology to simply pay the actual direct PE costs to provide a procedure or service.**

II. Potentially Misvalued Services under the Physician Fee Schedule

A. Improving the Valuation & Coding of the Global Service Package

CSMS believes that the current proposal would not accurately account for physician work, practice expense, and medical liability risk for services performed within the current surgical global period. CMS proposes to transition all 010-day and 090-day global codes to 000-day global codes by 2017 and 2018, respectively. However, it appears that one of the primary explanations given for this proposed transition is that CMS is having difficulty in obtaining available data to verify the number, level, and relative costs of post-operative visits included in global packages. CMS also expresses concern that the global packages may no longer reflect the post-operative care provided to the typical patient. The former is simply an issue of data collection and should not be cause to dramatically alter how surgical services with global periods are reimbursed. The latter really only highlights the need for much more analysis to document any changes in care modalities that have resulted in post-operative visit adjustments by surgical code and any corresponding need in change to global periods. CSMS also recommends that CMS work with the RUC Relativity Assessment Workgroup to collect and review existing, objective data in order to validate bundled post-operative visits and not make any decision or transition that could result in the elimination or adjustment of current global periods until physicians who provided those surgical services can review the data. **As a result of this need for much more detailed analysis, we believe that the proposed timeline is simply unrealistic.**

1. Problems with PE

There is a different mix of post-operative direct PE inputs for global period Evaluation and Management (E/M) services and separately-reported E/M services, simply because of the intensity of services tied to the post-operative E/M services. **If the proposed unbundling does occur, CMS should still account for these additional direct PE inputs for the post-operative period of surgical procedures via new**

and/or existing CPT/HCPCS codes or else these surgically associated E/M services will be significantly undervalued.

- An important and often unrecognized distinction is that E/M services performed in a surgical global period often include additional and justifiably more expensive supplies and equipment relative to standard, separately-billed E/M services. Post-operative follow-up care is directly related to the actual surgical service and, therefore, beyond the regular E/M history and medical decision making, there is specific attention paid to the surgical site and patient movement, experiences of pain, discomfort, or improvement (both compared to prior to the surgical service and since the surgery).
- Certain surgical E/M services also include additional clinical and administrative staff time relative to the staff time for separately reported E/M visits. The post-operative clinical staff time is carefully considered by the RUC, and is directly related to the typical patient condition and type of service performed for the specific CPT code that has been valued.
- CMS must also consider the effects of this proposal on the *indirect* PE payment, derived from the weighted average of the specialty mix that performs each service. Currently, the indirect PE related to the post-operative work for surgical services is correctly derived from the costs associated with the surgical specialties performing the service. Under the CMS proposal, this post-operative work would be inappropriately diluted due to the broad mix of specialties which perform separately reported E/M services. The main input for indirect PE in the PE RVU formula, indirect PE percentage, is higher for many of the surgical specialties than for the many separately-reported hospital and office visits. The unbundling of post-operative E/M visits would thus result in a decline in indirect PE payment for many specialties, which does not accurately reflect the actual indirect PE resources for post-operative services.

It is perplexing in an environment and time when CMS continues to highlight the need to bundle services and as a result payments, that with surgical global periods the reverse is being proposed, potentially resulting in more expensive resources and additional clinical labor time to be paid at correspondingly higher amounts and rates. If there was an unbundling of these services, CMS would have to reimburse the services and procedures tied to actual costs. **These direct and indirect PE inputs would need to be accounted for in any unbundled reporting system and because of the budget neutrality inherent in the current system, any corresponding increase in payment tied to these post-operative visits could significantly reduce other services significantly (because of the volume and cost that would be assigned to these services within the system).**

2. Medicare Payment for Professional Liability Insurance (PLI)

The risk of potentially severe complications that may result during the post-operative period of a complex procedure will be substantially undervalued if there is a transition away from 010- and 090-day global periods. It is unclear how CMS plans to address this. Another consequence of this proposal that needs to be addressed is the large redistribution of the PLI payment from the surgeons providing the surgical procedures to a more diverse group of physicians and others providing medical care and treatment in the post-operative period. The PLI RVU for each service is calculated by multiplying the work RVU by the specialty risk factor of the particular specialties which perform the

service. Currently, the work RVUs of the proxy E/M services contained in the global period for 010- and 090-day surgical codes are part of the PLI calculation. This is appropriate because the liability costs of a specific service should be derived from those performing the services. It appears that under the CMS proposal, the medical liability costs associated with the post-operative work would be removed from the primary service and would be artificially diluted by the wide mix of specialties performing all types of E/M services post operatively. **If CMS does unbundle surgical global periods, there needs to be an approach to account for this disparity. CSMS fears that** without global periods, a one-size-fits-all approach to PLI will result in great disparities between the actual and realized medical liability costs for many physician specialties, especially those providing highly complex surgical services that require significant follow-up that is presently part of the global period.

3. Administrative Burden

The separate submission, processing, and payment of post-operative E/M codes and other miscellaneous post-operative services and supplies would place an additional and substantial administrative burden on Medicare providers, Medicare Administrative Contractors (MACs), and CMS. Under the CMS proposal, there would be a significant increase in the total number of Medicare claims per year as a result of the unbundling of global periods and the associated post-operative E/M services. These would include millions of separate claims for post-operative E/M services, as well as the many miscellaneous post-operative services and supplies which are currently bundled. Private health insurers would very likely make their own decisions about maintaining the existing global periods or transitioning back to individually coded and billed E/M services in the post-operative period. This likely lack of consistency would create additional administrative burden for physicians and patients. Taking millions of surgical services with global periods and breaking out the post-operative E/M services into individual claims will result in a significant increase in expense for physicians who will bill for these services, the MACs who will experience a significant increase in claims processing, and CMS.

4. Data Collection and Post-Operative Period Validation

The CSMS believes that it is crucial to collect data on post-operative visits furnished by physicians reporting current 010-day and 090-day global codes. CMS should collect and examine existing post-operative visit data in order to validate current surgical bundles and to facilitate informed decision-making on how to proceed with current and future proposals. Changes in global periods and post-operative E/M services should not be initiated until this analysis is completed, and it should include the RUC and those national medical specialty societies representing the surgeons providing the services for which global periods are assigned.

5. Proposed Timeline Unachievable Without Inappropriate Shortcuts

The proposed timeline to transition codes from 010-day and 090-day global periods to 000-day global periods is too aggressive without credible data and is simply not achievable without seriously impacting the relativity of the resource-based system presently engaged to determine values of services and procedures provided by physicians. It would also have a profound and rather dramatic impact on the provision of surgical services and how follow-up care associated with post-operative E/M services are provided. This adjustment would significantly impact certain surgical specialists more

dramatically than others and could result in access issues, not only tied to the surgical service provided, but also the medically necessary follow-up care. This proposal may dramatically alter who is providing those post-operative visits, because of the lack of adjustment in valuation of these E/M services with the significant expense compared to other E/M services (PE, PLI). In many locations throughout the country, there are simply not enough non-surgical physicians available to provide post-operative care and many surgeons could see the lack of accurate PE and PLI adjustment as a disincentive for providing post-operative care.

6. Scope of the Proposal

There are thousands of services on the Medicare Physician Payment Schedule with a 010-day or 090-day global period. The scope of this proposal is extensive and would likely take a substantial amount of resources and effort to implement in the proposed timeframe. Is the upfront cost of transition, the questionable benefits of this transition, and the shifting away from bundling of services, really worth the potential savings identified? It appears that this is another example of using a hammer when only a fly swatter is necessary. Why not evaluate those surgical services with post-operative periods individually to determine if any debundling is worth it, given the significant disruption and administrative burden this effort will cause.

7. Adverse Impact on Patient Access to Care and the Cost of Care

Unbundling post-operative E/M services would result in patients having to pay co-payments separately for each visit, instead of upfront as a single bundled payment. An additional co-payment per visit would incentivize many patients to consider not showing up for follow-up visits in order to save money, potentially jeopardizing their short-term and long-term prognosis. In spreading these payments out, the physician's ability to properly manage a patient's status would be seriously mitigated due to the potential for the patient not to return for post-operative services, as well as result in an added burden to the practice of additional billing for each service and, if non-payment is experienced, additional efforts to collect.

Over time, most private insurers would follow CMS's lead and unbundle global periods, adding to further billing and billing complexities. Some of the more recent benefit designs for private payers do not charge a co-payment for some of these surgeries with global periods, but they would likely require co-payments for separately-reported office visits (and deductibles may be impacted as well). Patients covered by certain private payers would have to pay more out of pocket, adversely impacting them financially. This proposal has the potential to disproportionately impact chronically ill patients who will have the highest amount of return visits and therefore the most co-pays. Many of these patients are the least likely able to afford additional out of pocket expenses.

There are simply too many logistical challenges and likely unintended but not unforeseen consequences of the CMS proposal to unbundle surgical services with global periods. CSMS does not believe that the perceived benefits outweigh the overall burden to implement this proposal.

Until there is valid and reliable data at the service level that clearly demonstrates that this proposed change will have the desired cost savings and not harm patient access to care, eliminating the surgical global period is unlikely to accomplish the agency's limited concerns and could very likely cause much more harm than benefit.

III. Professional Liability Insurance (PLI) Relative Value Units

CSMS has concern that many of the problems with the current PLI RVUs are not addressed in the Proposed Rule, and that flawed status quo is maintained. In Connecticut, with some of the highest medical liability premiums in the nation, the issue of PLI is especially important, and changes that would reflect more realistic and reliable RVUs would be well received.

A. Annual Review of PLI RVUs

Given that CMS has modernized its process for updating the other two components of the Medicare RBRVS to reflect the most accurate information available, it seems only appropriate that the third component of physician payment, PLI, should also be updated annually and based on actual liability expenses associated with the provision of medical services, at the service level. CSMS believes that establishing some sort of yearly collection of PLI premium data would allow for the PLI RVUs to be based on the most currently available premium data, thereby increasing the reliability of the PLI payments and it would allow for greater engagement and involvement of physicians and other stakeholders. Under the current five-year review process for PLI RVUs, there is only one opportunity every five years to identify potential problems and/or improvements. An annual review would eliminate this problem and allow PLI RVUs to be treated identically to physician work and PE RVUs so that all aspects of the Medicare RBRVS would be reviewed yearly. **CSMS believes that a yearly collection of PLI premium data would allow for more timely and more accurate adjustments by service of PLI RVUs.**

B. Non-MD Risk Factor/Premium Crosswalk

CMS has once again chosen to crosswalk the PLI premiums of non-MD specialties to the lowest MD risk factor (Allergy Immunology), which CSMS believes is fundamentally inaccurate and continues to cause overstated PLI premiums and risks associated with non-physician services. The difficulty that CMS contractors have in obtaining comprehensive and accurate premium data across the large majority of states should not result in CMS using a MD specialty risk factor for non-MDs, who have inherently different clinical training and treatment modalities and, therefore, different PLI premiums and risks. **CSMS strongly recommends that CMS use actual survey data or some other analysis to assign accurate PLI premium rates for non-physician specialties.**

IV. Medicare Telehealth Services

CMS has proposed further expansion of covered telemedicine services in the Proposed Rule. The AMA has consistently supported Medicare's proposals to expand access to a telemedicine option for Medicare-covered services, including last year's proposal to broaden the definition of "originating sites" to include more geographic locations, and the CSMS believes that these types of expansions could lead to increased access to care for Medicare beneficiaries. However, CSMS believes that there needs to be some additional analysis tied to which services can be effectively, efficiently, and appropriately provided through telemedicine-based services. The CSMS has been engaged in discussions tied to telemedicine services at the state level and believes that these services can be a supplement, but not replacement, for on-site care provided by a physician. CSMS believes that in the absence of on-site physician care, telemedicine, with the appropriate standard of care consistent with newly adopted AMA policy, could

help patients in rural communities as well as urban centers access medically necessary care in a more timely and efficient manner, including mental and behavioral health care services.

The AMA's House of Delegates at its most recent June meeting adopted a report entitled, "Coverage and Payment for Telemedicine," which contains very well thought out and detailed policies on telemedicine. The report was the culmination of discussions and deliberations by a diverse cross-section of practicing physicians. As part of a comprehensive review of the various telemedicine issues, this report provides recommendations concerning the benefits, risks, and best practices associated with telemedicine services.

Though CSMS supports this AMA report and the associated policies, it is very important that physicians abide by state licensure laws, medical practice laws, scope of practice requirements, and other regulations in the state in which the patient receives services. CSMS strongly advocates that physicians delivering telemedicine services must be appropriately licensed in the state where the patient receives services.

The AMA policy outlines the conditions and factors applicable to establishing a valid physician-patient relationship. However, CSMS believes that CMS should also consider other factors that should apply to telemedicine services in order for coverage to apply. One important aspect of telemedicine services is making sure that the patient's treating physician, if not providing the telemedicine services directly, must be part of the ongoing coordination of care. Specifically, CSMS urges CMS only consider coverage of telemedicine services that include care coordination with the patient's medical home and/or existing treating physicians. Telemedicine should not be a replacement for or interfere with any existing physician-patient relationship. CSMS believes that the AMA policy on telemedicine is rather extensive, but not completely exhaustive. For example, there need to be more testing of telemedicine services and an evaluation of the cost-benefit analysis of telemedicine services before services that are predominately available face-to-face in the community are covered by CMS.

CSMS agrees with the following AMA policies associated with telemedicine services:

- Telemedicine services must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine;
- Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services;
- Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.
- The patient's medical history must be collected as part of the provision of any telemedicine service;
- The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient;
- Telemedicine services must abide by laws addressing the privacy and security of patients' medical information;
- The standards and scope of telemedicine services should be consistent with related in-person services; and

- The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive health outcomes.

CSMS also supports Medicare expanding pilot programs to enable coverage of telemedicine services, as well as demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation (CMMI), to address how telemedicine can be integrated into new payment and delivery models. However, there are some concerns about telemedicine services being used as a proxy or replacement for face-to-face physician medical care and treatment. CSMS believes quite emphatically that while telemedicine services can provide immediate care assistance for patients without regular or any access to medical care services, particularly for assessment and diagnostic situations, they can never replace the face-to-face encounter and the physician-patient relationship that exists in a physician's office setting. As adoption of new telecommunication technologies increases, the CSMS continues to carefully consider and evaluate the impact on patient clinical care and welcomes the opportunity to work with CMS and state officials and licensure bodies to make sure that telemedicine services are appropriately monitored and quality standards are developed and enforced, and patient access to care and care delivery is not limited, restricted, or eliminated. There are real fears that patients could lose access to local physicians within Medicare or private insurer networks, with governmental agencies and private payers opting for often less expensive telemedicine services rather than the longstanding and critically important face-to-face patient care.

V. Chronic Care Management (CCM)

The CSMS supports payment for chronic care management (CCM) services, and we support separate payment for other non face-to-face services that are critical components of care management, including team conferences, patient education, telephone calls, and anticoagulant management. In 2013, CMS implemented payment for transitional care management services (TCM). In 2015, CMS will begin payment for CCM services for patients with two or more complex chronic conditions that are expected to last at least 12 months or until the death of the patient and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We appreciate the CMS decision to pay for TCM and CCM services and urge CMS to continue consideration of payment for other non face-to-face services that lead to improved access to care when face-to-face care is not necessary for patient treatment.

VI. Access to Identifiable Data for the Center for Medicare and Medicaid Models

CSMS understands the need for CMS to monitor and evaluate the models being tested under the CMMI to make sure that there are both quality improvement and costs savings. However, we have concern that oftentimes requests for data are overly burdensome for physicians and their practices, adding to and not taking away from administrative hassles, further reducing the time a physician has to provide patient care. Before requesting any further data from physicians, it is really incumbent on CMS to first evaluate and estimate the potential burden and cost tied to a physician and physician office. Also, CSMS believes very strongly that physicians should have the right to opt out of producing information that may not be available due to cost limitations or other administrative barriers. If CMS is not going to pay for this additional data or reporting, then it should recognize the barriers that exist in the data retrieval, collection and reporting, and allow for physicians to opt out or provide alternative data. Further, CMS needs to

provide clear instructions and other educational resources to ensure that collection and reporting of the data complies with the HIPAA Privacy and Security rules and also does not duplicate other, already ongoing, requests for data. Finally, CSMS believes that CMS must recognize that issues of coordination of benefits and state-specific Medicaid reporting and payment requirements and regulations must be considered when collecting and analyzing the data presented.

VII. Private Contracting/Opt-Out

CSMS strongly urges CMS to amend its current opt-out policy by allowing physicians to opt out of the Medicare program indefinitely, and by ending the required submission of an affidavit every two years, in perpetuity. CSMS does support CMS' clarification that the physicians who have validly opted out of the Medicare program are nevertheless still permitted to write orders and referrals for Medicare beneficiaries. This will assist beneficiaries in receiving the care they need when they need it. The CSMS believes that physicians should not have to proactively reaffirm their opt-out status. Why must physicians have to constantly opt out of a program? CSMS believes it would be more appropriate to focus on the opting-in aspect of the Medicare program as a better model. If a physician proactively opts out once, it should be up to the physician to request permission to participate at any future time. Requiring physicians to opt out again and again makes no sense, is overly burdensome, and likely not very cost-effective because CMS has to handle all of the paperwork from these previously opted-out physicians. The current requirement – that every physician who opts out of Medicare must re-file an affidavit every two years in order to maintain his or her opt-out status – is unnecessary, is not required by law, and appears to be completely illogical and counterintuitive for an agency interested in creating efficiencies of process. Failing to submit such documentation may expose physicians to significant penalties, which again makes no sense since the physician has already proactively opted out of the program. Asking a physician to confirm his or her opt-out when they have first opted out may be a valid and reliable way to affirm the initial or original opt-out. However, requiring a legal attestation every two years by a physician, under penalty of fine, makes absolutely no sense. Verification and validation of opt-out, yes, repeated requirements for unnecessary and burdensome paperwork, no.

VIII. Reports of Payments or Other Transfers of Value to Covered Recipients

CMS has proposed removing the explicit Open Payments Program regulatory exclusion for continuing medical education (CME) that is applicable to certified and accredited CME activities that meet certain criteria for independence. Instead, CMS proposes to apply another regulatory exclusion to certified and accredited CME when manufacturers are “unaware of” or “do not know” the identity of the covered recipient(s) during the reporting year or by the end of the second quarter of the following reporting year. The CMS proposal will have a profound chilling effect on physician participation in independent medical education programs. The agency's proposal is simply unworkable as industry can and does learn the identities of speakers/faculty and potential participants fairly often after the funds have been transferred through brochures, programs, and other publications, or through their physician-employees' participation in these activities (either as speakers/faculty or attendees). Instead of actually increasing physician participation in independent CME programs, this provision would diminish the likelihood that physicians – particularly those without any ties to industry – would be willing to participate in independent CME. CME providers offering independent CME will either have to forgo all industry funding of the independent educational activity or lose the ability to recruit a fairly large number of physician

participants—either as speakers or attendees—to participate in such events. CMS will therefore be creating a system in which physicians will have reduced access to independent CME programs and could result in increased participation in industry-directed and provided CME programs. **CSMS strongly urges CMS to modify the proposal so that independent, certified and accredited CME activities remain excluded from reporting.** CSMS should allow this exclusion where independence is established when an applicable manufacturer:

- Does not pay covered recipient speakers or attendees directly;
- Does not select covered recipient speakers or provide a third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers or attendees for the CME program; and
- Does not control the program content.

Independent CME represents an important mechanism for providing physicians with information and sharing clinical insights with other physicians about medical practice. Independent CME also provides an important forum to conduct inter-professional educational activities that enhance care coordination and effective communication among the continuum of physicians and health care professionals. CSMS recognizes the concern that CMS has in safeguarding independent CME, but a better way to do this might be to focus on working with CME credentialing and accrediting entities. If those entities presently credentialing and accrediting CME have specific standards and safeguards in place that would meet specified CMS requirements and these entities are monitoring program development, participation and industry involvement in the offering of CME, it seems reasonable that those CME programs could be exempt. If CMS is to implement or cause CME providers to comply with the proposed standards and not offer any exemptions, CSMS strongly recommends that CMS allow CME providers adequate time to ensure that their processes comply with the modified exclusion, and we are asking CMS to delay implementation for a year, to be effective in 2016.

CSMS is interested and very willing to work with CMS and other stakeholders, including the AMA and ACCME, in developing further information and options to what has been suggested by CMS in the Proposed Rule to provide further guarantees of the true independence of CME, while not further restricting or creating barriers for physician engagement in such educational opportunities. CSMS is very concerned how the Open Payments data will be further presented and explained to the public and how it might be misinterpreted and misused by legislators and regulators. It is essential that CMS provide the context of the data reporting, presentation and use so that inappropriate and inaccurate value judgments are not made using the information available through the Open Payment portal.

IX. Physician Compare Website

CMS is proposing a significant number of changes and additions to the Physician Compare website in 2015 and 2016 that will do nothing but provide further inaccurate information to the public and lead to additional confusion for physicians. **CSMS adamantly opposes the multiple proposals to extensively expand the Physician Compare website, as serious and fundamental flaws and errors remain unaddressed and need immediate repair and correction.** The website continues to be problem-filled with little if any useable and reliable data being produced for consumers. Until CMS can make timely updates to the demographic data for individual eligible professionals (EPs) and group practices, CSMS has little confidence in CMS' ability to accurately report performance scores, benchmarks, and

composites. The website must provide accurate data in a manner that is both transparent and fair, so that physicians and consumers can have confidence in the information that is posted.

CSMS supports the AMA policy adopted at the June 2014 House of Delegates meeting that states that “[c]onsistent with the Medicare Improvements for Patients and Providers Act of 2008, the public reporting of quality and outcomes data for team-based care should be done at the group/system/facility level, and not at the level of the individual physician. . .”

CMS must consider the current state of data collection and aggregation accuracy. Equally as important and disturbing is that the agency has yet to put in place a formal appeals process for contesting Physician Compare information and only provides 30 days for an EP to review their information. **The CSMS urges CMS to expand the preview period to 90 days or longer, and if an EP or group practice files an appeal, CMS should postpone posting their information until the issues are resolved.**

Rankings or similar systems that display disparate quality scores in a simplified graphic result in distorted, inappropriate distinctions of quality for physicians whose performance scores are not statistically different. Furthermore, using small sample sizes often skews the results of quality reporting or quality scores. **CSMS requests that CMS look more closely at the measures in place and any proposed measures and also provide the opportunity for physician review and comment prior to the further implementation of any measures, especially those relying on such small sample sizes, as few as 20 patients, which could result in very inaccurate resulting quality scores based on one outlier.**

A simple examination of performance scores without adjustment for patients’ socioeconomic and/or socio-demographic situation ignores a number of factors that are believed to influence quality and cost of care. Ignoring these factors could lead to the conclusion that physicians and practices that serve low income patients provide lower quality care than those serving high income patients, when the difference in scores could actually be due to differences in patient mix rather than differences in quality of care provided. To hold physicians accountable if outcomes differ for these patients without accounting for the factors that contribute to that difference would unfairly penalize physicians for factors outside of their control, and could adversely impact both those physicians providing access and quality of care and these patient populations. Instead of rewarding physicians who treat the underserved patient populations and populations at risk, this could unfairly penalize those physicians who treat a number of socio-disadvantaged patients. **We strongly urge CMS to move forward with expanding its risk adjustment methodology to incorporate race, income, region type, and other socioeconomic and demographic factors. The lack of adjustment could easily lead to inaccurate and misleading conclusions about quality and performance measurement tied to physicians who are treating certain – or subsets of – patient populations. This could, in turn, lead to increases in disparities in healthcare and not improvements.**

X. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)

CMS is proposing changes in several key areas of PQRS, including the requirements for the 2017 PQRS payment adjustment. 2015 is the first year when no PQRS incentives are available under the program and

serves as the performance year for the 2017 payment adjustment of two percent, which will apply to EPs who do not satisfactorily report data on quality measures. CMS also proposes to remove a significant number of measures from the PQRS program due to CMS considering the measures as “topped out,” having no identified measure standards, or due to changes in recommended guidelines. CSMS is concerned that the growing complexity of PQRS and yearly program changes proposed by CMS pose a significant barrier to participation for many physicians and successful participation for physicians who have experience in the program. These constant and yearly changes to the program prevent physicians from effective and efficient participation. According to the last year of data that CMS has provided the public on PQRS participation rates, only 36 percent of eligible professionals participated in PQRS for 2012.

If physicians are not considered to successfully report in PQRS, Meaningful Use (MU), and the Value Based Payment Modifier (VM), in 2015 for 2017 penalties, they are potentially subject to a two percent PQRS adjustment, a three percent MU adjustment, and a four percent VM adjustment, plus an additional two percent adjustment due to sequestration, an 11 percent cut in reimbursement in 2017 (5.5% in 2015). At the same time, physicians must transition to ICD-10 by October 1, 2015, which could have serious repercussions for successful reporting and CMS’ ability to accurately process claims, not to mention the significant expense. **CSMS strongly recommends that CMS maintain stability in these programs – not change requirements on a yearly basis, but scale back on reporting requirements and not levy such high penalties on physicians at a time when they have to absorb such significant costs tied to electronic medical records and ICD-10 transition. At a minimum, PQRS requirements should stay the same without further penalties until the measures that are being proposed and those being eliminated are more fully analyzed and evaluated.**

A. Proposed 2015 PQRS Reporting Changes

CMS proposes to increase the number of measures that must be reported via the claims and registry-based reporting mechanisms to avoid a payment adjustment from three to nine measures, as well as the number of measures in a measure group. These nine measures must cover at least three of the National Quality Strategy (NQS) domains and must include two measures from the newly proposed cross-cutting measure list. CMS indicates that these changes are necessary to further the goal of aligning CMS’ various quality reporting programs.

Increasing the current reporting requirements threefold and requiring the reporting of two cross-cutting measures when physicians have still not seen their data for successful participation in 2013 or 2014 is an unreasonable leap and disregards the realities of the existing PQRS measures and other practice transformations that must occur in the coming years. The availability of measures to meet the needs of varying specialties and subspecialties becomes even more problematic as CMS proposes to remove a significant number of measures for 2015. Many specialties, particularly those that are procedure-based, continue to struggle in identifying meaningful clinical quality measures to report. **Therefore, CSMS opposes the increase from three to nine measures due to the unavailability of meaningful measures relevant to every specialty and the dramatic reduction of measures available to report at a time when physicians are already being asked to transform claims processing and practice management systems.** This dramatic change and reduction in available measures will create an undue burden on a

physician's ability to report on meaningful measures that actually improve care and will simply be a colossal waste of time and resources within many specialty practices.

B. Program Alignment

The agency's efforts to further align CMS quality programs are admirable, but CSMS continues to believe that effort is not enough, and the vast majority of physicians must report multiple times to avoid payment adjustments because of the detailed rules and requirements (that are often confusing for physicians to comply with in order to meet both programs requirements). CSMS believes for the purpose of simplification, **physicians who successfully participate in PQRS, regardless of the reporting mechanism, should be deemed as successfully meeting the MU quality measure requirements, and vice versa.** CSMS also believes that CMS needs to **reduce the number of quality measures required to report until there are enough eQMs that work for all physician specialties.**

CMS would be acting within its statutory discretion by permitting MU reporting to satisfy PQRS reporting, starting in 2015. Section 1848(k) of the Social Security Act (42 USC 1395w-4(k)) sets the general requirements for the "quality reporting system" that became PQRS. It requires the use of consensus-based quality measures, and grants the Secretary discretion to decide how quality data is submitted, including submission via Medicare claims. "Such data shall be submitted in a form and manner specified by the Secretary . . . which may include submission of such data on claims" Section 1848(a)(8) of the Act governs PQRS payment adjustments starting in 2015. It states that EPs must satisfactorily submit data on "quality measures for covered professional services" to avoid such adjustments, but it does not specify or require quality measures (or quality reporting) developed specifically for PQRS. CSMS believes these provisions allow CMS to use MU measures and reporting, to satisfy the requirements of PQRS reporting.

C. Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2015 and Beyond

According to statute, the Secretary is allowed to use measures not endorsed by the National Quality Forum (NQF) in the PQRS program if the medical topic for which a feasible and practical measure has not been endorsed or adopted by a consensus organization identified by the Secretary. **The CSMS supports the agency's ability to use non-NQF endorsed measures in the PQRS program, but strongly recommends that it consult with the AMA and national medical specialty societies on the measures to be selected. All selected measures for 2015 should be published in the CY 2015 Physician Fee Schedule Final Rule.** Not publishing a single comprehensive list puts the untenable burden on physicians and their practices to search multiple sources to clarify current PQRS requirements, leading to errors and failure in reporting.

1. Cross-Cutting Measures

CMS proposes criteria for the satisfactory reporting of PQRS measures for the 2017 PQRS payment adjustment, via claims and registry, which require an eligible professional or group practice to report on at least two of the 18 cross-cutting measures. **CSMS is supportive of the concept of cross-cutting measures and CMS instituting flexibility in the ability of an EP to choose the measures it would like**

to report on. But we are concerned there will be some specialties that cannot find two applicable measures to report on. Therefore, we do not support the requirement. The requirement becomes even more problematic as CMS has proposed to eliminate many measures from the program. If the measure list is finalized as proposed, some specialties will have trouble finding two germane measures.

CMS also proposes to require that a traditional registry must be capable of reporting on all 18 cross-cutting measures. This requirement is burdensome and unnecessary for most registries, particularly those that are specialty-specific. **CSMS recommends instead that CMS require only those measures that are relevant to registry participants to be available for reporting.**

2. Measures Proposed for Removal Beginning in 2015

CSMS understands the continued desire by CMS to improve the quality reporting process. **However, CSMS believes it is extremely premature and short-sighted to remove a measure as “topped out” simply because it has a high performance rate, particularly when physician reporting rates within the PQRS program are so low.** It is hard to demonstrate validity and reliability of measures when so few physicians are presently reporting. Also, there are significant gaps that will be created in the measure portfolio due to the number of measures CMS proposes for removal in 2015, without any advanced warning to physicians.

The CSMS also does not believe that performance rates alone provide a valid reason to consider a measure “topped out.” Removal from PQRS of any measure as “topped out” must be based upon consideration of several factors, including reporting rate and performance rate, at a minimum. Removal of these measures from PQRS may result in a drop in performance as well as the quality of care without any long term evidence that the majority of physicians will or will not report or achieve the desired performance rate – there is simply too little evidence at the current time to make major changes to the program, especially taking away measures that are being reported by the majority of the physicians in the program. CMS also states in the rule that many of the “topped out” measures are process measures, and the agency would like to move away from process measures. However, CSMS believes that process measures play a very important role in improving care as well as in fostering and measuring good outcomes and, for many physicians just beginning to report, process measures will be critical in their march toward quality improvement. **CSMS proposes a phase out period for any new measures being removed to allow for the submission of new measures to prevent gaps in the measure portfolio.**

3. Measures Groups

CMS is proposing in the Proposed Rule to increase the number of measures that may be included in a measures group from a minimum of four measures to a minimum of six. **CSMS does not support this, as CMS has not worked over the last year to ensure the appropriate measures are part of a measures group.** CMS has offered no evidence or rationale to support expanding measures groups by including two additional measures to groups with less than six measures. In fact, many of the measures groups which CMS is proposing to revise have been tested and endorsed by the NQF. The proposed revisions may make the group statistically invalid and/or alter the quality measurement process. Why shift away from demonstrated measures of quality reporting when there is no specific identified reason for change? Change alone does not constitute or demonstrate improvement and CMS with this expansion of

measures does not have any evidence for necessary change or true analysis or review of the existing measures or any gaps or deficiencies that might exist. Without this analysis, any increase in measures appears to be unnecessary.

D. PQRS Qualified Clinical Data Registries

For 2014, CMS added a new qualified clinical data registry (QCDR) option whereby EPs may report the measures used by their QCDR, instead of those on the PQRS measure list. **CSMS opposes CMS' proposal to modify the requirements for the QCDR option for 2015.** CSMS believes that the QCDR requirements are simply too stringent, and CMS' plan to modify the requirements in only the second year of this option is simply too aggressive without again evidence to support these further requirements of physicians using this option. QCDRs need a period of stability to allow those that are currently qualified to make minor adjustments. Clinical data registries that have yet to become a QCDR also need time to meet CMS' requirements. **Again, it is simply premature to require the reporting on three outcomes measures and/or two resource use or patient experience of care measures before QCDRs have had the opportunity to gain experience with the program.**

In general, medicine is currently developing tools to help physicians adopt and incorporate systems of learning into their practice, which will improve quality of care, provider workflow, patient safety, and efficiency. Capturing data through a registry allows for its collection and tracking across care settings and disease states, inpatient and/or outpatient settings, acute episodes or chronic diseases, surgical versus nonsurgical interventions, and resource-intensive versus relatively inexpensive therapies. Utilizing third-party registries provides an opportunity to evaluate the care provided within an entire specialty, as well as at the individual physician level. However, if CMS moves forward with its QCDR proposal, this will hinder registry progression and quality improvement activities occurring outside of Medicare. CMS' overly ambitious performance program requirements hinder the ability of physicians to tailor programs to their practice.

While the CSMS appreciates and recognizes the flexibility in a QCDR's ability to select measures to capture on behalf of its members, these multiple requirements are simply coming too quickly and changing too rapidly. If a QCDR wishes to submit quality measures data for the 2017 PQRS payment adjustment, it must provide the information to CMS by March 31, 2015. Reporting on meaningful and scientifically valid outcomes and resource use measures requires capturing data with a significant sample size. This is just too aggressive of a time table and asks physicians and their QCDR's to make too many changes.

1. Program Alignment and Electronic Interoperability Issues

CMS did not address in the rule issues around QCDR reporting for satisfactorily meeting quality requirements for the MU program and represents a missed opportunity for CMS to align reporting requirements for PQRS and EHR Incentive programs to make the programs meaningful for physicians. Alignment of quality reporting efforts is essential to reduce practical and economic burdens on individual physicians and physician groups. **CSMS encourages CMS to promote flexibility in its performance program requirements so that physicians participating in a QCDR can receive credit for multiple quality improvement activities.**

The intention behind section 601(b) of the American Taxpayer Relief Act of 2012 (ATRA) was to provide physicians with greater flexibility to report on and receive credit for their quality improvement activities relevant to their practice and patients. The QCDR EHR Incentive program requirements do not allow for the true utility and purpose of registries, or the evolution of the quality measurement process. CMS needs to encourage the development of standards for sharing/transmitting data between EHRs and registries. Presently, practices are forced to manually enter data into a registry because no streamlined process exists, and because of the proprietary nature of health information technology (HIT) products. This existing data-sharing process is particularly challenging for solo and small practices, and prevents many from participating in registries. Finally, the manual data entry process requires staff resources, which is an added cost that most practices cannot easily absorb.

The current certification requirements also fail to address the need for bi-directional exchange for national clinical data registries or clinical data standardization for any other purpose. EHR vendors charge providers to map and transmit data from an EHR to a registry. The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems to move to a more advanced state of quality measurement. Physicians who have purchased EHR systems should not have to incur the cost of middleware vendors mapping and transmitting the data. **CMS should work with physicians, ONC and others to require EHR vendors provide clinical data in a standard format backed by standardized data definitions.**

2. Proposed Changes to the Requirements for the QCDR Program

CSMS supports transparency, but we believe that required public reporting on first year data for new measures is problematic and in general premature as both physicians and CMS evaluate the effectiveness of those measures. There should be a scaled approach to public reporting: the necessary processes and safeguards required to make public reporting meaningful for physicians, patients, and the public take time, resources, and careful consideration. Until patients understand critical components of care that relate to the measures used within the QCDR, measure reporting seems meaningless. Explaining the importance of measures and what they are should help in building toward a shared responsibility for engaging the public on quality and performance. CSMS also asks for clarification from CMS on the process it will employ to determine whether a QCDR measure is deemed valid and reliable for use for public reporting and how it plans to analyze the measures. CSMS believes that the public reporting of the data will lead to more questions, more concern and less certainty and clarity. CMS should reconsider this proposed approach to QCDR public reporting, which appears to be putting the cart well before the horse – let us evaluate the reporting and the measures first and then publish, not do both at the same time.

E. EHR Reporting Option

For 2015, CMS proposes to modify the criteria for satisfactory reporting by individual EPs (to avoid the 2017 PQRS payment adjustment) to require the reporting of individual measures via a direct EHR that is CEHRT, or an EHR data submission vendor that is CEHRT. The EP would report nine measures covering at least three of the NQF domains. If the EP's CEHRT does not contain patient data for at least nine measures covering at least three domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least one measure for

which there is Medicare patient data. This proposed change is rather confusing and CSMS is looking for clarification from CMS.

F. Group Practice Reporting Option

For 2017, CMS proposes to modify the requirements for group practices that choose to participate in 2015 PQRS through a registry. Group practices that choose to report using a qualified registry and elect to participate in the GPRO for the 2017 PQRS payment adjustment would be required to report at least nine measures, covering at least three of the NQS domains. Of these measures, if a group practice sees at least one Medicare patient in a face-to-face encounter, the group practice would report on at least two measures from the cross-cutting measure set. As indicated above, we do not support the requirement of having to report two cross-cutting measures due to CMS' proposal to eliminate such a significant number of measures from the program. We believe that group practices, especially specialty-based practices, will have difficulty finding two measures that work for the group. **CMS should scale down the number of required measures to allow specialty group practices the option to participate through GPRO. We also recommend that group practices who report through a registry be able to report measures groups.**

G. Clinical and Group – Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS)

The Proposed Rule singles out the CG-CAHPS survey as the most appropriate instrument for physician groups and individual physicians to measure patient experience under the PQRS and VM programs. If this is the most appropriate instrument, it is disconcerting then that CMS will no longer cover the cost for administering CG-CAHPS through a CMS certified survey vendor, especially since it is now a requirement for GPRO practices of 100 or more EPs. Since CMS requires CAHPS to be administered through a CMS-Certified Survey vendor, rather than a vendor of the practice's choosing, administration of CAHPS becomes more of a burden, especially for practices that have already implemented CAHPS. We are also concerned with the cost to implement and administer the survey, given that CMS will only allow for administration through a CMS-Certified Survey vendor, which may also stifle competition. CMS should continue to pay for this survey and/or allow for other options regardless of practice size. Restricting physicians to one survey option eliminates competition and could cause physicians to have excessive fees for measuring patient experience. **CSMS opposes CMS' proposal to move in this direction. If CMS moves forward, practices should not be held liable or penalized for lack of patient compliance, which is beyond their control.** It also needs to be acknowledged that with all experience surveys, regardless of survey type, patients' opinions vary based on cultural and regional differences, and this needs to be taken into consideration in the questions, the analysis, and the reporting.

H. Informal Review

CSMS does not support the CMS change in timeline for requesting an information review to only 30 days, which is much too short of a time for a physician practice to evaluate the PQRS Feedback Report. CMS proposes to modify the payment adjustment informal review deadline by two-thirds, from 90 to 30 days from the release of the PQRS Feedback Reports. The process for accessing a PQRS Feedback Report is extremely cumbersome. It could take upwards of 30 days just for a physician or

group practice to obtain a PQRS Feedback Report, not to mention the time needed to analyze the report and assess whether to request an informal review. CMS specifically states they would only allow resubmission of data that was submitted using a third-party vendor, qualified registry, EHR data submission vendor, or QCDR reporting, and would not allow resubmission of data submitted via claims, direct HER, or GPRO web interface. Therefore, any identified errors resulting from the Informal Review process would be on the vendor side and not with the EPs reporting incorrectly, which does not allow an EP to internally analyze their data and potentially contest incorrect calculations by CMS.

I. Transition to ICD-10

The ICD-10 transition is scheduled to occur on October 1, 2015, and there are serious potential implementation issues for how ICD-10 will affect PQRS, VM, and MU. CMS plans to collect non-electronic health record-based quality measure data coded only in ICD-10. CMS has highlighted its own concern that the transition to a new coding system may have unintended consequences for quality measure data denominators, statistical adjustment coefficients, and measure rates. CSMS agrees with these concerns, **but also must raise significant concern that CMS has not addressed ICD-10 with respect to Medicare Part B and CMS' plan for handling physician quality measures in programs such as PQRS, VM, and MU.** CSMS believes that in the 2015 Physician Fee Schedule file rule, CMS will need to discuss its plans for dealing with the transition and fully explain both the rationale for having the baseline year vary from the performance year and the codes that will be used to perform calculations. We urge CMS to test submission of all measures with updated ICD-10 specifications prior to the deadline, and CMS must hold physicians harmless if CMS and vendors cannot accurately accept and calculate the measures. **CMS should exempt physicians from all penalties if CMS cannot accurately calculate measures due to the transition.** It is also unclear how CMS will address claims that must be resubmitted with a service date prior to October 1, 2015, and how the agency plans to handle all appeals.

XI. Medicare Shared Savings Program

A. Proposed Changes to the Quality Measures

1. Controlling the Burden of Quality Measurement

We support efforts by CMS to retire measures that are duplicative or no longer useful, to replace measures that are outdated, and to change to measures that are more likely to address important quality goals. However, this should occur without a net increase in quality measures over time and should be based on sound and scientific evaluation of the measures being retired and being implemented.

CSMS believes it is important to ensure that Accountable Care Organizations (ACOs) are not achieving savings simply by inappropriately withholding or limiting medically necessary care. However, adding more quality measures that are untested does not necessarily mean better protection for beneficiaries. Moreover, too many quality measures can make the program too burdensome for physicians, deter physician participation in ACOs, and thereby deny patients the benefits of better care coordination. CMS should not be adding measures for measurement sake.

The proposed regulations retire or replace eight measures but then disturbingly add 12 new ones, resulting in an increase in the number of overall measures. CMS inaccurately asserts that this will not increase the burden on ACOs because the new measures would be calculated by CMS using administrative claims data or patient survey data. However, in order for an ACO to improve performance on any evaluative measure, it will need to collect its own data relevant to that measure, adding cost and administrative burden. Further, if the measure is being computed by CMS from claims data, the ACO will also need to analyze the calculations done by CMS to verify their accuracy, reconcile them with the ACO's own data, and determine appropriate actions. Consequently, adding any new measure, even if computed from claims data, will increase the burden on ACOs and potentially on the physicians participating in ACOs with no compensation for that additional time and questionable benefit.

Changes in measures require ACOs to shift focus to different aspects of clinical care, change data collection and analysis systems, etc. Under the Proposed Rule, more than one-third of the new set of measures would be different from the current measures, which would create a significant burden for ACOs in a very short time frame. Frequent changes in quality measures are a recipe for disaster. Instead of continuously changing measures, CMS should be working to provide more stability for Medicare ACOs by setting quality standards for the entire three-year agreement period and only changing them during that time if both CMS and the **majority of ACOs** agree the change is needed or on an individual ACO basis as there are geographic and demographic differences that need to be considered.

2. Measuring Care Coordination

Nearly half of the completely new measures are inconsistent with CMS' own criterion not to include "measures addressing high cost services or utilization" or its statement that "the potential to earn shared savings offers are an important and direct incentive for ACOs to address utilization issues in a way that is most appropriate for their organization, patient population, and local healthcare environment."

3. Measuring Clinical Care for At-Risk Populations

We strongly support updating measures to match the latest clinical evidence and to ensure that they do not encourage care that is inappropriate for the elderly, particularly frail elderly and patients with multiple health problems. However, **we are concerned by the proposal to create wholly new composites of measures for certain chronic conditions.** In the Proposed Rule, CMS is creating an entirely new composite using a combination of measures. The rule does not define the methodology that will be used for the new composites, but if it is based on all-or-nothing scoring, there will be no ability to benchmark providers' performance because no similar composite measure is being used in the Medicare program or elsewhere in the country. **If CMS is going to create wholly new composites, then it should extend the phase-in period to allow for reporting before performance is used to modify shared savings payments.**

The Proposed Rule adds a new measure for depression remission because it "is a serious health condition for the Medicare population," it "can decrease patient adherence to treatment for chronic conditions," and it "is appropriate to be addressed by ACOs." However, no information is given to suggest that ACOs are in any fashion delivering lower-quality care to patients with depression than are any other providers, nor

is there any information given to support adding a measure for this condition rather than measures for other conditions.

4. Measuring Patient/Caregiver Experience

Patient experience measures can be a helpful way of ensuring that patient care does not suffer when providers are under pressure to reduce spending. However, it seems unlikely that most patients would view a discussion about the cost of their medicines—the issue addressed by the proposed ACO-34 measure (“Stewardship of Patient Resources”)—as equivalent in importance to their ability to get timely care, communicate with their physician, or improve their health status. Yet the proposal would give this new measure equal weight with the other CG-CAHPS measures. The measure itself is also ambiguous, failing to specify whether the discussion with the patient should emphasize the cost of the medicines to Medicare, or to the patient.

5. Truly Rewarding Higher Quality

If CMS wishes to expand the number of quality measures or to make quality improvement into a primary goal for the ACO program, then it should provide a higher share of savings to ACOs than under the current MSSP rules. Today, the *maximum* share of savings that ACOs can receive is 50 percent in Track 1 and 60 percent in Track 2. That share is reduced if *any* of the quality measures fall below the highest performance level. The more quality measures that are added, the less likely it is that the ACO will receive the maximum share of savings. Yet the more quality measures an ACO needs to pursue, the more it will need to spend in order to improve quality and the greater the financial losses it will likely incur, particularly in areas where the fee-for-service system either fails to pay for high-value services (e.g., chronic disease management) or reduces providers’ revenue when quality improves (e.g., fewer readmissions), or both. The more quality measures an ACO pursues, the higher its costs and the lower its revenues will be, but it will be less likely to receive shared savings to offset those costs and losses. Moreover, increasing the share of savings given to ACOs will not necessarily reduce the amount of savings to the Medicare program. It is quite possible that CMS would obtain more savings for the Medicare program *in total* if increasing the proportion of savings given to ACOs creates a greater incentive for physicians to participate in the shared savings program and for ACOs to find ways to generate savings. **Nothing in the Affordable Care Act requires that ACOs receive such a small share of the savings they generate for Medicare.** Once sufficient savings have been achieved to assure CMS that the savings were not due to random variation, an ACO could be paid a much higher percent of the savings, and it would still reduce net spending for the Medicare program.

B. Future Quality Measures

If CMS wants quality measures to *improve* care for beneficiaries, then the measures should focus on areas where (a) CMS believes that Medicare beneficiaries are receiving poor care today, and (b) it is feasible for an ACO to make changes in care that would improve care in those areas using the limited resources available in the shared savings program. If the goal is quality improvement—rather than preservation of current quality—then the shared savings formula needs to be restructured to ensure that adequate resources are directed to ACOs to achieve this.

It is important for CMS to continue to provide information on utilization to ACOs but it should not add measures of utilization to the quality measurement formula. An ACO is a structure not just to share savings but to expand and improve the quality of medical care provided. ACOs should have the flexibility to use different combinations of services to achieve the best outcomes for their patients at the lowest cost. Higher-than-average utilization of a particular service may help reduce utilization of other services or improve quality for patients. This should not be precluded by creating separate measures of specific types of utilization. ACOs need the flexibility to find what works best for their patients at the lowest cost.

CSMS agrees with CMS that it is important to begin to move away from process-based measures toward outcome-based measures. However, the outcomes that are measured must be within the control of the ACO, and there must be effective risk adjustment to avoid penalizing ACOs that manage the care of beneficiaries with more needs and to avoid causing access problems for such beneficiaries. Until we have the appropriate risk adjustments in place, this slow transition to outcomes based measures should be slowed.

CSMS believes that measures should be retired when they are no longer supported by clinical evidence or when use of them could lead to undesirable consequences or jeopardize care quality. However, CSMS does not believe that measures should be retired simply because they are “topped-out,” and that measures that demonstrate improved quality should remain as measures even when the vast majority of physicians are recognized as meeting the measure’s reporting requirements. CMS should prioritize improving the attribution methodologies and the spending measures for ACOs. **ACOs should be held accountable only for services they have the ability to control, and they should receive “credit” for patients who are healthy and do not need frequent office visits.**

C. Electronic Health Record (EHR) Reporting

If the use of EHRs and HIE (health information exchange) will improve quality of care, improve care coordination, reduce duplicative services, etc., then the Shared Savings Program gives ACOs a natural incentive to use them, and there is no need for the program to separately require or incentivize the use of the technology. If ACOs find that EHRs and HIEs are the most effective way to improve quality, then reporting quality measures through EHRs will also become the simplest approach to reporting. Rather than requiring EHR-based reporting, CMS should give physicians the option to report through EHRs.

D. Revisions to “Topped Out” Measures

As previously stated, CSMS opposes removing measures simply because they are “topped out.” If a measure was appropriate to include as a quality measure for ACOs when it was *not* “topped out,” then the mere fact that it is now “topped out” does not justify removing it since it is likely improving quality of care provided within ACOs. Quality measures are intended to protect Medicare beneficiaries from receiving inappropriate care. Removing a measure on which physicians perform well, in order to add a measure on which they do not perform well, penalizes ACOs for making the investments of time and money needed to achieve high performance. The fact that a measure is currently “topped out” does not mean that it was easy to achieve that level of high performance or to maintain it consistently over time. In addition, the current standards for determining that measures are “topped out” are based on the quality

measure experience of early adopters, generally larger health systems. As smaller ACOs and smaller practices enter the programs, these measures may not remain “topped out.” CMS should wait until smaller practices and solo physicians are engaged in ACOs before determining to eliminate effective measures simply because they are “topped out.”

E. Standards in Subsequent Performance Periods

A performance standard for a quality measure should not be continued into a second or a subsequent participation agreement if there have been any significant changes in the specifications used to calculate the measures. An ACO’s performance level on quality measures will vary depending on how the measures are calculated. Moreover, there are serious problems with the attribution methods currently used in the Shared Savings Program. Improvements in attribution could result in significant changes in an ACO’s performance on some or all of the measures, making it inappropriate to continue using benchmarks based on previous, flawed attribution methodologies.

F. Timing for Updating Benchmarks

ACOs need to have stable benchmarks in order to plan quality improvement interventions and predict the impact on their shared savings payments. However, if the specifications for a quality measure change, then the benchmark for that quality measure should be updated immediately so that the ACO’s performance on the measure and the benchmark are comparable.

G. Rewards for Quality Improvement

CSMS believes that if CMS wishes to create greater incentives for quality improvement, then ACOs need to receive a higher share of savings than under the current MSSP rules, rather than simply receiving bonus points for improvement under the current formula. Even if CMS retains a lower share of savings, it would still be spending less than it would have otherwise.

XII. Value-Based Payment Modifier and Physician Feedback Program

In this Proposed Rule, CMS accelerates a rapid and risky expansion of the ACA-mandated VM with proposals to essentially double both the number of physicians affected and the size of the penalties they could incur. **CSMS believes that CMS should conduct a rigorous impact analysis of its VM framework before proceeding hurriedly with plans to increase the VM penalty from two percent to four percent, leaving some practices vulnerable to total Medicare payment cuts of 11 percent in 2017.**

What little analysis has been conducted is based on the previous iteration of the PQRS program with much less rigorous requirements, and what data that is available tends to suggest that the modifier discriminates against Medicare’s frailest patients and their physicians. Numbers cited in the NPRM to justify the rapid adoption and escalation of VM penalties focus on “average” impacts and fails to highlight the impact to the individual patient or a category of patients and physicians. When dealing with quality and access, the averages may be important, but the individual impact is what is critical and that is what needs to be studied more specifically – how these programs impact individual physicians, especially

those who see the frail elderly and certain populations that currently have experienced disparities in health care.

There are also serious questions about the efficacy of the VM as CMS' own studies have recently shown that even medical groups of 25 or more often have inadequate data from which to draw conclusions about costs and/or quality. How then can the VM be applied with any confidence to even smaller groups and solo practitioners in the given time frame outlined in the proposed rule? CSMS has some serious concern that some of Medicare's sickest patients could lose access to their personal doctors and some physicians who remain in independent and solo and small practice could be driven out of business.

CSMS opposes increasing the VM penalty from two percent to four percent; mandating participation in the tiering competition; and continuing the use of cost and outcome measures that have never been tested for use in physician offices, especially smaller practices without ready access to quality and cost data.

A. Trouble Signs

CMS offers reassurance that based on their 2012 cost and quality data, only 11 percent of physicians would have incurred a VM penalty. This means that a minimum of around 125,000 physicians and other practitioners would face penalties of up to four percent. This does not even include those physicians who incur a penalty because neither they nor their group successfully participated in PQRS. This does not seem to be an insignificant number of physicians, and the concern is that more of those in smaller practices would be adversely impacted by these changes than larger practices. In Connecticut, with a large number of physicians still in solo and small practices who provide a large amount of the primary and specialty care for some of the sickest patients, this is very disturbing and could have a disastrous impact on access to quality medical care as physicians simply cannot absorb this level of a penalty and continue to operate in practice. There is already a shortage of certain specialists and primary care physicians around the country. In Connecticut we have more health care professional shortage areas than ever before, and we question transitions that could increase shortages of physicians in our rural and urban areas.

B. Structure of the VM/Two Category Approach

CMS is proposing to retain a two-step structure that divides physicians into two groups: those who did comply with PQRS reporting requirements, and those that did not. Non-compliant practices would automatically receive the maximum four-percent penalty. Those who did comply would be placed in a mandatory competition or "tiering" process where their cost and quality is compared to that of other successful PQRS participants—which could result in a four-percent penalty, a two-percent penalty, no adjustment, or an as yet undetermined bonus.

CSMS believes that it is counterproductive to mandate participation in a tiering competition where physicians who fulfilled the PQRS reporting requirements are at risk for the same penalties as practices that did not – this seems unfair and rather disingenuous. It is also irresponsible to apply penalties to practices that have done their best to comply with PQRS requirements, but were scored as having high costs and/or low quality because of the risk and specialty adjustments and overlapping cost measures

employed in the VM disadvantage practices that treat Medicare's frailest patients or those that may have critical access issues. The proposed exemption from negative adjustments in the first year a practice is subject to the VM is better than nothing, but ultimately insufficient to compensate for all the methodological problems that plague the VM and could further limit access to care to the most vulnerable patients.

We are also concerned that some physicians will incur penalties in the tiering process, simply because CMS had insufficient data on which to judge them. The agency's solution for these groups is to default them into the "average" tier, but groups could still incur a two-percent penalty if they had enough data to be scored for one category but not the other. It is fundamentally unfair to disadvantage these groups simply because the VM methodology does not work for them. To resolve the issue, **CMS should go back to making tiering voluntary for all practices until more data has been analyzed.**

C. Maximum VM-Related Penalty

Penalties are not the answer. A far better motivation for physicians would be to put more effort into improving the PQRS program, deal with the array of methodological issues that plague the VM, and create feedback reports that provide data that is timely, reliable, and relevant to daily practice so that positive and proactive changes in quality improvement and cost reductions can occur. It is also worth noting that many of the practices that will be subject to 2016 VM adjustments based upon their performance in 2014, have still never received a QRUR and have no idea what is coming or how they have done on the measure spectrum. With the doubling of the program, more and not less resources need to go towards education as the QIN-QIO's begin to roll out their information on the program.

D. Application of the VM to ACOs

CMS' decision to reverse its own policy of exempting ACOs and other alternative payment and delivery models approved by the CMMI is problematic. The NPRM suggests that the policy reversal stems from a rigid interpretation of the legislative language stipulating that the VM should apply to ALL physicians in 2017. **However, CSMS believes that Congress did not intend such a broad interpretation, nor that physicians and entities already adhering to stringent quality and cost standards should be held to these measures. Bringing these physicians and entities under the VM umbrella is duplicative, unnecessary, counterproductive and counterintuitive.** CSMS believes that physicians who participate in ACOs should be deemed to have met these quality and cost standards. Otherwise, physicians in ACOs could very likely be held to two separate sets of quality and cost standards. The fact that meeting quality and cost standards of the shared savings program of an ACO could mean a penalty in the VM program is both impractical and ridiculous.

E. Quality Measures in the VM

CSMS is concerned that the simultaneous expansion of PQRS requirements and VM penalties will increase the risk of physicians incurring penalties for both programs due to misunderstandings or unresolved problems surrounding the expanded PQRS requirements. Moreover, we continue to believe that due to the ever-changing nature of both the PQRS program and the VM, as well as potential problems related to the upcoming transition from ICD-9 to ICD-10 diagnosis codes, physicians should

continue to have the option of avoiding penalties under both programs by asking CMS to calculate quality and cost data from administrative claims measures.

F. Process for Correcting the VM

CSMS appreciates CMS' decision to develop a process that would permit physicians to contest various aspects of the calculations used to compute their particular VM adjustment. CSMS anticipates that the final rule will further clarify how and when this process is to occur for physicians. **Regardless of the timing or specific date of contesting their VM adjustments, physicians should not be expected to continue checking various web sites at various times of the year simply to determine whether they need to take action.** Given the complexity of the VM and the length of time it takes CMS to compile the data, it seems highly unrealistic to expect physicians to review and contest the data within a 30-day period. Other elements that must be considered in the correction process include the accuracy of patient attribution and risk adjustment.

G. Modifications in the Total Per Capita Cost Measures

As currently constructed, the overlapping cost measures used in the VM will punish physicians repeatedly for the treatment of a subset of patients with multiple chronic diseases and acute conditions who require more frequent hospitalizations than the average patient. It is little wonder that practices treating high risk patients fared poorly in the 2012 QRUR evaluation. **CSMS believes that CMS needs to reconsider the use of multiple measures which are all heavily influenced by the same patient population, especially when physicians who treat very vulnerable populations are most negatively impacted.**

CSMS is very troubled by CMS' failure to make adequate adjustments for differences in patients' socioeconomic status. However, CSMS sees the adoption of two other modifications in the cost and outcome measures as premature and leading to further issues and potential patient access issues.

CMS proposes modifying the process of attributing patients to a practice by including care provided by nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) in the initial determination of which group provided the plurality of primary care to a given patient. This approach ignores the fact that a large percentage of NPs, PAs, and CNSs are not actually providing primary care, but instead work in various specialty practices and areas. This assumption has ramifications well beyond the calculation of Medicare cost measures, including the adjustments that are made for a group's specialty composition. Under this proposal, specialty practices that include non-physician practitioners would be expected to show lower costs than those that did not include the non-physicians, potentially discouraging team-based practices that include both specialists and non-physician practitioners. CMS should withdraw this proposal until the agency has studied its impact on group benchmarks and other unintended consequences as it could have a detrimental impact on team-based care when both primary care and physician specialists are involved.

A second proposal would include patients who died during the performance year that is being assessed. Data presented to NQF indicates that the average mean per capita cost of these patients was 11 percent higher than the average for full-year patients. In view of the evidence that suggests that groups treating

high risk patients are already at the greatest risk of incurring VM penalties, we do not support a policy that has the potential to exacerbate that problem.

H. Physician Feedback Reports/Quality and Resource Use Reports

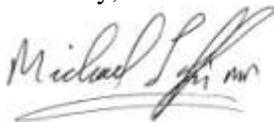
CSMS appreciates CMS' efforts to make the QRURs more informative and actionable for physicians. However, CMS may be relying too heavily on these reports to warn physicians that they face substantial payment cuts if they do not participate in PQRS and do well in the VM tiering process. Experience with earlier QRURs suggests that very few physicians are actually reviewing them or understand what they suggest for a physician or physician practice. Many physicians, especially those in small practices with limited administrative staff, will not have the administrative resources or time to fully evaluate the QRURs and make the information actionable.

XIII. Conclusion

We greatly appreciate this opportunity to share the views of the CSMS, many of which comport to the AMA's raised concerns, regarding the proposals, issues, and questions that CMS has presented in the Proposed Rule entitled *Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015* [CMS-1612-P].

If you should have any questions regarding this letter, please feel free to contact Matthew Katz, Executive Vice President/Chief Executive Officer at mkatz@csms.org or 203-865-0587 extension 135.

Sincerely,



Michael F. Saffir, MD
President



Matthew C. Katz
EVP/CEO