September 2, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1612-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850.

Submitted electronically via: ***http://www.regulations.gov*.**

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:

The Medical Society of New Jersey (MSNJ) is the largest physician membership organization in the state of New Jersey. We appreciate the opportunity to provide our comments in response to the proposed Medicare Program rule revisions under CMS-1612-P.

Value-Based Payment Modifier and Physician Feedback Program

MSNJ is gravely concerned about the proposed rule's rapid expansion of the ACA-mandated Value-Based Modifier (VM) to double the number of physicians affected. We object to the proposed VM penalty from two to four percent which could subject practices to a total payment cut of 11 percent in 2017.

With certainty many small practices in New Jersey are not ready for PQRS, much less the overly ambitious VM program. CMS' own studies have shown that even medical groups of 25 or more often have inadequate data from which to draw conclusions about costs and/or quality. It is simply premature to apply the VM program to practices that are ill-equipped to avoid its penalty. We have serious concerns that even the exposure to the combined penalty amounts in 2017 will cause physicians to stop treating Medicare patients, opt-out, or to retire early. This could create significant access to care issues for seniors. Most physicians in New Jersey practice in a small practice environment. Many physicians practicing in New Jersey are approaching retirement age. In addition, we have also not been able to retain the physicians trained in state. Access to care is not a theoretical concern.

Data suggests that the VM discriminates against Medicare's frailest patients and their physicians. It is irresponsible to forge ahead with this program without more analysis of the impact that it will have both on small physician practices and the patients that they serve. CMS should slow the VM's expansion and provide a more stable environment for physicians and their patients as the VM is implemented.

There are also serious questions about the efficacy of the VM, which shares the flaws of many of the current approaches to measuring and assigning accountability for health care spending, as outlined in a recent paper

by Center for Healthcare Quality and Payment Reform President Harold Miller.[1] These include the assignment of accountability based on aggregate costs rather than those services that a particular physician or group actually had control of, failure to incorporate prescription drug costs, the inability to distinguish between appropriate and inappropriate spending, and inadequate adjustment for patient risk and structural differences in costs.

We support the proposal to exempt non-assigned claims from payment cuts triggered by the VM and request that this policy also be applied to penalties tied to PQRS and MU of health information technology.

MSNJ specifically 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. We also believe that it is not necessary to compound the complexity of the VM by extending it to ACOs and other alternative payment and delivery models.

Professional Liability Insurance RVUs

MSNJ urges CMS to adopt the RUC's recommendation that CMS implement an annual collection and review of professional liability insurance (PLI) premium data. The current five-year review cycle is inadequate to accurately capture the cost of professional liability insurance.

Of the three components, work, practice expense, and professional liability insurance, this is the only component that is not updated frequently. **This is a particular concern to physicians in New Jersey for three reasons.** First, the practice of medicine is high compared to other parts of the country. Second, the cost of professional liability is also high. Finally, New Jersey is penalized because of the floors on the practice expense component that Congress has placed on other parts of the country, including the Frontier States. Physicians in states with floors on practice expense are benefitting with extra payments compared to physicians in urban states, like New Jersey, that receive less payment because of the payment "boost" from the floor. The floors create a geographic disparity in payment that these very rules are meant to avoid. This should not be compounded by a five-year PLI premium review cycle in high practice expense states like New Jersey. While an annual review of PLI premium data and corresponding adjustment will not address the practice expense issue directly, and is unlikely to have the weight to correct the payment disparity, at least the PLI component will be more accurate.

Definition of Colorectal Cancer Screening Tests

MSNJ has a long-held position that anesthesia administered by a professional during colonoscopy is a patient safety issue and should be covered as medically necessary. As early as 2006 we formally took the position that:

> [C]olon cancer is a major cause of death among New Jersey's citizens, the cure for which is dependent upon its early detection. … [R]outine colonoscopy examinations are recommended to ensure early detection of colon cancer. Appropriate anesthesia services are required to ensure the safe and comfortable performance of colonoscopy examinations. In providing appropriate anesthesia the use of deep sedation for colonoscopy examinations is preferred as it

[1] Miller, H.D. "Measuring and Assigning Accountability for Healthcare Spending." Center for Healthcare Quality and Payment Reform, August 2014. http://www.chqpr.org/downloads/AccountabilityforHealthcareSpending.pdf

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decreases significant risks associated with alternative anesthetic agents, including the risks of: (i) incomplete examination due to the patient's inability to tolerate the procedure; (ii) failure to detect colon cancer; (iii) necessary additional examinations; (iv) significant patient discomfort; and (v) significant side effects, including possible fatalities.

Indeed, in 2008 we were able to convince a major New Jersey insurance carrier that it should cover the cost of separately administered anesthesia in its commercial plans; other payers continued to pay for these services. Articles in the *Journal of the American Medical Association* and *Gastrointestinal Endoscopy* on the growing practice of anesthesia professionals participating in screening colonoscopies provided to detect colorectal cancer confirm that this standard of care has become more prevalent nation-wide. As the use of separate anesthesia services is becoming more common than moderate sedation provided intravenously by the gastroenterologist, the anesthesia service should now be included in the definition of the Medicare preventive service and the cost-sharing should be waived. **MSNJ fully supports CMS's proposal to waive the deductible and copayment for anesthesia services during screening colonoscopies.**

MSNJ agrees with the AMA that the proposal does not go far enough to address barriers to greater use of the colorectal cancer screening benefit. Specifically, when a polyp or abnormal growth is removed during the colonoscopy, or when a biopsy is done of suspicious-looking tissue, the Medicare Part B deductible is waived but patients are billed co-insurance of 20 percent of the cost of the procedure. This situation has led to a great deal of patient confusion and consternation, because patients think they are going in for a "free" screening colonoscopy and then are shocked to later receive a bill for a portion of the costs. In contrast, under regulations issued to implement the ACA provisions on preventive screenings covered by private insurance plans, polyp removal and tissue biopsy are considered to be an integral part of a colonoscopy and therefore patients incur no cost-sharing. Medicare coverage of colonoscopies should be defined in the same fashion, which would remove a significant cost barrier discouraging Medicare patients from undergoing preventive colorectal cancer screenings.

We urge CMS to review Novitas' drift away from payment for anesthesia administered by a professional during colonoscopy and other GI procedures through a local coverage determination (LCD). Clearly, there has been a local standard of care in New Jersey for the use of anesthesia by a professional during colonoscopy. The decision of whether an anesthesiologist should be involved in these procedures should be between the treating physician and the patient. Nonetheless, Novitas would limit the circumstances under which this service would be deemed medically necessary. Not only would Novitas up-end a long held standard of care in New Jersey through an LCD, its actions are inconsistent with this proposal.

We also urge CMS to give careful consideration to comments on this proposed rule submitted by the specialty societies representing those who furnish these services.

Private Contracting Opt-Out

MSNJ has a long-standing view that the requirement for physicians who have opted-out of Medicare to reaffirm their opt-out status every two years is unnecessary and burdensome. It also puts physicians who neglect to reaffirm in non-compliance and subject to significant penalties. We urge 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. MSNJ further supports a safe-harbor period for a physician to remain opted-out of the Medicare program, without penalty or possibility of recoupment, when a physician has mistakenly not reaffirmed his or her intention to be opted-out.

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Reports of Payments or Transfers of Value to Covered Recipients—"Open Payments"

The proposed rule would revoke the existing Sunshine Act reporting exclusion for continuing medical education (CME) activities, due in large part to requests from other accrediting bodies that they be added to the list of exempt organizations covered by the exclusion. Instead, the proposal would exempt third party transfers to Continuing Education (CE) only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. MSNJ believes that this raises concerns as industry could learn the identities of speakers/faculty and potentially participants after the funds have been transferred through brochures, programs, and other publications, or through their physician-employees' participation in CE activities (either as speakers/faculty or attendees). MSNJ is concerned that this would have a significant, chilling impact on CE, which runs contrary to the public interest. In a letter to CMS dated August 5 we joined the AMA and virtually all of organized medicine expressing our objection to this proposal and suggesting a modification.

We urge CMS to take the more measured approach suggested in the letter:

> [M]odify the proposal to add the language that the exemption applies under section 403.904(i)(1) when an applicable manufacturer provides funding to a CE provider, but does not select or pay the covered recipient speaker/faculty directly, or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program. The agency can include the guidance in the regulation or preamble that the foregoing is achieved where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity under section 403.904(i)(1).

This accomplishes CMS' goal while eliminating the potential for negatively impacting CE. **We urge CMS to make this change effective six months after the final rule is issued to allow CE providers time to ensure that their processes comply with the modified exemption.**

One of the many challenges with the Open Payments System is that it will not allow physician users to download industry reported information into Excel (or other formats) for ease of sorting and comparing the reports to one's own records. This creates additional frustration with an already complex system. **We ask that CMS consider allowing an export option, so that physician users may analyze industry submitted data in a manner that is compatible with their own internal recording mechanisms.**

MSNJ urges CMS to help interested stakeholders to develop contextual information that will enhance the public understanding of these relationships. We are concerned about how the Open Payment data will be presented and explained to the public. We believe that all data releases to the public should include an assessment of the data's limitations. In some cases and particularly with respect to indirect transfers of value, an individual physician may not even appreciate how the reporting provision impacts them. Transfers of value to support research grants may falsely create the impression of a relationship between individual physicians and companies that have no real association.[2] It is critical that CMS preface the data release with appropriate context so that the public can make educated judgments on the benefits of

[2] Ratain, Mark J. "Forecasting Unanticipated Consequences of 'The Sunshine Act:' Mostly Cloudy." *Clinical Oncology*, Vol. 32, No. 22, Aug, 1, 2014.

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various transfers of value, such as medical journal reprints and industry-funded clinical research, in the practice of medicine.

We continue our objection to the inclusion of the cost of medical journals, reprints, and text books. We encourage CMS to analyze whether this component of reporting produces any meaningful data for the public or is simply an administrative burden.

Medicare Telehealth Services

CMS has proposed further expansion of covered telemedicine services. MSNJ is generally supportive of the agency's proposed inclusion of the following services via telemedicine: psychotherapy services (CPT codes 90845-7); prolonged services (CPT codes 99354-5); and annual wellness visit (HCPCS G0438-9). We agree with the AMA's position that the definition of "originating sites" should be expanded to include more geographic areas. As a federated member of the AMA, MSNJ shares the policy adopted by it in June 2014 on "Coverage and Payment for Telemedicine."

Chronic Care Management

MSNJ has been in favor or payment for care coordination for at least a decade. We support payment for chronic care management (CCM) services. We urge CMS to continue consideration of payment for more non face-to-face services and to extend payment for care coordination to more specialist.

We recommend the use of the CPT Editorial Panel's new code 99490X rather than a G code. The G code description is based on "30 days" whereas the new code would be based on a "calendar month." Using the calendar month as the period is far more efficient for practices and Medicare Administrative Contractors. We have had numerous member complaints about the difficulties presented by the 30-day standard.

Physician Compare Website

CMS is proposing a significant number of changes and additions to the Physician Compare website, starting in 2015 or 2016, including plans to:

- In early 2015, publicly report on Physician Compare 20 2014 PQRS measures for individual EPs, collected via registry, EHR, or claims.
- Perform concept testing to test consumers' understanding of each measure under consideration.
- In 2016, make available for public reporting all 2015 PQRS GPRO measure sets across group reporting mechanisms (GPRO web interface, registry, and EHR), for groups of two or more eligible professionals (EPs). All measures reported by Shared Savings Program ACOs would also be available for public reporting on Physician Compare. CMS would select some of these to include on the profile pages, based upon consumer testing and stakeholder input, as too much information can negatively impact consumers' ability to make informed decisions.
- In 2016, publish composite scores by grouping measures according to the PQRS GPRO measures groups, e.g., care coordination, coronary artery disease, diabetes, and preventive care.
- In 2016, include benchmarks for 2015 PQRS GPRO data, using the Shared Savings ACO benchmark methodology. Benchmarks would be calculated using data at the group practice TIN (tax identification number) for all EPs who have at least 20 cases in the denominator, for each percentile from the 30th through the 90th percentiles. A group practice would earn quality points

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on a sliding scale, with a level of performance based on an average of their scores for each measure group.

- In 2016, begin reporting patient experience data for group practices of two or more EPs who meet sample size requirements and collected 2015 data via a CMS-specified certified CAHPS (Consumer Assessment of Health Providers and Systems) vendor.
- In late 2016, make available for reporting all individual EP-level PQRS measures collected via registry, EHR, or claims. Some would be published on the profile pages, based upon consumer input, and CMS would set benchmarks and calculate composite scores for individual EPs.

MSNJ, together with the AMA and virtually all of organized medicine, adamantly oppose the multiple proposals to extensively expand the Physician Compare website, as serious and fundamental flaws and errors remain unaddressed. While we appreciate CMS taking a phased approach to expanding Physician Compare, the website continues to be riddled with problems. Until CMS can make timely updates to the demographic data for individual EPs and group practices, we have little confidence in CMS' ability to accurately report performance scores, benchmarks, and composites. It is vitally important that quality information is utilized to improve care and support new delivery and payment models. But this must be done in a manner that is transparent and fair, so that providers and consumers can have confidence in the information that is posted. Recent efforts by CMS to publicly post individual physician data (i.e., the Medicare Physician Data Release and the Sunshine Open Payments Website Data) have been far from ideal and riddled with problems. Many physicians now believe that CMS cannot accurately post information regarding the quality of their care.

We agree with the AMA policy adopted in June of 2014 that "Consistent 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. 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. **MSNJ urges CMS to expand the preview period to 90 days at a minimum. And if an EP or group practice files an appeal and flags their demographic data or quality information as problematic, CMS should postpone posting their information until the issues are resolved.** It often takes medical practices several weeks and sometimes months to register and obtain their PQRS reports and Quality and Resource Use Reports (QRURs). It is also unclear how CMS plans to notify EPs of the preview period for reviewing their pubic ratings. We anticipate problems and backlogs with obtaining reports, as CMS greatly expands all of its quality programs and moves to profile all EPs.

We urge CMS to move forward with expanding its risk adjustment methodology to incorporate race, income, and region type. The lack of adjustment can lead to inaccurate and misleading conclusions about quality and performance measurement. This could, in turn, lead to increases in disparities in health care. A simple examination of performance scores without adjustment for patients' socio-economic and/or socio-demographic situation ignores a number of factors that are believed to influence quality and cost of care. For example, economic and cultural status can affect health status, impede ideal communication between the patient and the physician, and hamper the patient's desire and/or ability to follow a given treatment plan. 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. This also runs the risk of unfairly penalizing those physicians who treat a number of socio-disadvantaged patients.

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

CMS is proposing changes in several key areas of PQRS, particularly the requirements for the 2017 PQRS payment adjustment. By statute, CY 2015 is the first year when no PQRS incentives are available under the program. The year 2015 also serves as the performance year for the 2017 payment adjustment of two percent, which will apply to eligible professionals (EPs) who do not satisfactorily report data on quality measures. CMS continues to maintain a two-year look-back period for satisfactorily reporting data on quality measures to avoid a penalty. 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 steward; or due to changes in recommended guidelines. CMS, however, maintains all of the reporting options for 2015 (claims, registry, qualified clinical data registry, group practice reporting option, GPRO web interface, and EHR), which we support.

We agree with CMS' decision to maintain the claims-based reporting option for 2015 and urge CMS to maintain the option for future years as it continues to be the most popular reporting option and one that small physician practices depend upon. As CMS considers alterations to try to meet the varying needs of newly electing participating EPs, it is imperative that CMS take into consideration the simultaneous and compounding demands of rapid changes in health care delivery systems and the effects upon physicians, as CMS develops requirements for its programs. We continue to remain concerned that the growing complexity of PQRS and yearly program changes pose a significant barrier to participation for many physicians and successful participation for physicians who have experience in the program. Monitoring the yearly changes to the PQRS reporting options, measures, measures groups, and physician group participation options requires an overwhelming layer of administrative burden that is extremely costly and resource intensive. For some physicians, this is simply not feasible and probably leads to the continually low PQRS participation rate. 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, for a total 11 percent cut in reimbursement in 2017. The maximum cumulative penalties (with sequestration) in 2015 total five and a half percent, increase to eight percent in 2016; 11 percent in 2017; and 12 to 13 percent (or greater) in 2018 and 2019. These penalties far exceed the maximum penalties that hospitals can receive under the hospital quality and value based purchasing programs. 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. **Therefore, we urge CMS to institute stability into these programs by not changing requirements on a yearly basis and by scaling back on reporting requirements.**

At a minimum, PQRS requirements should stay the same for three years. We believe three years is an appropriate timeline as physicians are not provided a PQRS Feedback Report until six months after the close of the previous reporting period. For example, a physician who participated in 2013 PQRS is not provided a PQRS Feedback Report until approximately September of 2014. At that point, the physician or practice is well into the next reporting cycle when they learn of potential errors, and whether they will receive a payment adjustment for 2015. Based on this timeline, the first opportunity EPs may have to correct their mistakes and successfully report is 2015. An additional year of stability is necessary so that physicians can have the opportunity to learn and follow standard quality improvement protocols, such as

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the Plan, Do, Study, Act (PDCA) method. Furthermore, multiple studies and editorials have seriously questioned the ability of pay-per-performance programs to improve quality of care in the long term.[3] 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.

Many specialties, particularly those that are procedure-based, continue to struggle in identifying meaningful clinical quality measures to report, e.g., pathologists, urologists, neurosurgeons, and other subspecialists. **Therefore, the AMA 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.** Until there are a clinically significant number of measures that are relevant to every individual specialty, it is contrary to the intent of the PQRS program to require every EP to report on nine measures, of which two must be from the cross-cutting measure list.

It is imperative that CMS maintain the options of reporting three measures or electing reporting via administrative claims to avoid the 2017 PQRS penalty. Since 2015 is the first year the VM will apply to all physicians, regardless of practice size, it behooves CMS to give physicians more flexibility in avoiding the penalty, as CMS works to fix methodological issues with the VM program and physicians work to better evaluate the PQRS measure portfolio and reporting options, as well as work on developing clinically relevant measures available through EHR and registry reporting modalities. Reinstating the administrative claims option will provide an additional gateway for physicians and other EPs to participate in and achieve PQRS and VM penalty avoidance.

MSNJ is disappointed that the different quality reporting programs have not been better aligned. For example, as pointed out by AMA, for MU quality reporting to count towards PQRS, a physician must take into consideration the following detailed rules and requirements:

- PQRS quality measures must be reported for a full year, as opposed to 90 days, so first year MU participants must report twice;
- Regardless of calendar year, the first year of participation in MU only requires 90 days of reporting;
- In 2015, MU requires reporting through Version 2014 Certified Software;
- Some of the MU eCQMs include "look back" or "look forward" periods requiring data outside of the PQRS and VM reporting periods. If CMS cannot calculate a performance rate for that electronic clinical quality measure (eCQM), a physician would be subject to both PQRS and VM penalties;
- Measures reported through the PQRS Qualified Clinical Data Registry (QCDR) option must be part of the MU program;
- The QCDR must be certified by ONC; and
- For MU, it is acceptable to report zeroes on measures (including not having any denominator-eligible patients for any of the measures for which their EHR is certified). This is not permissible for the PQRS EHR reporting option or any other option under PQRS. If a physician does not have any data on Medicare patients (i.e., none of their Medicare patients fall into the denominator

[3] Caroll, A.E. "The Problem with 'Pay for Performance' in Medicine." *New York Times*, July 28, 2014.
Jha, A.K, Joynt, K.E., Orav, E.J., and Epstein, A.M. "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes." *New England Journal of Medicine,* Vol. 366, No. 17, April 26, 2012.
Serumaga, B., et al. "Effect of Pay for Performance on the Management and Outcomes of Hypertension in the United Kingdom: Interrupted Time Series Study. " *British Medicine Journal*, Vol. 342, No. 108 (2011).
Werner, R. M., Kostad, J.T., Stuart, E.A. and Polsky, D. "The Effect of Pay-For-Performance in Hospitals: Lessons for Quality Improvement." *Health Affairs,* Vol. 30, No. 4 (2011); 690-698.

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of any of the quality measures for which their EHR is certified), then the physician needs to report separately for PQRS.

To truly streamline reporting, 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. **We also urge CMS to reduce the number of quality measures required to report until there are enough eCQMs 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. We believe these provisions allow CMS to use MU measures and reporting, to satisfy the requirements of PQRS reporting.

In addition:

- MSNJ supports the use of non-NQF endorsed measures in the PQRS program.
- We join in the request of the AMA that a comprehensive list of the finalized measures for 2015 be published in the final rule.
- We urge CMS to provide more guidance materials for practices to better understand the program.
- We object to the elimination of so called "topped out" measures simply because they have a high performance rate. This is not fair to those who may be new to the reporting program.
- We object to the proposal to modify the requirement for the QCDR option for 2015 and urge CMS to gradually incorporate QCDR requirements.

Under the proposal group practices that choose to report using a qualified registry and select 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. We believe that group practices, especially specialty practices (e.g., ophthalmology, emergency medicine) will have difficulty finding two measures that work for the group. **CMS should scale down the number of required measures to three, consistent with our recommendation on individual reporting 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.**

We are also disappointed to learn that CMS will no longer bear the cost for administering CG-CAHPS through a CMS certified survey vendor, especially since it is 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 also proposes for the 2018 payment adjustment to require group practices comprised of 25 or more EPs that are participating in GPRO to report and pay for the collection of the CAHPS for PQRS survey measures. **We oppose CMS' proposal to move in this direction due to the reasons mentioned above for group practices of 100 or more EPs**. Besides cost, the implementation of CAHPS is extremely

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burdensome on a practice, especially a small private practice with limited resources that are subject to a 12 to 13 percent payment adjustment and who may just be beginning to participate in PQRS. In addition, response rates are typically low. We have received feedback from providers that patient compliance is very difficult to obtain, and expressing concern with ample sample size for CMS to make a fair assessment of a practice. The collection of CAHPS data may also lead to survey fatigue by patients due to the requirement and inclusion in the Medicare Shared Savings Program and Inpatient Quality Reporting program. Patients do not know the difference between the CG-CAHPS, Surgical-CAHPS, and Hospital-CAHPS surveys, and this will only become more problematic if the requirement expands. A patient managed for a chronic condition by multiple group practices will be bombarded with filling out lengthy and highly subjective surveys. **If CMS moves forward, practices should not be held liable or penalized for lack of patient compliance, which is beyond their control. CMS should only require a group practice to report on three measures since implementation of CAHPS is so resource intensive and cumbersome**.

The proposal would modify the payment adjustment informal review deadline from 90 to 30 days. **We strongly object to this reduction in time. This shortened period simply does not allow enough time for physicians to review the data and attempt to correct errors.**

Finally, MSNJ is gravely concerned about the impact of the implementation of ICD-10 later this year. We urge CMS to test submission of all measures with updated ICD-10 specifications prior to the deadline, and to 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. CMS could consider an alternative reporting period of 90 days for the 2015 PQRS and VM programs. Or create a reporting period that only uses ICD-9 (Jan. 1-Sept. 30).

Congress left it up to HHS to define the "quality reporting period" for PQRS penalties in 2015 and beyond. Section 1848(a)(8) of the Social Security Act requires a PQRS adjustment "if an eligible professional does not satisfactorily submit data on quality measures for covered professional services for the **quality reporting period** for the year (as determined under subsection (m)(3)(A) . . ." Section 1848(a)(8) also states that "The term 'quality reporting period' means, with respect to a year, a period specified by the Secretary." There is no explicit requirement that the "period specified by the Secretary" has to be an entire year. Moreover, the phrase "with respect to a year" logically refers to the year in which penalties would apply; otherwise, Congress could have said that the "quality reporting period" means a "prior year" specified by the Secretary, instead of a "period specified by the Secretary." The referenced subsection (m)(3)(A) (of section 1848) says "an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported" in the number specified, for "services of such professional furnished during the period . . ." Again, the term "for the year" refers to the year that penalties will apply, as differentiated from the quality reporting period**.**

Improving the Valuation and Coding of the Global Package

MSNJ agrees with the AMA that unbundling global packages and eliminating all the global periods over a number of years is ill-advised at this time. It is difficult to square this concept with the movement toward bundled payments and episodes of care. We urge CMS to use the misvalued code process to study whatever defects may be present in certain global surgical packages.

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Off-Campus Provider-Based Outpatient Departments

In order to understand trends in hospital acquisitions of physician practices, CMS proposes to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on both the CMS–1500 claim form for physicians' services and the UB–04 (CMS form 1450) for hospital outpatient claims. MSNJ has concerns that the proposal is administrative burdensome and may not yield meaningful information on the trend from office based care to hospital based care. While MSNJ supports this effort to study the trend, we believe that CMS should simultaneously evaluate the cost differential for the different sites of service. This would further the goals of healthcare reform by providing information on whether services may be provided at a more reasonable cost, but in an equally safe environment. We urge CMS to consider what existing data might be available for further analysis.

Medicare Shared Savings Program

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. 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. The proposed regulations retire or replace eight measures but add 12 new ones, resulting in a 12 percent increase in the number of measures. Adding any new measure, even if computed from claims data, will increase the burden on ACOs with no compensation for that additional time.

However, focusing only on changes in the total number of measures underestimates the burden that is created by changes in the underlying measures. 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. Frequent changes in quality measures are a recipe for failure of this vital Medicare program. **Instead of continuously moving the goal posts, 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.**

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. So the ACO is in a Catch-22; the more quality measures it pursues, the higher its costs and 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

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greater incentive for providers 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 70 percent, 80 percent, or 90 percent of the savings and they would still reduce net spending for the Medicare program. If CMS wants to encourage improvements in quality, particularly in areas of patient care where such improvements are difficult to achieve, then it should *increase* the share of savings above 50 percent or 60 percent for those ACOs that achieve higher quality.

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

We recognize the need for CMS to monitor and evaluate the models being tested under the CMMI. However, we ask that the agency not impose overly burdensome requirements on physicians to collect and report data from these programs. Before requesting data, CMS should estimate and publish the potential burden and cost on physicians and other providers. Physicians should have the right to opt-out of producing information that may not be available due to cost limitations or other administrative barriers. CMS should also consider the potentially major barriers in producing data that are stored in electronic health records. Producing this data can be problematic given concerns with data lock-in, the current lack of interoperability, and other problems with these systems. We appreciate that, wherever possible, CMS will make use of existing administrative systems to receive the data, but caution that CMS should provide clear instructions and other educational resources to ensure that collection and reporting of the data complies with the HIPAA Privacy and Security rules.

Sincerely,

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