AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

American Medical Association
515 N. State Street
Chicago, Illinois 60654

ama-assn.org

(p) 312.464.5000
(f) 312.464.4184

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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, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Payment Policies under the Physician Fee Schedule Proposed Rule for CY 2014
78 Fed. Reg. 43,281 (July 19, 2013); CMS-1600-P; RIN 0938-AR56

Dear Administrator Tavenner:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding the Centers for Medicare & Medicaid Services' (CMS) Medicare Physician Fee Schedule proposed rule for calendar year (CY) 2014. Our principal recommendations are set forth below, followed by more detailed comments on these and other issues.

Practice Expense Relative Value Methodology

- **The AMA calls upon CMS to correct its current practice expense (PE) methodology in order to appropriately reimburse the actual PE direct costs involved in providing each service and to accept the PE recommendations and relative value units (RVUs) submitted by the AMA/Specialty Society Resource-Based Relative Value Scale/RBRVS Update Committee (RUC).**

Using OPPS and ASC Rates in Developing PE RVUs

- **The AMA implores CMS to rescind its proposal to cap non-facility PE RVUs at either the Outpatient Prospective Payment System (OPPS) or Ambulatory Surgical Center (ASC) facility payment level.** We strongly dispute the fundamental premise behind this proposal, that higher payment rates for services in physicians' offices must be based upon inaccurate data.

- **This proposal's underlying premise is irreparably flawed. CMS has ignored fundamental differences in Medicare payment methodologies between the statutorily-required resource-based relative value scale (RBRVS) that is the basis for the Physician**

Fee Schedule (PFS) and the ambulatory payment classifications (APCs) used for OPPS and ASC rates. These differences render service-by-service comparisons inappropriate and inaccurate. APCs are the bundled payment method that averages low- and high-margin hospital services within a single APC. In contrast, the RBRVS captures the relative resource costs of each individual service. While hospitals can make up for losses on one service with profits on another, physicians will have no opportunity to make up their losses because CMS does not propose to increase payments for the hundreds of codes where the PFS rate is lower than the APC rate.

- **An AMA analysis found that, for 82 percent of the codes with proposed reductions, the direct expenses alone (i.e., clinical labor, supplies, and equipment employed in the service as adopted and implemented by CMS) exceed the proposed payment rate**. Also, only eight of the 112 codes that are being tied to the ASC payment rate are actually provided in an ASC at least 5 percent of the time, and only 34 of these codes would have hit the OPPS payment cap. In other words, 78 of the 211 services for which CMS proposes to reduce payments are already paid less under the PFS than the OPPS rate, meaning that Medicare and patients will actually pay more, not less, if these services are driven out of physician offices and into hospital outpatient departments.

- **If CMS is concerned about instances where payments in physician offices are higher than when a service is performed in a hospital outpatient department (HOPD) or ASC, the agency should work with the RUC to create a screen that could be used to identify and revalue these cases.** Since 2006, the RUC has identified over 1,500 potentially misvalued services through objective screening criteria and has completed review of approximately 1,300 of these services. **The AMA encourages CMS to continue to seek input from the RUC in its future efforts to identify and review potentially misvalued services.**

Medicare Economic Index (MEI)

- **The AMA appreciates the efforts by CMS to convene the MEI Technical Advisory Panel (MEI-TAP), urges the agency to continue work on the remaining issues the panel identified, and expresses concern that the physician productivity factor for 2014 is about double the productivity factors for HOPDs and ASCs.**

Geographic Practice Cost Indices (GPCIs)

- **The AMA supports the use of more current data in the GPCIs, appreciates the special effort to obtain updated premium data for Puerto Rico, and welcomes CMS' effort to use commercial rent data in the practice expense GPCI.**

Medical Telehealth Services for the Physician Fee Schedule

- The AMA commends CMS for proposing to expand both the geographic locations where telehealth services may be covered by Medicare, as well as the codes eligible for reimbursement in Medicare for services delivered via telehealth.

Complex Chronic Care Management (CCCM) Services

- **We applaud CMS for the decision to pay for Transitional Care Management (TCM) and CCCM services.** We recommend that CMS work closely with the CPT Editorial Panel to align the final patient requirements for CCCM services with the CPT guidelines. The CPT code structure is also preferable to the proposed 90-day time increment. We support the physician practice criteria listed by CMS which appear in the CPT guidelines.

- **We believe that any physician practice which meets the practice requirements should be able to qualify for payment of CCCM services, regardless of certification as a medical home. We strongly disagree that employment of advanced practice nurses and/or physician assistants is an appropriate requirement for practices to bill these services.** We further suggest more flexible requirements regarding ready access to patients' medical records.

Proposals Regarding the Clinical Laboratory Fee Schedule (CLFS)

- We strongly urge CMS to shift the molecular pathology codes from the CLFS back to the PFS and to allow stakeholder input prior to proceeding with its plans for reexamining payments under the CLFS.

Liability for Overpayments

- The AMA strongly opposes the longer five-year look back period for without fault overpayments. Extending this time period requires physicians to be subject to audits, recovery initiatives, and other burdens for an additional two years despite inadvertently or unknowingly receiving such overpayments. As we urged in our comments to CMS' proposed rule on Returning and Reporting Overpayments, CMS should maintain a three-year look back period to encourage consistency and avoid confusion with existing CMS overpayment initiatives.

Physician Compare Web Site

- **The AMA strongly urges CMS to alleviate current problems with accuracy of the underlying database, prior to posting quality measure performance information.**

- We encourage CMS to convene a multidisciplinary team to identify highest priorities within programs, such as *Choosing Wisely*, and develop an appropriate quality improvement model most suited for widespread adoption.

- The AMA urges CMS to allow physicians the flexibility to select between survey instruments and quality measures regarding patient satisfaction.

- **CMS should clearly and prominently state on Physician Compare that certain physicians (or physician groups) are not included in the performance reports for the *Million Hearts* initiative.**

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

- The growing complexity of the PQRS program poses a significant barrier to participation for many physicians. **The AMA is pleased that CMS has expanded the recognition of registry reporting across its performance programs and urges the agency to use its authority to also deem other quality measurement and improvement activities as qualifying for PQRS.**

Proposed 2014 PQRS Reporting Changes

- **CMS' proposal to increase the current reporting requirements from three measures to nine, covering at least three National Quality Strategy domains in one program year, is unreasonable and disregards the existing PQRS measure portfolio**. It would be far more reasonable to increase the required number of measures from three to five.

- The AMA highly recommends that CMS undertake a study, working with the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) and other affected stakeholders, to better evaluate the current PQRS measure portfolio.

It is imperative that CMS maintain the current option of electing to report one measure or one measures group, and the option of electing to report via administrative claims, in order to avoid the 2016 PQRS and Value-Based Modifier (VBM) penalties.

PQRS Quality Measure Development and Updates

- The AMA continues to support the agency's ability to use non-NQF endorsed measures in its performance programs, including PQRS. **Quality measures should be developed through a multi-stakeholder, public and transparent process, which ensures measures are meaningful to users, uphold national standards, and are harmonized with existing measures in widespread use. Also, prior to finalizing updated specifications and measures, CMS should engage affected stakeholders on the mechanics and anticipated impact of this proposal.**

PQRS Measures and Measures Groups

- **The increase in the minimum number of measures in a measures group from four to six appears to be arbitrary and should be withdrawn. Measures should only be added to a group when they are substantively appropriate to the clinical topic.** CMS should work with affected stakeholders to appropriately develop and revise PQRS measures groups.

Future of Claims-Based Reporting under the PQRS

- **The AMA supports a reasonable transition to registry and EHR reporting, but opposes elimination of the claims-based reporting option until it is abundantly clear that all physicians understand and are able to consistently, meaningfully, and accurately capture quality measures using EHRs or registries, while meeting other CMS reporting requirements.**

- The AMA asks CMS to provide at least a two-year look ahead for eligible professionals (EPs) to be made aware of the changing reporting modalities for their relevant measures, and allow them to allocate their resources accordingly and better understand the reporting requirements for a new modality.

PQRS Qualified Clinical Data Registries (QCDRs)

- **The AMA urges CMS to incorporate the QCDR requirements listed in the proposed rule more gradually; make the QCDR reporting option available to group practices as well as individuals; and allow QCDRs to report on measures groups as well as single measures.**

- The AMA recommends that CMS designate a grace period during which physicians are allowed to resubmit the measures that were disqualified. Also, in line with our earlier recommendation, **a QCDR for the initial reporting year should be required to report a minimum of only five measures covering at least one measure domain.**

Electronic Health Record (EHR) Incentive Program

- The AMA appreciates CMS' efforts to further recognize registry reporting across its performance programs and supports the proposals to allow QCDRs to report CQMs for the EHR Incentive Program and to require EPs to use the most recent version of the CQM specifications.

Value-Based Payment Modifier (VBM)

- Based upon CMS' own estimates, it appears that 30 to 40 percent of physicians could see both a two percent PQRS and a two percent VBM penalty in 2016. **When added to a potential two percent sequester reduction, and possibly another two percent EHR penalty, this could push some older physicians to retire or close their practices to Medicare patients**.

- **The AMA believes this expansion is too rapid and too risky and therefore is opposed to: increasing the VBM penalty from one percent to two percent; mandating participation in the tiering option; and making Medicare Spending Per Beneficiary an additional cost measure. We also recommend that the modifier be required only for groups of 50 or more EPs.**

Cost and Outcome Measures

- The AMA opposes CMS' persistent reliance on measures that were never developed for and tested in physician practices, especially in the absence of any CMS analysis of how these measures affect different types of practices and in the context of a mandatory, rather than an optional, tiering process.

- As of the date of publication of the proposed rule, neither the Measures Application Partnership nor the National Quality Forum had approved the use of the Medicare Spending Per Beneficiary measure in the physician setting. Absent a more reliable adjustment for specialty mix, this proposal could routinely penalize certain physicians whose practices are focused on nursing home or home care, or those patients who generally require rehabilitation care.

Specialty Adjustment

- The AMA agrees that adjustment for physician specialty is appropriate. **But the fact that CMS' proposed approach to specialty adjustment could result in a "high cost" designation for about 15 percent of geriatricians, geriatric psychiatrists, neurosurgeons, and medical and surgical oncologists suggests a systemic problem in the methodology**.

Physician Feedback Program

- The AMA greatly appreciates the efforts by CMS staff to obtain physician input on the design of the Quality and Resource Use Reports (QRURs), and we are pleased the next round of reports will include patient names and other information essential to evaluating and responding to the reports' findings.

Updating Existing Standards for E-Prescribing Under Medicare Part D

- The AMA supports CMS' proposal to upgrade electronic prescribing (e-prescribing) standards for the Medicare Part D prescription drug benefit program by replacing National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard 3.0 with Standard 1.0.

- Exemptions or accommodations are needed in the e-prescribing requirements to accommodate the need for paper prescriptions for military patients, and to support physicians who are close to retirement.

Modifier 25 Edits For Childhood Immunization and Wellness Visits

- CMS should support childhood immunizations by deactivating the edits associated with the use of Modifier 25 for billing childhood immunizations and wellness visits, effective January 1, 2013.

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" practice expense (PE) RVU methodology, whereby actual direct practice expense costs for clinical labor, supplies, and equipment are artificially decreased to obtain the direct PE RVUs for each service. Actual labor, supply, and equipment costs are multiplied by a direct budget neutrality adjustment resulting in adjusted labor, adjusted supplies, and adjusted equipment costs; then converted into RVUs by dividing them by the current conversion factor. The AMA has a longstanding concern that this methodology leads to inaccurate results, since it accounts for only a percentage of the actual PE direct costs to provide a service. CMS considers this consistent with the overall Physician Fee Schedule budget neutrality requirements, and calls this direct adjustment in their methodology a "scaling" factor.

While we acknowledge some improvement in the percentage of direct PE costs since 2010, we remain opposed to this adjustment methodology. In 2009, the direct costs covered were 62.5 percent and then dropped to 50.8 percent in 2010, under the new "bottom-up" PE RVU methodology. In 2011, that percentage dropped further to 50 percent and then in 2012 increased to 55 percent and again in 2013 to 60 percent. The AMA is disappointed that the percentage of direct costs covered by CMS has dropped again this year and has been proposed at less than 55 percent for 2014. **We call upon CMS to revise its methodology to accurately reflect the actual PE direct costs to provide each service.**

Changes to Direct PE Inputs for Specific Services - Ultrasound Equipment Recommendations: In the CY 2012 PFS proposed rule, CMS requested the RUC to review the ultrasound equipment

described in the direct PE input database. This involved reviewing 17 different ultrasound and ultrasound-related pieces of equipment associated with 110 CPT codes. CMS requested review of the clinical necessity of the ultrasound equipment as well as the way the equipment is described for individual codes. The AMA supports the RUC recommendations for general and vascular ultrasound rooms, addition of the cardiovascular ultrasound room as submitted, and suggestions for minor changes. We also understand that the RUC is working with specialty societies to provide paid invoices for this equipment.

Ultrasound Equipment Input Recommendations for Particular Services: We fully support the recommendations of the RUC regarding the typical ultrasound items used in furnishing 110 CPT codes (Table 10, 78 FR 43,300). We call upon CMS to:

- Add the *room, ultrasound, cardiovascular,* to its direct inputs equipment list, and reevaluate the room when paid invoices can be provided. This is significantly different from the current vascular room.

- Consistent with the proposed rule, replace the current equipment input of *room, ultrasound, general,* EL015 with the *ultrasound unit, portable,* EQ250 for CPT code 76942 *Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation*.

- Delay changes to the work intra service time and PE clinical staff time and equipment time for CPT codes 20610 and 76942, pending consideration of their bundling at the October 2013 CPT Editorial Panel meeting and review at the April 2014 RUC meeting.

Direct PE Inputs for Stereotactic Radiosurgery Services, CPT Codes 77372 & 77373: The AMA encourages CMS to accept the RUC's PE recommendations and RVUs for CPT codes 77372 and 77373, which are based upon direct inputs accurately reflecting the typical resources for furnishing these services in the office setting. The AMA also supports elimination of the G-codes.

B. Using OPPS and ASC Rates in Developing PE RVUs

The AMA strongly opposes the CY 2014 PFS proposal to cap payment rates for 211 physician services at Hospital Outpatient Prospective Payment System (OPPS) or ambulatory surgical center (ASC) rates. The proposal will reduce payments for some services by 50 percent or more, potentially driving them out of physician offices altogether and requiring patients to obtain these services in a more costly, less convenient facility setting. We urge CMS to withdraw this proposal.

CMS proposes to begin capping payments to services performed in the non-facility setting when those payments are greater than what is paid when the same service is performed in either the hospital outpatient or ambulatory surgical center facility setting. The agency offers two arguments to support the appropriateness of this proposal. First, the proposed policy is premised on the idea that there are

significantly greater indirect resource costs when a service is performed in a facility compared to the non-facility setting. Second, CMS assumes that the cost data are more reliable in the OPPS and in the payment structure for ASCs, compared to cost data collected under the resource-based relative value scale (RBRVS). Therefore, the agency concludes:

> We believe that this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting.

Services provided less than five percent of the time to hospital outpatients are supposedly exempt from the cap. However, as the cap was actually applied in the proposed policy, any of the 211 listed codes meeting that utilization threshold would have its PFS payment capped at the ASC rate, whether or not it exceeded the OPPS payment cap and whether or not it was provided at least 5 percent of the time in an ASC. As a result, the proposal would expand codes affected by the policy by more than a third and reduce payment rates for these services to 40 percent below the OPPS level, since ASC payments are just 60 percent of the OPPS rate for the same service.

An AMA analysis found that, for 82 percent of the codes with proposed reductions, the direct expenses alone (i.e., clinical labor, supplies, and equipment employed in the service as adopted and implemented by CMS) exceed the proposed payment rate. Also, only eight of the 112 codes that are being tied to the ASC payment rate are actually provided in an ASC at least 5 percent of the time, and only 34 of these codes would have hit the OPPS payment cap. In other words, **78 of the 211 services for which CMS proposes to reduce payments are already paid less under the PFS than the OPPS rate**, meaning that Medicare and patients will actually pay more, not less, if these services are driven out of physician offices and into hospital outpatient departments.

This proposal's underlying premise is irreparably flawed. **CMS has ignored fundamental differences in Medicare payment methodologies between the statutorily-required RBRVS that is the basis for the PFS and the ambulatory payment classifications (APCs) used for OPPS and ASC rates.** These differences render service-by-service comparisons inappropriate and inaccurate. APCs are the bundled payment method that averages low- and high-margin hospital services within a single APC. In contrast, the RBRVS captures the relative resource costs of each individual service. While hospitals can make up for losses on one service with profits on another, physicians will have no opportunity to make up their losses because CMS does not propose to increase payments for the thousands of codes where the PFS rate is lower than the APC rate.

In addition, as many services targeted by the CMS proposal are rarely even provided in hospitals, it is easier for a hospital to absorb the lower rate than it would be for a physician practice that provides the services more frequently. This also means that the services' costs may not be accurately reported by hospitals and not adequately reflected in the APC calculations. For individual services within an APC, guidelines allow for up to a two-fold difference in costs, although for low-volume services the actual gap can be much wider. If the frequency with which they are provided in a hospital is low

enough, even very high cost services do not show up in APC rates because higher frequency, lower cost services bring down the average payment for the entire APC bundle.

An example helps to illustrate the problem. In the PFS, the practice expense for *peritoneal chemotherapy infusion through an indwelling catheter* (96446) is valued at $185 while the practice expense associated with *pleural cavity chemotherapy infusion, including thoracentesis* (96440) is pegged at $806. Both services are grouped together in APC 439 and will be subject to a payment cap of $146.21 according to the proposed rule. The pleural cavity code requires a disposable catheter with an invoice cost of $329, so the catheter cost alone is nearly double the CMS proposed payment rate for the service. The payment rate for APC 439 is actually driven by a non-chemotherapy infusion code that is paid at $75 under the PFS and is responsible for 90 percent of the OPPS volume for this APC. Clearly, the $146 payment rate for the APC bears no relationship to the costs of performing either the high or low end of the APC services in physician offices.

As required by law, the proposal must be implemented in a budget neutral manner for the PFS overall, yet the impacts on the affected codes and about 20 specialties that provide them are far from neutral. CMS has not provided an estimate of the total dollars involved, but it appears that more than $500 million per year would be redistributed among specialties. In pathology, for example, which CMS projects would see total Medicare revenues fall by 6 percent as a result of this proposal, the direct practice expenses for nearly 40 codes exceed the APC payment by amounts ranging from just over $3 to more than $400. Dermatologists, physicians who provide angiography, and several other specialties report that their procedures are being capped at the ASC rate even though they are virtually never done in the ASC. Radiation oncologists have 16 codes on the list even though they are already undergoing a comprehensive review at the request of CMS. The proposed cap would cut radiation oncology payments for breast and lung cancer treatment episodes by 16 percent. Neurology faces a 25 to 75 percent reduction for 16 neurology diagnostic testing services.

While the AMA and affected specialties agree that, if properly structured, a comparison of facility and non-facility practice costs might be an appropriate screen to identify services for review as potentially misvalued, we are confident that the PFS data are the most accurate data available, not the APC data. For starters, the APCs are based on hospital charge data that, as detailed in recent press reports, can be highly inconsistent and, as laid out in the recently proposed OPPS/ASC rule, subject to a variety of methodological manipulations. We note that elsewhere in the proposed PFS rule, CMS states that it has "considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report" because currently "this practice is not consistent or standardized."

In addition, APC data are much more volatile than the information used in the PFS, creating the potential for significant yearly payment shifts that will exacerbate the instability in PFS rates due to the SGR. There are numerous examples of codes that have experienced payment swings of 10 to 20 percent or more in a given year for reasons that appear to be related to the particular vagaries of hospital charging practices and the mix of hospitals in the data rather than any actual change in service inputs. The proposed rule indicates concern that physician specialties do not always submit sufficient verification of the costs of equipment and other supplies. Yet each list of the resources

needed to provide services in the physician office is collected using standardized processes, carefully examined by a cross-specialty panel, and is typically submitted with invoices for expensive equipment and supplies. CMS participates in all deliberations and makes final decisions on the practice expense values.

Another major flaw in the proposal is that the cap that would apply to 2014 PFS rates is based on a comparison to 2013 OPPS and ASC rates. This means that the policy will ignore anticipated payment updates of 1.8 percent for the OPPS and 0.9 percent for the ASC payment rates as well as any APC weight changes that CMS has proposed, which in some cases will result in significant disparities between the OPPS/ASC cap and the actual rate that is being paid in these settings in 2014. For example, for code 96446 that, as described above, would be paid $146.21 under the PFS in 2014, the 2014 APC rate is actually increasing to $201.73. Similarly, the physician fee schedule payment for the technical component of CPT code 95928 *Central motor evoked potential study* which currently is set at $218 would be capped to a $79.83 cap even though the APC rate affecting this code is being increased by over 50 percent ($121.86) in 2014.

As noted above, for 82 percent, or 172 of the 211 codes subject to the proposed cap, the new payment rate would not even cover the direct practice expense component of the current PFS payment. Besides the cost of the disposable catheter used in code 96446, we offer the following examples of services which are rarely provided to hospital outpatients and for which the capped rate would not even cover a single high cost supply that is needed each time the service is provided, as shown by current paid invoices:

- CPT code 88367 *Insitu Hybridization Auto* is commonly performed in the non-facility setting (65 percent). This service requires CMS supply code SL196 HER-2/neu DNA probe kit costing $157. The total payment for this code in the non-facility setting is currently $258.23. The proposed cap would allow a total payment of $103, which is a 60 percent cut and is $54 below the cost of the DNA probe kit alone.

- CPT code 91120 *Rectal sensation test* is performed almost entirely in the physician's office (99.77 percent). This service requires a custom barostat catheter (CMS supply code SD216) with a price point of $217. The current total payment in the non-facility setting is $427. The proposed cap would lower the total payment to $138, a decrease of 68 percent and $79 below the cost of the barostat catheter.

- The code descriptor for CPT code 65778 *Placement of amniotic membrane on the ocular surface for wound healing; self-retaining* clearly includes the amniotic membrane itself. In 2011, however, only 39 percent of OPPS claims for the APC for this service included the V2790 code for amniotic membrane products. The supply code for amniotic membrane (SD248) is quite expensive, $895. The fact that 61 percent of hospital claims did not include the device means that CMS was missing a considerable amount of cost information when it set the 2013 payment rate for this service and used it to propose a 14 percent cut in the PFS payment rate.

With payments that often do not cover the direct costs of care, the only alternative for physicians in many cases will be to send patients to hospitals, where care may be more fragmented, further away, less convenient, and more costly. Patients will face disruption in longstanding relationships with their physicians and may be forced to seek care outside their local community, creating significant obstacles for those whose condition or treatment makes driving risky or impossible. Moreover, for the 78 services where OPPS payments exceed PFS payments, both the Medicare program and patients may actually pay more, not less, for their care than they do currently. It is clear that the proposal to cap PFS payment rates at the OPPS and ASC rates is erroneous and misconceived, and we strongly urge that it be withdrawn. Here are some further examples of the absurd effects this would have upon particular services and procedures, provided by several specialty societies:

- CPT code 96910 *Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B,* and 96912 *Photochemotherapy; psoralens and ultraviolet A (PUVA)* are performed 90.6 and 91.8 percent of the time in a physician's office, respectively. The proposed caps would reduce their payment by 48.52 percent for 96910, and 59.82 percent for 96912. Phototherapy is a relatively safe and less costly way to treat conditions like psoriasis, vitiligo, cutaneous lymphoma and eczema, and there is already a shortage of phototherapy units. The caps would likely lead to additional closures of phototherapy units and decreased availability of the treatments, adversely affecting millions of patients. According to the National Psoriasis Foundation, the average cost of phototherapy is $2,000 to $3,000 per year, while systemic therapies that include biologics can cost up to $30,000 a year.

- The American Academy of Neurology points to eight EEG (electro-encephalogram) services due for an average reduction of 54 percent in the non-facility PE RVUs. This will force many physicians to direct patients to an outpatient hospital for these procedures, which, especially in a rural area, could add significant travel time for the patient. Moreover, transportation is extremely problematic for patients experiencing or at risk of seizures or seizure-like episodes, often subject to legal prohibitions against driving. These patients are especially vulnerable to shifting sites of care.

- As indicated by the American Academy of Otolaryngology, CPT code 30903 *Control Nasal Hemorrhage* is performed only 2.4 percent of the time in the HOPD; 0.19 percent of the time in the ASC. The current reimbursement is $216.39 under the PFS. As part of APC0250, it receives only $43.82 when performed in an ASC. The APC rate is driven primarily by CPT 41250 *Repair of Tongue Laceration,* now paid at $284.77 under the PFS, plus several unlisted codes with a wide array of payment levels. CMS has set direct PE for this service at $83.38, including an epistaxis balloon valued at $43.06. The 2013 ASC payment of $43.82 leaves exactly 76 cents to cover the remaining $39.56 the physician must expend to provide this service in their office. This and other nasal hemorrhage codes (30905 and 30906) represent emergent procedures, requiring immediate attention. These cannot be rescheduled at will.

- CPT code 21215 *Reconstruction of Mandibular Rami; Grant, bone; mandible (includes obtaining graft)* is paid at $4,287.92 in the non-facility setting; $3,278.89 in the HOPD; and $1,839.88 in an ASC. Per Medicare claims data, the procedure is performed by maxillofacial surgeons 49 percent of the time; oral surgeons 45 percent of the time; and predominantly in the office setting (65 percent of the time among Medicare patients; likely higher for non-Medicare patients). CMS' direct practice expense is $2,509.76, which is 76 percent of the OPPS payment rate of $3278.89 and 136 percent of the ASC payment rate of $1,839.88. The American Association of Oral & Maxillofacial Surgeons indicates that physicians would have no choice but to render this service in a facility setting, causing unnecessary financial and personal burdens on the patient.

- The American College of Physicians notes three affected CPT codes: 12057 (*intermediate repair to face*); 15786 (*treatment of abrasion/lesion/single*); and 86580 (*Tuberculosis intradermal test*). Both CPT codes 12057 and 15786 are very low volume. The CY 2012 Medicare claims data show frequencies of only 77 and 756, respectively. For CPT code 86580, the 2012 data refer to internal medicine as the dominant specialty, with the service never performed in the HOPD (according to CMS regulation) nor in the ASC.

C. Collecting Data on Services in Off-Campus, Hospital Provider-Based Departments

CMS notes that the growing trend in hospitals acquiring and integrating physician practices has led to a rise in physician services furnished in a hospital outpatient setting, and billed under the Medicare Hospital Outpatient Prospective Payment System (OPPS). Many of these are performed in what are considered "off-campus provider based departments" under the OPPS. To collect information regarding the frequency, type and payment for services furnished in these off-campus provider-based hospital departments, CMS is considering creating either a new place of service code as part of item 24B of the CMS-1500 claim form, or a new Healthcare Common Procedure Coding System (HCPCS) modifier to be reported with every code. The agency is also considering requiring hospitals to more consistently break out their costs and charges for these departments, as outpatient cost centers on the Medicare hospital cost form, 2552-10.

If this proposed collection of information is finalized, the AMA would not support the addition of a new HCPCS tracking modifier. There are currently numerous modifiers, in addition to other reporting requirements, which must be considered when billing current Part B services. Adding another modifier, which would have to be appended to every physician service delivered in the hospital outpatient setting, would increase both the administrative burden and the likelihood of future billing errors. As a simpler and reasonable alternative, **the AMA would prefer adding a new site of service code that specifically identified Medicare claims for services delivered in off-campus provider-based hospital departments.**

II. Misvalued Codes

CMS acknowledges the significant progress to date in identifying and reviewing potentially misvalued services. Indeed, the Medicare Payment Advisory Commission (MedPAC) is quoted in the proposed rule as recognizing that "CMS and the AMA RUC have taken several steps to improve the review process." Since 2006, the RUC has identified over 1,500 potentially misvalued services through objective screening criteria. The RUC has completed review of approximately 1,300 of these services. A decrease or deletion was recommended for nearly *half* of the identified services (see Table 1). The RUC potentially misvalued codes review project has identified services that account for approximately $38 billion in Medicare allowed charges (see Table 2).
The RUC has worked vigorously over the past several years to identify and address misvaluations within the RBRVS. Many recommendations have been provided to CMS reflecting revisions in physician time data as well as resource costs. Some services are indeed performed more efficiently now than in the past. Many of those codes have already been addressed. For example, the time and valuation for cataract surgery was significantly reduced in 2013. The RUC's efforts from 2009 to 2013 have resulted in $2.5 billion in redistribution within the Medicare Physician Payment Schedule.

As CMS continues to examine potentially misvalued services in the coming years, the AMA fully supports the efforts of the RUC to work with CMS, specialty societies, and other individuals and stakeholders, in a concerted effort. A full report on these efforts is being submitted with the RUC formal comment letter to CMS.

Table 1
RUC Potentially Misvalued Services Project by Total Number of Codes in Project (1,553)

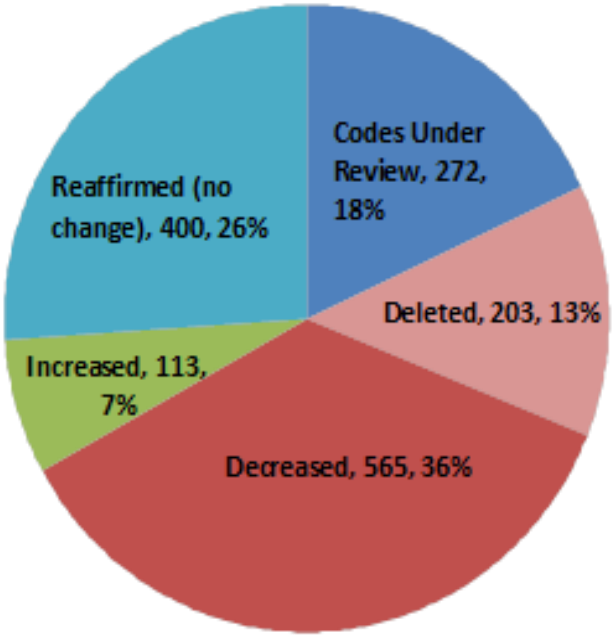
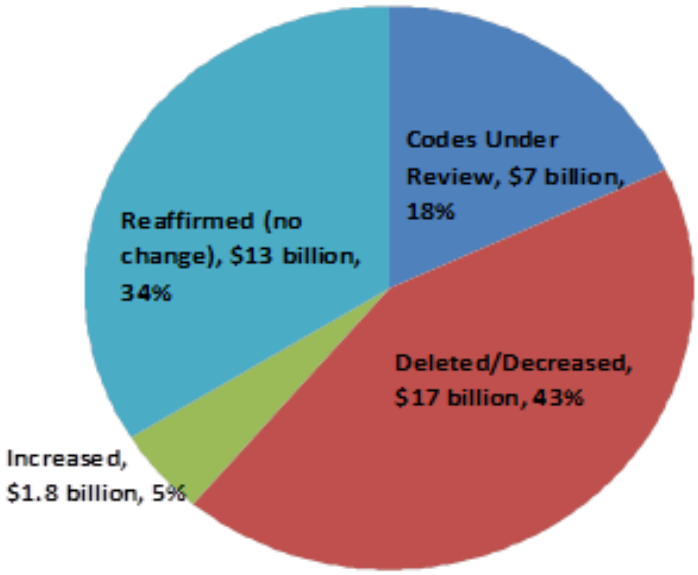


Table 2
RUC Potentially Misvalued Services Project by Medicare Allowed Charges (2012)



III. Medicare Economic Index (MEI)

In 2012, CMS convened a Technical Advisory Panel (MEI-TAP) to conduct a comprehensive review of the Medicare Economic Index (MEI). The panel made 13 recommendations to improve the accuracy of the index, ten of which are included in the proposed rule. CMS' proposed changes follow the MEI-TAP recommendations closely. Planned changes to the cost categories and weights are aimed at improving the accuracy of the MEI as a description of the cost structure of medical practice. Changes to the price proxies generally move away from broad price measures to those more closely associated with physicians. Key changes proposed by CMS include:

- *Professional workers' earnings would be used as the price proxy for the physician compensation portion of the index*. The price proxies for physician compensation would be changed from general economy-wide earnings and benefits to wage and benefits indices for "Professional and related occupations." The AMA has long advocated for physician compensation measures based on workers facing market conditions similar to those of physicians.

- *CMS would use commercial rents in place of residential rents for the rent portion of the index*. For most physicians, commercial rents should be a more appropriate measure of changes in the price of physician office space than residential rents. The commercial rent index is, however, more volatile than the current office rent measure.

- *The physician benefits share of the index would be increased.* The MEI-TAP concluded that retirement benefits are currently excluded from the physician benefits portion of the MEI. Increasing the benefits share would correct that oversight and ensure consistency with the benefits price proxy.

- *Payroll for nonphysician personnel who can bill independently would be moved from practice expense to the physician compensation (work) portion of the index*. The MEI-TAP noted that nonphysician clinicians are increasingly providing and billing for Medicare PFS services, raising concerns about the appropriate classification of this payroll category within the MEI. The CMS proposal would increase the physician compensation share from 48.3 to 50.9 percent, and reduce the nonphysician compensation share by the same differential. CMS has proposed corresponding changes to the work and practice expense shares of total RVUs and GPCI cost shares.

- *A health sector wage category would be added to the index*. The current MEI lacks a nonphysician wage category specific to health care workers. The proposed "Health related, nonphysician wage" category would improve the accuracy of the MEI if changes in health workers' wages differ from the norm.

- *A new "All other professional services" category would be created*. This category would encompass purchased services such as contract billing, legal, and accounting services. The proposed category would employ appropriate wage/salary proxies in place of the economy-wide inflation measure used for the current "Other professional expense" category.

CMS did not implement changes related to three TAP recommendations. These called for further CMS research into whether: (1) using self-employed physician data for the MEI cost weights continues to be the most appropriate approach; (2) additional data sources could allow more frequent updates to the MEI's cost categories and their respective weights; and (3) there is a more appropriate price proxy for Moveable Capital expenses. CMS indicated plans to continue to investigate these three issues.

The AMA greatly appreciates the efforts of CMS to convene the MEI-TAP panel. The AMA has a longstanding interest in improving the accuracy of health related price indices, and looks forward to continued work with CMS to maintain and refine the MEI. We believe the changes proposed by the MEI-TAP successfully bring the "market basket" of MEI inputs up to date and improve the accuracy of the index going forward. CMS is strongly encouraged to continue work on the remaining issues identified by the MEI-TAP. Of particular importance is the collection or identification of practice cost data to keep the MEI cost shares up to date. The AMA looks forward to working with CMS in that effort.

The proposed changes to the MEI are positive, but it will remain difficult for practicing clinicians to reconcile changes in the MEI with their own practice cost increases. The projected increase in the proposed MEI for 2014 is just 0.7 percent, but this amount reflects a reduction for economy-wide

productivity growth of 0.9 percent. Excluding the productivity adjustment, inflation for medical practices is projected to be 1.6 percent for 2014. In addition, as is the case with any price index, this amount does not take into account any change in the quantity of inputs (for example, changes in the number of staff that practices employ).

The AMA strongly supports continued monitoring of physician productivity growth as it compares to economy-wide growth. Medical practices have been subjected to a number of regulatory requirements in recent years that likely impacted their productivity. To ensure compliance with these regulatory requirements, physicians often must take actions that reduce practice productivity, including hiring additional office staff, retaining attorneys for legal and regulatory compliance, and contracting with accountants and billing companies to ensure proper processing of claims. Monitoring of physician productivity growth is necessary to determine if the continued use of economy-wide productivity growth in the MEI is appropriate.

As for the productivity adjustment for 2014, it is unclear why this adjustment in the MEI, at 0.9 percent, is so much greater than the productivity adjustment that is projected for the 2014 Medicare OPPS and ASC updates. All these productivity adjustments should be based on ten year averages of private non-farm business multifactor productivity growth, but the OPPS and ASC adjustments, at 0.4 percent and 0.5 percent respectively, are about half the MEI adjustment.

Finally, questions have been raised about CMS' implementation of the MEI-TAP recommendation concerning payroll for nonphysician personnel, which stated that, in evaluating the appropriate classification of the expenses associated with nonphysician clinical staff who can bill Medicare independently, CMS should consider any definition of "physicians" that exists under current law in relation to the Medicare PFS and whether these definitions might limit CMS' ability to make changes. Several state medical societies have noted that state laws in multiple states preclude nonphysicians from practicing and billing independently, and that the statutory definition of "physicians" in the Medicare law appears to preclude CMS from treating nonphysician clinical staff payroll as physician work. The AMA recommends that CMS further evaluate these questions, as the MEI-TAP recommended, share the results of its analysis, and provide a more detailed rationale for any changes proposed to the MEI regarding the classification of nonphysician personnel expenses.

IV. Geographic Practice Cost Indices (GPCIs)

As required by law, CMS proposes to update the GPCIs for 2014 through reference to more recent data sources. For example, in the GPCIs for work and practice expense (employee wage and purchased service indices), CMS plans to use Bureau of Labor Statistics Occupational Employment Statistics from 2009 through 2011 to replace similar statistics for 2006 through 2008. Likewise, CMS proposes to update the malpractice GPCI by referencing professional liability insurance premium information from 2011 and 2012 instead of the 2006-2007 data used in the previous GPCI update. In addition, as CMS had been unable to obtain professional liability insurance premium data for Puerto Rico for a number of years, the agency worked directly with the Puerto Rico Insurance Commissioner and Institute of Statistics to obtain data for Puerto Rico, which boosts that area's malpractice GPCI by

17 percent. **The AMA supports the use of more current data in the GPCIs and appreciates the special effort that CMS has made to obtain updated premium data for Puerto Rico.**

CMS also seeks comments on whether it should use a proprietary source it has identified for commercial rent data in the future, instead of continuing to use residential rent data. The AMA has long objected to the use of residential rents in the practice expense GPCI as a proxy for physician office space costs. **We agree that CMS should explore the possibility of using the commercial rent data source that it has identified. It would also be very helpful if CMS could elucidate how incorporating the commercial rent data would impact the practice expense GPCI and payment rates in each Medicare payment locality.**

V. Medical Telehealth Services for the Physician Fee Schedule

CMS proposes an expansion of geographic locations where telehealth services may be covered by Medicare. Currently, CMS is permitted to cover Medicare telehealth services in a county that is not a Metropolitan Statistical Area (MSA), in designated rural health professional shortage areas (HPSA); or sites participating in a federal telemedicine demonstration project. CMS proposes to expand permissible sites located in rural census tracts as determined by the Office of Rural Health Policy. **The AMA strongly supports this proposed modification as it will ensure that Medicare beneficiaries who face significant geographic challenges are able to obtain Medicare covered services delivered via telehealth.**

CMS also proposes to expand further the services eligible for reimbursement in Medicare for services delivered via telehealth**. The AMA strongly supports the proposal to add transitional care management services where there is communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge with parameters defined by the complexity as well as length of time post-discharge.** The AMA strongly supports this proposal as it will enhance care coordination, and we expect will result in the decrease in re-admissions.

VI. Requirements for Billing "Incident to" Services

Section 1861(s)(2)(A) of the Social Security Act and section 410.26 of Medicare regulations set forth the requirements that must be met for physicians (and select nonphysician practitioners) to bill Medicare for services and supplies furnished "incident to" the professional services of a physician. CMS has proposed adding a new subsection 410.26 (a) (1) with the following language:

> *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

"Auxiliary personnel" refers to "an individual who is personally performing the service or some aspect of it." This provision is intended to revise Medicare requirements to specifically make compliance with state law a condition of payment for "incident to" services and supplies, as recommended by the HHS Office of Inspector General in 2009.[1]

We support this clarification. CMS notes that this and other technical amendments are consistent with the agency's "traditional approach of relying primarily on the states to regulate the health and safety of their residents in the delivery of health care services. Throughout the Medicare program . . . the qualifications required for the delivery of health care services are generally determined with reference to state law." 78 Fed. Reg. 43336. The AMA supports the fundamental concept of determining such qualifications pursuant to state law. However, in considering additional steps to ensure compliance with these provisions, we strongly urge CMS to take into account the already significant administrative burden that physicians face under Medicare, and avoid adding to that burden.

VII. Complex Chronic Care Management (CCCM) Services

CMS recently implemented payment for transitional care management services (TCM). CMS proposes to provide payment for CCCM services beginning January 1, 2015. **We applaud CMS for the decision to pay for TCM and CCCM services and urge CMS to continue consideration of additional payment for other non face-to-face services.** CMS contemplates paying for CCCM services provided to 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 and/or decompensation, or functional decline. CMS will delay implementation to develop standards, through public rulemaking, related to physician office capability to perform these CCCM services.

The CPT Editorial Panel and the RUC are eager to resolve any differences in the structure, valuation and understanding of the CCCM services over the next several months to allow for successful implementation on January 1, 2015. Accordingly, it will be imperative for CMS to include in the November 2013 final rule a clear direction regarding the required structure of coding CCCM services.

Proposed CCCM Descriptions Compared with CPT CCCC Codes: The CPT Editorial Panel developed CCCM codes for reporting per calendar month, which are quantified by the first hour of clinical staff time, with an add-on code for each additional 30 minutes. CPT code 99487 is reported when no face-to-face visit was performed in a month and 99488 is reported when a face-to-face visit is performed. In contrast to the CPT codes, CMS has proposed G-codes that would: (1) pay for all face-to-face visits independently of the CCCM codes; and (2) follow a 90-day reporting structure, instead of the calendar month reporting period for the CPT codes. CPT included a code with a face-

[1] Department of Health and Human Services Office of Inspector General, "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services," OEI-09-06-00430 (2009).

to-face visit to prevent duplication of the pre- and post-work of the evaluation and management (E/M) code reported in the same month as care coordination. If CMS prefers that E/M services be reported separately, the CPT Editorial Panel may wish to discuss potential deletion of 99488. The proposed 90-day reporting period is more problematic, as it would be difficult to evaluate for both work and practice costs. At a minimum, an add-on code for each additional half-hour provides the level of granularity required to ensure that the services is valued correctly.

CPT CODES		CMS PROPOSAL
99487	Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month	Complex chronic care management services furnished to patients with multiple (two or more) complex chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline GXXX1, initial services; one or more hours; initial 90 days GXXX2, subsequent services; one or more hours; subsequent 90 days
99488	first hour of clinical staff time directed by a physician or other qualified health care professional with one face-to-face visit, per calendar month	
✚99489	each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	

Definition of Complex Patient: CMS should work closely with the CPT Editorial Panel to align the final patient requirements for Medicare payment of CCCM services, with those in the CPT guidelines. CMS has indicated its intent to do so, specifically limiting services to patients with two or more chronic conditions. CMS should also address the guidelines as described for CPT 2014, including the expectation that the typical adult patients take three or more prescription medications and may be receiving other types of therapeutic interventions (such as physical therapy). These patients commonly require the services of a number of different specialists and are unable to perform activities of daily living. A specific care plan must be established for these patients.

Physician Practice Capability: The AMA supports the proposed inclusion of practice requirements for providing CCCM services, which also appear in the CPT guidelines. These would require eligible practices to: (1) provide 24/7 access to care providers or clinical staff; (2) use a standardized methodology to identify patients who require chronic complex care coordination services; (3) have an internal care coordination process/function whereby a patient identified as meeting the requirements for these services starts receiving them in a timely manner; (4) use a form and format in the medical record that is standardized within the practice; and (5) be able to engage

and educate patients and caregivers as well as coordinate care among all service providers, as appropriate for each patient.

However, we urge the agency to reconsider going beyond these practice criteria. The notion that practices "must employ one or more advanced practice registered nurses or physician assistants" to provide CCCM services is particularly ill-advised. **We strongly disagree that employment of this level of staff should be a consideration in providing these services.** Many practices employ registered nurses who are well qualified to provide care coordination.

We also believe the notion that there should be immediate online access to every patient's complete EHR is unrealistic for many physicians, particularly those who would most benefit from reimbursement for CCCM services. Physicians who would otherwise be qualified to provide CCCM services, and can demonstrate timely access to a patient's medical records, should be eligible to report CCCM as EHR systems become more streamlined, interoperable, and affordable.

CMS is also considering suggestions that designation as a medical home by a national organization, such as the National Committee for Quality Assurance (NCQA) or the Joint Commission, could also demonstrate sufficient capability to provide CCCM services. **We believe that any physician practice should be able to qualify for payment of CCCM services, as long as the individual practice meets the practice requirements established to report these individual codes.** We do not support a requirement that physician practices be certified as primary care medical homes in order to receive payment for complex chronic care management.

If, however, CMS decides to recognize certified medical homes—through accrediting organizations or otherwise—the certification standards should fully reflect the Joint Principles for the Patient-Centered Medical Home (http://tinyurl.com/ccbhvzz). These Joint Principles, adopted by the AMA and the primary care organizations, require physician leadership of the medical home. Other accreditation programs do not require physician leadership. Some do not even require the participation of a physician in any capacity. The CCCM services are designed to ensure that (1) each patient has an ongoing relationship with a personal physician, and (2) the personal physician of the patient leads the medical home interdisciplinary care team. Requirement of accreditation would not be consistent with the model of care described by the CCCM services.

Individuals Who May Report the Service: The CPT guidelines contain practice capabilities to report CCCM services; the physician must be able to engage and educate patients and caregivers and coordinate care among all service providers. CMS would also require the patient to undergo an Annual Wellness Visit (AWV) G0438, G0439 (or Initial Preventive Physical Exam (G0402) for new Medicare Patients) within the prior 12 months. The AWV must list the patient's current practitioners and suppliers. CMS assumes the physician who performs the AWV should generally provide the CCCM services. Patients could select another physician for CCCM services, who would need a copy of the AWV assessment and care plan, prior to billing. While the AWV may not be directly related to the needs of these chronically ill patients, we recognize it is a mechanism for CMS to identify the appropriate physician to provide CCCM services. **We believe it is critical that CMS allow a different physician to provide CCCM services, if he or she obtains the AWV assessment and care plan.**

Patient Notification and Consent: The CPT codes require a plan of care to be documented and shared with the patient and caregiver. CMS is considering a more elaborate process. Beneficiary consent would be required before the service and every 12 months thereafter; the care plan would be part of the patient's electronic medical record, and shared with the patient. We seriously question the need for an additional condition, that the patient be separately notified of any claims submission (including dates of services, what was provided, and why). This appears to transcend current notice requirements for other services to Medicare beneficiaries, and would create an unnecessary administrative burden.

Requirements for Clinical Staff: With certain exceptions, Medicare generally pays for services billed "incident to" the services of a physician, only when the person performing those tasks or services is working under the *direct* supervision of a physician. CMS proposes that the time spent by the clinical staff outside of the practice's normal business hours (with no *direct* physician supervision) would count toward the one hour of CCCM services. These staff would be considered under the *general* supervision of the physician, *i.e.,* performed under the physician's overall supervision and control. The tasks or services would naturally have to be directly related to the CCCM services. **We fully support this clarification in light of the current "incident to" policy.** A critical component of CCCM services, crucial to preventing unnecessary hospital and emergency department admissions, is the ability of nurse care managers to make phone calls and serve as a resource for patients, beyond normal business hours.

Unlike the CPT guidelines, the proposed rule also contemplates requiring clinical staff to be directly employed by the physician. We trust that CMS will carefully consider comments from physicians on this point—particularly if this would prevent billing by physicians with longstanding arrangements with care managers (even working within their offices) who do not employ these staff directly, for various reasons.

Valuation of Services and Budget Impacts: CMS opted not to set values corresponding to the proposed G-codes. If the final coding structure varies from the *CPT 2014* descriptions, the CCCM services will need to be resurveyed and revalued. Changes in coding and valuation will necessitate reconsideration of budget neutrality assumptions. We appreciate CMS recognizing that improvements in chronic care management would decrease costs through reductions in hospitalizations, use of post-acute care services and emergency department visits.

VIII. Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage

CMS proposes to establish new criteria governing coverage of the costs and routine items and services in Category A and B Investigational Device Exemption (IDE) studies and trials. A Category A device is one for which the initial questions of safety and effectiveness have not been resolved, and the FDA is unsure whether the device type can be safe and effective. A Category B device is a non-experimental/investigational device for which the underlying questions of safety and effectiveness have been resolved. CMS would establish new scientific and ethical standards that are uniform. In addition, CMS also proposes IDE coverage decisions will be made by CMS centrally, rather than by

Medicare contractors. The agency notes that variability from region to region is not a factor impacting the administration of national clinical trials.

CMS suggests that new scientific and ethical standards could establish uniformity and centralization. We are concerned, however, that these could also prove a significant barrier to access, particularly if CMS does not utilize an open and transparent process for establishing relevant standards and issuing such determinations. **The AMA strongly urges CMS to issue a public notice of its proposal for developing the relevant standards which includes an opportunity for public comment. Similarly, CMS should follow an equally transparent process that will provide for stakeholder feedback for individual determinations.**

IX. Ultrasound Screening for Abdominal Aortic Aneurysms

The AMA supports the CMS proposal to modify Medicare coverage of screening for abdominal aortic aneurysms (AAAs), consistent with recommendations of the U.S. Preventive Services Task Force, for males 65-75 years of age who have ever smoked. The proposed change would eliminate the existing one-year time limit for this group of patients, to receive a referral for this service. Males in this age group with a history of smoking would no longer be required to receive a referral for AAA screening during an Initial Preventive Physical Examination (IPPE).

The Society for Vascular Surgery (SVS) indicates that AAA screening is underutilized under the current policy, and the proposed change will allow for expanded access to this important preventive service. Coverage of the screening service for the specific group of beneficiaries who are male ever-smokers 65-75 will be expanded beyond those who are referred during their IPPE. The AMA supports the proposed expansion of coverage.

Unfortunately, the prevalence of AAAs has been steadily growing. Advances in treatment have led to prevention of catastrophic or fatal complications – provided there is timely detection. At-risk men and women with a family history of AAA will still be subject to the one-time screening referral in conjunction with the IPPE. We agree with the SVS, **that CMS should also expand access to AAA screening for patients with a family history of AAA**, also a considerable risk factor.

X. Proposals Regarding the Clinical Laboratory Fee Schedule

CMS proposes to establish a new process for systematically reexamining the payment amounts established under the Clinical Laboratory Fee Schedule (CLFS). This analysis would determine whether changes have occurred in the technology required to deliver a particular service, which may warrant adjusting the reimbursement for that service. CMS considers such adjustments to be warranted in light of the rate of technological change and often dramatic decrease in costs, as evidenced by the dramatic reduction seen over the past decade in the costs of sequencing the human genome. CMS does not specify how it will undertake the reexamination process.

The AMA has significant concerns regarding the ability of Medicare contractors to undertake such reexaminations, should CMS place this responsibility in their hands. Medicare contractors do not

have the requisite expertise, data, and resources necessary to accurately perform such reexaminations. The most recent effort by Medicare contractors to re-examine pricing and payment of the molecular pathology codes (Mopath codes) utilizing the gap-fill methodology underscores the significant shortcomings of delegating such a task to the Medicare contractors. We strongly urge CMS to issue a clear proposal regarding the agency's plans for the reexamination process and standards to be employed. CMS must also ensure that stakeholders have an opportunity to comment on both the process and the standards, before CMS pursues such an approach. Anything short of an open and transparent process will continue to create upheaval in the molecular diagnostics industry.

The AMA also strongly urges CMS to move the Mopath codes to the PFS. There has been and continues to be significant disruption that has resulted from delegating the responsibility for pricing and payment of the Mopath codes to the Medicare contractors, as discussed above. To the extent that CMS adopts the broader policy of re-examining tests on the CLFS, it is essential that CMS return the molecular pathology testing services to the PFS. There is an established process for generation of data on costs that CMS is able to use in order to reach accurate and fair payment determinations. Furthermore, CMS erred in underestimating the involvement and role of physician services in the molecular pathology services rendered. Mopath diagnostics are highly complex tests that require significant and substantial physician expertise and input. Furthermore, the technology used to deliver these services is frequently predicated on complex algorithms, and we urge CMS contractors to acknowledge this in making pricing decisions.

XI. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

Under longstanding CMS policy and regulations, the agency waives the recovery of claims-based, fee-for-service overpayments in certain situations where the provider or supplier is "without fault" in incurring the overpayment. Under existing regulations, "without fault" may be presumed if an overpayment is not determined after a three-year look back period. CMS is proposing to implement changes enacted by the American Taxpayer Relief Act of 2012 that give Medicare more time to recover such overpayments—extending the three-year time frame to five years.

The AMA strongly opposes the longer five-year look back period for "without fault" overpayments. Extending this time period requires physicians to be subject to audits, recovery initiatives, and other burdens for an additional two years despite inadvertently or unknowingly receiving such overpayments. As we urged in our comments to CMS' proposed rule on Returning and Reporting Overpayments, CMS should maintain a three-year look back period to encourage consistency and avoid confusion with existing CMS overpayment initiatives. In particular, the Medicare and Medicaid Recovery Audit Contractor (RAC) programs both utilize a three-year period. CMS and numerous medical specialty societies have spent substantial resources to educate physicians about these time limits. To finalize a different, substantially longer look back period would confound those efforts and prove unduly burdensome for physicians. CMS is proposing to maintain the current time periods for reopening claims. We support that aspect of the proposal, which will mitigate confusion and provide stability for physicians and other practitioners and providers.

XII. Physician Compare Web Site

The AMA has worked extensively with CMS during the implementation of the Physician Compare web site to provide critical physician input and ensure the site provides information that is accurate, meaningful and useful for patients as well as physicians. The AMA is pleased with several changes CMS recently made to the site, particularly the use of claims data to verify physicians' information, and modifications to the search function related to how physicians and specialties are listed. **Additional improvements are still necessary to ensure the accuracy of both the search function and the underlying demographics of the data. These efforts must be undertaken before incorporating any additional performance information.**

CMS proposes to post on Physician Compare, no earlier than 2015, information regarding physicians' performance in the Group Practice Reporting Option (GPRO) registry, and specific EHR measures reported via the GPRO web interface in 2014. Quality measures would expand to include performance on *all* measures collected through the GPRO web interface, for groups of all sizes participating in 2014 under the PQRS GPRO and for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). In addition, the agency proposes to expand public reporting for both group practices and individual eligible professionals (EPs) starting in 2015, based upon 2014 data.

The AMA strongly urges CMS to alleviate current problems with accuracy of the underlying database, prior to posting quality measure performance information for group practices, ACOs, and individuals. Physician Compare needs to have a firm, solid base with a workable design and search functions, and accurate demographics data. Without corrections to these basic aspects of the site, any additional detailed performance data will be tainted. Once the underlying demographics data and search function are accurate, the AMA would support the agency's proposal to provide a 30-day preview period prior to publication of quality data on Physician Compare. In addition, CMS must allow physicians, group practices, and ACOs the opportunity to correct and/or appeal any errors found in the performance information, before it is posted on the site. **As part of this effort, we urge CMS to work in collaboration with affected stakeholders on reviewing the methodology used for calculating and posting quality performance information on the site.**

Minimum Patient Threshold for Publicly Reporting Performance Information: In the CY 2013 final rule, CMS lowered the minimum patient sample size for reporting performance information to 20 patients. **As stated in past comments to the agency, the AMA believes the appropriate minimum sample size for validity of performance information is 30 patients, and we oppose a lower sample size as statistically invalid and prone to misleading conclusions.** It is highly likely that a physician's actions with respect to 20 patients may not be representative of his or her general practice activities. Using a sample size any lower than 30 can seriously compromise the validity of the performance information. It can also result in publicly reported information that is misleading. With only 20 patients in a sample, each case could lead to a change in the results which is unjustified in light of the small proportion that these patients may represent of the physician's patient load. It is not statistically significant. Misleading information may steer patients to conclusions that do not

serve their best interest and could unnecessarily harm the reputation of a group practice and/or individual physicians.

The *Choosing Wisely* Campaign: CMS seeks comment on publicly reporting participation by individual eligible healthcare professionals on initiatives such as *Choosing Wisely*. The American Board of Internal Medicine's (ABIM) *Choosing Wisely* Campaign involves specialty societies identifying and providing recommendations regarding the provision of tests and procedures which may be overused, and thus should be avoided either generally, or in certain circumstances. Lists of overused tests and procedures are accompanied by a list of questions that the physician and patient should discuss in evaluating whether the test or procedure should be ordered. It is important to recognize that *Choosing Wisely* does not produce a list of well-defined quality measures, with a numerator and denominator for collecting data in the medical record. Rather, *Choosing Wisely* is an effort to help engage patients and physicians in medical decision making to consider appropriate use of medical tests and procedures. The AMA supports activities like *Choosing Wisely* that further strengthen the patient/physician relationship in the appropriate delivery of health care services. **However, it is very premature to consider initiatives such as *Choosing Wisely* for inclusion in a public reporting effort such as Physician Compare, until these can be translated into measurable improvements in quality for use at the point of care. That process should be undertaken by a team of quality improvement organizations, stakeholders and clinical experts.** The AMA-PCPI has unique and extensive experience in the development of quality measures that address overuse. However, this issue presents particular challenges with respect to data collection, incorporation into the clinical workflow, and evidence support to clearly identify the eligible patient population as well as any exclusions or exceptions that may be appropriate. **We encourage CMS to convene a multidisciplinary team tasked with identifying the areas of highest priority within programs, such as *Choosing Wisely,* and developing an appropriate quality improvement model most suited for widespread adoption.**

Clinician & Group Consumer Assessment of Healthcare Providers & Systems (CG-CAHPS): CMS seeks comment on posting performance on patient experience survey-based measures for individual eligible professionals (EPs), starting with data collected for 2015. In addition, CMS proposes to continue public reporting of CG-CAHPS data in 2014, for PQRS GPRO group practices of 100 or more EPs which participate in the GPRO via the web interface, and for MSSP ACOs which report through the GPRO web interface or other CMS-approved tools or interfaces. As done in 2013, CMS will administer and fund the collection of CG-CAHPS data for these groups. The agency encourages groups of 25 or more EPs to report CG-CAHPS by making these measures available for reporting through PQRS and for the Value-Based Payment Modifier (VBM). While CMS proposes to publicly report 2014 CG-CAHPS data for any group practice (regardless of size) which voluntarily chooses to report CG-CAHPS, CMS will not fund the surveys for these groups. CMS also proposes to publicly report comparable CG-CAHPS data collected by a group of any size via a "certified CAHPS vendor."

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 VBM programs. The AMA continues to support the use of the CG-CAHPS survey as one means of

measuring the patient centricity of a medical practice. However, other survey instruments are available which provide actionable feedback to physicians that can inform their actions and contribute to high quality care in everyday practice. And some of the CG-CAHPS questions relate to factors beyond the control of a physician or his or her staff. As result, the data may leave a practice wondering what steps it can take to improve quality at the point of care.

The AMA urges CMS to allow physicians the flexibility to select between survey instruments and quality measures regarding patient satisfaction, and choose those most relevant to their particular practice. Additionally, survey instruments approved by CMS should involve visit-specific questions. Finally, when a practice makes changes in an effort to better meet the needs of its patients, it is crucial that the practice be able to track and evaluate the results of those changes from the patient perspective over the course of their visits. Survey instruments should have the capability to take account of such changes and results.

The *Million Hearts* Initiative: In support of the *Million Hearts* initiative of the Department of Health and Human Services, CMS proposes to publicly report performance rates for the measures included in the Cardiovascular Prevention measures group reported by individual EPs participating in the 2014 PQRS. The AMA appreciates the laudable goals of the *Million Hearts* initiative and its focus on cardiovascular health. However, we have concerns about unintended consequences of making this type of data public, without a clear explanation. In particular, if an individual physician is not listed on Physician Compare as successfully reporting on the Cardiovascular Prevention measures group, members of the public may make incorrect assumptions about that physician's negative performance in cardiovascular care. Patients may assume the physician had poor performance, did not attempt to report quality data, was not successful in reporting, or does not have sufficient patients. In fact, the physician may indeed provide high quality cardiovascular care, but elected to report via an EHR, which does not collect data on a measures group. **Therefore, CMS should clearly and prominently state on Physician Compare that certain physicians (or physician groups) are not included in the performance reports for various reasons, including: (1) the requirement to develop a performance report does not apply to all physicians and groups, and therefore if a report is not available for a particular physician or group, this in no way reflects the performance level of that group; or (2) some physicians or groups elected the EHR reporting option which enables the reporting of a different mix of cardiovascular related measures.**

XIII. 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 2014 PQRS incentive and 2016 PQRS payment adjustments. By statute, 2014 is the last year an EP can qualify for an incentive payment of 0.5 percent under the program. 2014 also serves as the performance year for the 2016 penalty adjustment of two percent, which will apply to EPs who do not satisfactorily report data on quality measures. CMS will maintain a two-year look-back for applying PQRS penalties. CMS proposes to add and remove several PQRS measures, expand the number of measures groups, and increase the total number of measures in a measures group from four to six.

CMS also proposes a new PQRS reporting option—satisfactory participation in a "qualified clinical data registry." The AMA appreciates the agency's efforts to further align quality measure reporting across its performance programs and improve the number of measures available through registry and EHR reporting. **But the growing complexity of the PQRS program remains a serious concern to the AMA, and poses a significant barrier to participation for many physicians.** 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.

To ensure high quality health care across the country, every practicing clinician must have workable options for implementing quality measurement. These options must function within routine practice, with measures captured as an integral part of ongoing clinical workflow. The number of physicians participating in the PQRS program will be increasing due to the impending payment adjustments in 2016. CMS is considering alterations to try to meet the varying needs of newly 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. It is essential that physicians continue to have options for receiving credit for quality measurement activities already embedded in their workflow at the local level.** CMS has expanded the recognition of registry reporting across its performance programs, as discussed below. In this spirit, **we urge CMS to use its authority to also deem other quality measurement and improvement activities as qualifying for PQRS.**

Proposed 2014 PQRS Reporting Changes: CMS proposes to increase the number of measures that must be reported via the claims and registry-based reporting mechanisms, from three to nine measures. These nine measures must cover at least three of the National Quality Strategy (NQS) domains: Patient and Family Engagement; Patient Safety; Care Coordination; Population and Public Health; Efficient Use of Healthcare Resources; and Clinical Processes/Effectiveness. CMS believes that requiring the reporting of nine measures covering three NQS domains across all of its performance programs will promote alignment and make it easier for physicians to participate in one performance program and get credit across many programs.

While the AMA appreciates the agency's efforts to further align quality measure reporting across its performance programs, increasing the current reporting requirement threefold, from three measures to nine, and covering at least three NQS domains in one program year, is an unreasonable leap and disregards the realities of the existing PQRS measure portfolio. Many specialties, especially those that are procedure-based, continue to struggle in identifying meaningful clinical quality measures to report, e.g., pathologists, urologists, and other sub-specialists. The AMA opposes the dramatic increase from three to nine measures, due to the unavailability of meaningful measures relevant to every specialty. Until development of clinically significant measures of relevance to every individual specialty, it would be contrary to the intent of the PQRS program to require every EP to report on nine measures. This will create an undue burden on their ability to provide high quality care in their clinical practice.

Recognizing CMS' desire to "raise the bar" on quality reporting, the AMA suggests employing a more thoughtful and gradual approach, which serves to increase the meaningfulness of the measures being reported, not just the quantity. For example, the number of measures that must be reported via the claims and registry-based reporting mechanisms could increase from three to five (covering up to two of the NQS domains). This would accomplish a considerable increase in the number of measures required, yet still enable the EPs to choose measures that are meaningful to their clinical practice. Further, the jump from three to nine measures in one program year, for both claims and registry reporting, ignores the potential challenges for physicians in selecting meaningful measures through an appropriate reporting modality. CMS is moving away from claims measures and towards registry and EHR capture. But it is important to point out that not all registries—including those that may qualify for the new Qualified Clinical Data Registry Option—will be able to report nine measures covering three NQS domains by January 1, 2014. Moreover, a physician may have nine measures that are relevant to his or her patient population, but these measures may only cover one or two domains, and not three. If CMS wants to raise the bar on measurement and further align reporting efforts, it should transition the reporting requirement from three to five measures. The proposed dramatic, threefold increase in one program year is not practicable and would likely lead some physicians to report on measures which are not meaningful for improving patient care.

The AMA urges CMS to undertake a study, working with the AMA-PCPI and other affected stakeholders, to better evaluate the current PQRS measure portfolio. This analysis should identify and evaluate which measures are clinically relevant to which specialty; which modality(ies) support PQRS measure reporting; the amount of effort, resources, and time needed to prepare certain measures for EHR and/or registry capture; and how many measures are available for reporting for each of the six NQS domains. This measure portfolio evaluation will help CMS, medical specialties, and measure developers identify priority areas to better focus their resources for quality measure development, testing, and implementation.

It is imperative that CMS maintain the options of reporting one measure or one measures group, or electing Administrative Claims to avoid the 2016 PQRS penalty. Since 2014 is only the second performance year for applying PQRS penalties, it behooves CMS to give physicians more flexibility in avoiding the penalty, as they 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.

Finally, the proposed rule is not clear on how the Measure-Applicability Validation (MAV) Process would apply in verifying whether a physician has reported nine measures covering three NQS domains. Historically, the MAV Process has only applied if a physician reported through claims. **The AMA requests that CMS clarify how the MAV Process will apply in evaluating whether a physician satisfactorily reported the requisite number of measures and measure domains.** It is likely that many physicians will make a good faith effort to report the relevant measures available to them, only to find out after the fact that they did not meet new measure reporting requirements because they did not have nine clinically relevant measures to report, or the nine measures they reported on did not cover at least three NQS domains. Physicians must have a clear understanding at the program's onset as to how they will be deemed successful PQRS participants. CMS may need to

create a validation process for specialties that do not believe they have measures that apply. This validation process will need to evaluate the application of other data sources, including registries and other measures groups in reporting measures under the PQRS program.

PQRS Incentives & Penalties: According to the impact table at the end of the proposed rule, CMS estimates that PQRS participation will rise incrementally to approximately 300,000 EPs in 2013 and 400,000 EPs in 2014. CMS expects to distribute 2014 incentives to approximately 270,000 (of the 4000,000) EPs, or 27 percent of the approximately 1 million total EPs. At $1,059 per EP incentive payment, the PQRS would distribute approximately $286 million in incentive payments in 2014. This reveals that PQRS participation will increase only slightly, hovering at around 40 percent. "Successful participation" is expected to be considerably lower, at less than 30 percent. Considerably more work remains in assisting physicians and other EPs with their ability to meaningfully and successfully participate in PQRS, either through traditional reporting options (EHRs, registries, or claims) or through allowing successful participation in an alternative deemed quality measurement or improvement activity.

The PQRS program cannot make a widespread and lasting impact on the quality of patient care, until there is widespread participation and acceptance across the physician community and among the vast majority of EPs. **In order to fulfill the goals of the PQRS program, CMS must maintain the current options allowing EPs to elect reporting one measure or one measures group, as well as the option to elect reporting via Administrative Claims, in order to satisfy reporting requirements and avoid the 2016 PQRS penalty.** Otherwise, PQRS participation is likely to stagnate or even decrease. **And with PQRS participation serving as the gateway for VBM participation, it is essential that CMS not create a reporting environment where over 50 percent of Medicare EPs are being penalized by two separate programs simultaneously.**

CMS finalized in the CY 2013 Medicare Physician Fee Schedule final rule several new polices for the 2014 PQRS program year. However, the CY 2014 Medicare PFS proposed rule does not reference those policies. This is a considerable source of confusion for the health care professional community. **The AMA urges CMS carefully spell out all of the finalized and proposed policies for the closest PQRS reporting year in future proposed rules.** For example, Tables 24 and 25 in the proposed 2014 rule should include those options finalized for the 2014 PQRS program, but listed in the 2013 final rule, e.g., report three claims-based measures to avoid the 2016 penalty. **The AMA also urges CMS to include a comprehensive list of the finalized measures for 2014, in the CY 2014 final rule.** It is unreasonable to shift the burden on EPs to refer to multiple resources to clarify current PQRS policies and measures, particularly given the inherent complexity of the program, and also raises a considerable risk of confusion and error in reporting.

It is also imperative that CMS work with the medical specialty and state societies on education and outreach to the physician community, regarding the differences between criteria for satisfactory reporting for 2016 PQRS payment adjustment versus qualifying for the 2014 PQRS incentive. Transparency in the differences between the criteria for satisfactory reporting for the PQRS incentive payment versus PQRS payment adjustment is crucial for increasing physician engagement in the program.

Group Practice Reporting Option (GPRO): For groups reporting individual measures via registry, CMS proposes to increase the number of measures that must be reported from three to nine, and proposes a 50 percent threshold instead of the current 80 percent threshold, as proposed for the individual satisfactory reporting criteria. **As discussed above, the AMA does not support the dramatic increase, in one calendar year, from three to nine measures for groups reporting in PQRS. We recommend a stepwise increase from three measures in 2013 to five measures in 2014 for the GPRO program, consistent with our recommendation for the claims/registry option.**

CMS proposes to use a single web site whereby a group practice may make multiple elections, such as submitting the self-nomination statement to register to participate in the PQRS GPRO, be evaluated for the PQRS GPRO using CG-CAHPS measures, and also elect quality tiering for the VBM. The AMA supports the ability of physicians and physician groups to manage their participation in the PQRS program through one web site. **In fact, moving forward, the AMA urges the agency to create one web site that would assist individual physicians and groups of physicians in managing their participation across PQRS, VBM, and the EHR Incentive Program.**

There appears to be a serious disconnection between the option for GPROs to meet PQRS and VBM requirements. Under PQRS, the threshold for reporting nine measures is 50 percent of the group cases. There is currently a 70 percent threshold for the non-GPRO option for avoiding the VBM penalty; in other words, 70 percent of individuals in a group must satisfy PQRS. As proposed, GPROs will not be able to report measures groups or report through a Qualified Clinical Data Registry (QCDR) in 2014. These two factors limit the number of measures that a specialty-specific GPRO can report. In addition, these GPROs may have trouble meeting the requirement to report nine measures covering three NQS domains, due to a lack of measures available across everyone in the group. **To address these reporting discrepancies, the AMA recommends that CMS: (1) permit GPROs to report on measures groups or through a QCDR; (2) increase the number of measures required from three to five, rather than from three to nine, covering up to two NQS domains for both registry and QCDR reporting; and (3) lower the threshold for the non-GPRO group option below the current 70 percent for avoiding the penalty pursuant to both PQRS penalty and the VBM penalty.**

These changes would increase the number of meaningful measures to report, as well as provide a more delineated opportunity for avoiding a PQRS penalty for group practices. Moreover, lowering the 70 percent threshold would encourage and allow a greater number of physicians to participate in PQRS.

Group EHR Reporting Option: In a June 14, 2013 letter to Health and Human Services Secretary Kathleen Sebelius, the AMA urged the department to further align the Physician GPRO within the EHR Meaningful Use Program (MU). Starting in 2014, group practices have the option to report quality measures at the group-level using their EHR. The single data submission could meet the clinical quality measures (CQM) reporting requirement of MU and satisfy the reporting requirements for the PQRS GPRO. The VBM program requires most large group practices to participate in the

PQRS GPRO or face a penalty. As a result, many physician groups are currently evaluating how two different group reporting options, the GPRO web Interface and the GPRO EHR, will align with the MU program. **The AMA was disappointed that more detail was not provided in the 2014 proposed rule regarding the GPRO EHR reporting option, and urges the agency to issue Frequently Asked Questions (FAQs) or a sub-regulatory guidance regarding this reporting option as soon as possible**. **In addition, we ask that for the 2014 PQRS reporting period, those physician groups electing the EHR reporting option be allowed to report CQM data only for the first quarter.**

PQRS Quality Measure Development and Updates: 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 the measure covers was determined to be an appropriate, feasible, and practical measure. **The AMA continues to support the agency's ability to use non-NQF endorsed measures in its performance programs, including PQRS.**

As in previous rules, CMS again states that there should be no special restrictions on the type or make-up of organizations developing physician quality measures. **The AMA disagrees. We support the development of quality measures through a multi-stakeholder, public and transparent process, which maintains certain processes to ensure measures are meaningful to users, uphold national standards, and harmonize with existing measures in widespread use.** Standardized measures (using standardized specifications) can be used to compare results nationally, which is especially important when there are financial penalties to consider. As the field of measure developers expands, there is an increased risk of un-harmonized measures and duplicative efforts. Providing incentives to coordinate efforts and co-produce Clinical Quality Measures (CQMs) are prudent considerations as well. **It is imperative that measure developers have the necessary expertise with CQM standards currently in use (e.g., Quality Data Model, HL7 HQMF eMeasure) and are involved in national efforts focused on the future direction of health care standards**.

For PQRS, CMS proposes to update specifications throughout the calendar year based on updates to measures as part of the NQF measure maintenance and annual update process. This proposal appears to have the potential for dramatic impact on physician reporting in PQRS, if CMS' intent is to re-publish the PQRS specifications manual to incorporate updates to measure specifications on a more frequent than annual basis. Alignment between quality measurement programs and maintenance of measures are clear priorities. However, it is not clear that this proposal will serve these purposes. These interim updates are a departure from current practice**. Prior to finalization of changes in updating specifications and measures, CMS should engage affected stakeholders, including the AMA-convened PCPI, on the mechanics and anticipated impact of the implementation of this proposal.** This must be done in a timely fashion so as to allow EHR vendors and physicians to update their own specifications for reporting.

PQRS Measures and Measures Groups: For 2014, CMS proposes to add 47 new individual measures and three measures groups to fill existing measure gaps, and to retire a number of claims-based measures to encourage reporting via registry and EHR-based reporting mechanisms. **Based**

upon what has been published in the proposed rule, the AMA would like to provide additional comments related to the AMA-PCPI measures CMS has proposed for addition, removal, and changes in reporting modalities for PQRS 2014. These comments have been broken down into relevant tables and can be found in Appendix A. With respect to the proposed removal of the claims reporting option for many measures, by several measures developers, the AMA is concerned about the impact this could have on EPs' reporting capabilities. **We encourage CMS to be transparent about a phase-out approach for claims reporting, if that is the intent for the future state of PQRS, and provide at least two years advance notice to afford EPs sufficient time to allocate resources and implement a registry or EHR, knowing if the measures they report on will have limited reporting modalities.**

CMS proposes to modify the definition of a measures group for 2014, requiring a measures group to consist of six measures, rather than four. EPs must report on all measures contained in the measures group. Increasing the number of measures in a measure group is arbitrary, and does not take into account the overall intent of a measures group—to present a relatively complete picture of patient care. As voiced by several medical specialty societies, measures that have been proposed for addition to the measures group to bring the total number of measures in the group to six are not necessarily clinically relevant to the care being provided by all specialties that may report the specific measures group.

The AMA urges CMS to only add measures to a measures group when the additional measures are substantively appropriate to the clinical topic. The increase in the minimum number of measures in a measures group from four to six appears to be arbitrary. For example, CMS proposes adding three measures to the cataract measures group, including "use of a surgical risk calculator." This measure was developed for general surgery and cannot produce a risk profile for ophthalmic surgeries. Thus, it is completely inappropriate for the cataract measures group, according to the American Academy of Ophthalmology. **CMS should work with affected stakeholders, including the AMA-convened PCPI, on appropriately developing and revising PQRS measures groups.**

PQRS Informal Review: CMS proposes allowing EPs to request informal review of the determination of whether their participation in a qualified clinical data registry was considered to be satisfactory. The AMA supports this approach.

Future of Claims-Based Reporting under PQRS: According to the 2011 PQRS and Electronic Prescribing Experience Report, approximately 72 percent of EPs (229,282 out of 320,422 EPs) participated in the program through the claims-based reporting mechanism. CMS discusses how claims-based reporting allows for the most errors compared to EHR or registry reporting. CMS seeks comment as to whether the agency should eliminate the claims-based reporting mechanism beginning with CY 2017, the reporting period for the 2019 PQRS payment adjustment. Elimination of claims-based reporting continues to be contingent upon there being an adequate number and variety of registries available and/or the continuation/expansion of the EHR reporting option. Potentially, CMS would continue to retain claims-based reporting in years after 2017 principally where claims-based reporting is the only available mechanism for certain categories of physicians to report PQRS quality measures.

As discussed above, the AMA supports the transition to registry and EHR reporting, but also encourages CMS to be cautious in how it determines to phase-out the claims-based reporting option until it is abundantly clear that all physicians understand and are able to consistently, meaningfully, and accurately capture quality measures using EHRs or registries, while meeting other CMS reporting requirements. If completely eliminating the claims-based reporting option is the ultimate goal of CMS, we encourage transparency for measure developers and EPs so they can allocate resources accordingly. Reporting of quality measures via claims, accounts for the majority of participation in PQRS. With that in mind, if individual measures and measures groups are not allowed to be reported through claims, then EPs who have not yet used a registry or EHR, due to any of a number of reasons, will have an increased burden to not only implement a registry or EHR with no experience, but also could then run the risk of failing to satisfactorily report under PQRS. **The AMA asks CMS to provide at least a two-year look ahead for EPs to be made aware of the changing reporting modalities for their relevant measures, and allow them to allocate their resources accordingly and better understand the reporting requirements for a new modality.**

CMS must also consider whether the eventual elimination of claims-based reporting would unnecessarily penalize physicians who do not own an EHR or participate in a registry because of extenuating circumstances, e.g., small, rural providers lacking digital connection. The availability of a claims-based reporting option enables most physicians to participate in PQRS without incurring the significant expense of purchasing and implementing an entirely new technology. **Transitioning away from claims-based reporting too quickly, without consideration of the small or rural provider, could inappropriately burden physicians who are making a good faith effort to report measures for quality improvement.**

Regardless of the reporting mechanism, CMS should provide developers of measures utilized in PQRS with support to carry out the crucial and time-intensive work of testing the validity and reliability of quality measures. The AMA-PCPI has extensive and unique experience in testing quality measures in various platforms, and would be a valuable resource as CMS continues to evaluate all reporting options for PQRS. **The AMA opposes elimination of the claims-based reporting option until more physicians are participating in the PQRS program using alternative reporting modalities.**

PQRS Feedback Reports: CMS is exploring ways to merge the feedback reports provided to participants in the PQRS and VBM so that an EP would receive one, merged feedback report showing reporting data for PQRS and performance data for the VBM. **The AMA supports CMS' efforts in improving the integration and timeliness of CMS feedback among the Quality Resource Use Reports (QRURs), PQRS, and VBM**. But it remains unclear just how quarterly feedback for the PQRS GPRO would be operationalized through these efforts. Thus, we ask CMS to provide additional information on how issues of patient attribution would be addressed. **In addition, we also urge CMS to work with the AMA and the Federation of Medicine on creating work groups to secure meaningful input on how best to integrate timely feedback across these programs.**

PQRS Qualified Clinical Data Registries: For 2014, CMS proposes to add a new qualified clinical data registry (QCDR) option whereby EPs report the measures used by their QCDR instead of those on the PQRS measures list. EPs would report measures with respect to all patients, including those subject to Medicare Part B. EPs would meet the criteria for satisfactory participation by reporting on at least nine measures to the registry covering at least three of the NQS domains, and report each measure for at least 50 percent of the EP's applicable patients. At least one of the measures must be an outcome measure. CMS believes that a "qualified clinical data registry" should serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data.

The 2014 requirements set out in the proposed rule for qualifying clinical data registries are too stringent, and therefore inappropriate for the initial program year. **The AMA disagrees with the very high bar CMS has established for 2014, and urges CMS to gradually incorporate the QCDR requirements listed in the proposed rule. Adopting a phased approach will help ensure that all registries—advanced, newly developed and those in the early stages of development—have an opportunity to have their data export and capture strategies aligned with CMS' efforts in recognizing registry reporting across its performance programs.** Enabling a more phased approach, as was done for vendors involved in the EHR Incentive Program, will help ensure that all registries have an opportunity to develop a reporting and transmission infrastructure capable of aligning with CMS' registry reporting options. **CMS must work directly with medical specialty registry stewards on the development and implementation of the QCDR reporting option.** It is critical that the agency avoid any unintended consequences of establishing a new reporting option that is too rigid, which would prevent a large number of physicians from receiving successful participation credit under the PQRS program.

The AMA is disappointed that the QCDR reporting option is not available to group practices under the GPRO, or for the reporting of measures groups. The AMA understands that the statute requiring implementation of the QCDR reporting option (Section 601b of the American Taxpayer Relief Act) did not explicitly list group practices. **However, we believe that the Congressional intent of this provision was to create more meaningful reporting options for *both* individual and group practices under the PQRS. Therefore, we urge CMS to reevaluate its determination for only allowing individuals to utilize the QCDR reporting option.** In addition, measure performance rates may be more statistically accurate at the group reporting level due to denominator size.

As for why QCDRs cannot report measures groups, this limitation creates one less option for physicians who want to report on a set of measures that presents a relatively complete picture of patient care. **We urge CMS to allow QCDRs to report on measures groups.**

Proposed Requirements for QCDRs: As mentioned above, the AMA urges CMS to adopt a phased approach regarding its proposed QCDR requirements. As it works on developing a phased approach, we seek clarification regarding the following proposed requirements:

1. A QCDR must demonstrate a plan to publicly report quality data. The requirements of this proposed plan are unclear. If qualified clinical data registries will be required to publicly report quality data, there must be safeguards in place that will prevent the reporting of inaccurate or incomplete data. Where will the quality data be reported? How will it be verified? What kind of communication strategy with providers will be enacted? Current experience indicates that public reporting is generally a function of more mature registries. Early phase registries are focused primarily on data collection, auditing, and reporting, which help set the foundation for public reporting. **The AMA urges CMS to work closely with both established and emerging clinical data registries to understand how a public reporting strategy can be best undertaken. It is understood that the development of such a strategy, which includes review and reconsideration processes, requires at least one year, if not more, to finalize.**

2. Should a QCDR become disqualified for submitting erroneous or inaccurate data, the entity would not be allowed to submit quality measures data on behalf of its EPs for purposes of meeting the criteria for satisfactory participation for the following year. If a registry is disqualified due to inaccurate data, it appears from the proposal that the EPs would not be considered to have successfully met criteria for satisfactory reporting. This proposal puts physicians at risk due to factors outside of their control. Physicians will select a registry that has been qualified by CMS for the purposes of PQRS reporting, and will contract with that entity at their own expense. Should a QCDR, at a later date, be disqualified, the contracted physicians will then be subject to PQRS penalties and perhaps additional negative payment adjustments. **The AMA recommends that CMS include the designation of a grace period for physicians, during which they are allowed to resubmit the measures that were disqualified. Additionally, information should be available to physicians regarding the past performance of a QCDR, including any prior disqualifications due to audits.**

3. As proposed, a QCDR must report nine measures covering three NQS domains, with one of these measures being an outcome measure. While the AMA appreciates the flexibility provided to QCDRs in selecting the measures it will capture on behalf of their members, the requirement of nine measures covering three domains is too high of a bar for the initial reporting year. For example, if a registry is currently reporting on ten measures on behalf of its members, but they only cover two domains, the QCDR will need to identify which measures and domain(s) it would like to add to its portfolio, embed these functionally in the data capture platform, test these changes, and ensure their accuracy—all by January 31, 2014, less than five months from now. **The AMA recommends that a QCDR for the initial reporting year should be required to report on only five measures covering at a minimum two measure domains.** As the program evolves and more specialty-specific measures are in use, QCDRs can further embed the functionality of reporting additional measures, covering more domains. This includes the functionality of capturing an outcome measure.

QCDRs and VBM: CMS proposes to use the quality measures data reported under PQRS to assess EPs with regard to applying the VBM in an upward, downward, and neutral adjustment to an EP's

Medicare Part B PFS charges. Therefore, CMS proposes to require that qualified clinical data registries submit quality measures data to CMS. To achieve this, the agency proposes to require QCDRs to collect and transmit the data on quality measures in one of two formats: (1) CMS approved XML format; or (2) Quality Reporting Document Architecture (QRDA) category III format**. The AMA agrees with efforts to align the data transmission standards of QCDRs with those used by other CMS reporting options. As the QCDR reporting option evolves, the data capture and transmission standards (as discussed below) should also align with the EHR Incentive Program.** CMS is also considering a proposal where the qualified registry would provide CMS with a list of the EPs (TIN/NPI combination) who participated in and reported quality data to the qualified clinical registry in order to determine which individual EPs met the criteria for satisfactory reporting. **The AMA believes that this second proposal represents a more reasonable, phased approach for the program's first year of recognizing clinical data registry participation.**

Qualifying Clinical Data Registries: As CMS moves forward in establishing a robust QCDR reporting option, the AMA urges CMS to work with the Office of the National Coordinator (ONC), so that the manner in which data quality measurement data are captured and exported can be aligned with the certification of EHR technology. We do not want to create separate, non-interoperable pathways for how physicians collect data for quality measurement/improvement and eventual public reporting. Clearly registries can do much more than just collect data for reporting on measures. However, we need to ensure that the initial years of recognition of QCDRs involve a phased approach over a reasonable period of time. **CMS should: (1) build upon experience and procedures for qualifying traditional registries; (2) allow QCDRs adequate time to meet requirements for capture and transmission of data; and (3) utilize experience gained by ONC in certifying EHR technology, e.g., CCHIT.** There is no need to reinvent the wheel regarding certification and standardization for registries. The Department of Health and Human Services (HHS) has a wealth of experience through ONC and the EHR Incentive Program, which can inform this process.

Finally, the work of developing standards and certification methods for registries *must* be done in partnership with affected specialty societies and the National Quality Registry Network (NQRN). The NQRN is a voluntary network of private and public registry stewards and other stakeholders interested in advancing the development and use of registries to measure and improve patient outcomes. The NQRN aims to disseminate registry leading practices related to data quality and standardization, measurement, operational practices, participant engagement and adherence to applicable regulations.

It is important to recognize that QCDRs provide more functionality than the traditional PQRS registry reporting option, and require significant resources to build and maintain. Due to resource constraints, the number of QCDRs that will be in operation over the coming years will be limited, compared with traditional registries.

Integration of CQMs from Hospital Inpatient Quality Reporting Program (IQR): CMS has proposed to include in PQRS several measures currently used in their inpatient quality reporting program (i.e., Emergency Department throughput time; antibiotic selection; venous

thromboembolism (VTE) care; HCAHPS). These measures may be "retooled" to apply at the individual physician level rather than the facility level, and CMS believes would provide "statistical data representing care provided by individual EPs." By including these measures, CMS is responding to feedback from hospital-based physicians who believe that PQRS measures do not adequately capture the nature of their practice. CMS is suggesting that a physician could choose to have these measures used in their PQRS reporting. **The AMA supports the proposal to allow hospital-based specialties to receive performance reporting credit for quality measures collected in the hospital inpatient setting.** We defer to the individual specialties as to which additional IQR measures should be retooled for use in PQRS. It is important to note that retooling a measure for capture in a different setting and at a different level of measurement (i.e., facility/hospital as compared to individual physician level) is not an insignificant task. **We encourage CMS to work very closely with the affected specialties to ensure careful selection of measures and a smooth process for their retooling.**

CMS also seeks comment on whether the agency should attribute the reporting periods and performance results from the hospital IQR program to individual eligible professionals or group practices that elect to have their hospital's performance scores attributed to them. The AMA defers to the individual specialties affected by this proposal on whether attributing the hospital-based quality performance to the individual physician is appropriate. **In evaluating this approach, the AMA urges CMS to consider how hospital performance on a measure would be attributed to a physician who practices in multiple hospitals treating the same condition.**

Clustering of Quality Performance for Group Practices and ACOs: CMS proposes to use a standardized method for calculating benchmark rates when a measure's performance rates are tightly clustered. Specifically, the agency will apply a methodology to reduce measure clustering, which would only apply to quality measures whose performance rates are calculated as percentiles. The methodology would not apply to measures whose performance rates are calculated as ratios, e.g., measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. CMS believes that measures whose performance rates are calculated as ratios already demonstrate a high degree of clinically meaningful differences because they are risk-adjusted to reflect the health status of the patient population being measured. The agency proposes to define a tightly clustered measure, including clinical process and outcome measures reported through the GPRO web interface and CAHPS measures, as one that demonstrates less than a 6.0 percentage point spread in performance rates between the 30th and 90th percentiles.

The AMA does not support a "spreading out" of clustered quality performance for GPROs and ACOs. A GPRO or ACO's quality performance scores should not be artificially adjusted because they are too close in range for comparison. Rather, CMS should acknowledge that many GPROs and ACOs are performing at or around the same level. Clearly, there is a minimal quality standard ACOs must meet in order to enter the realm of cost evaluation for shared savings. **The AMA urges CMS to keep the quality scoring simple and allow for improvement, rather than keeping the current bands.** While there may not be a significant spread for comparison, those entities that do perform at a relatively close level of quality performance should be recognized for their actual level of performance. Developing policies to artificially change quality performance so

that CMS can create a spread is not a fair or honest policy approach. **The AMA supports CMS using all available relevant data to accurately evaluate realistic performance.**

XIV. Electronic Health Record (EHR) Incentive Program

CMS has proposed that a QCDR may be used for reporting clinical quality measures (CQMs) for the EHR Incentive Program, within certain parameters. These include that the measures must have been finalized as CQMs under Stage 2. The EP must ensure that the selected registry is certified for the functionality for which it is intended, is a certified EHR module, and part of the Certified Electronic Heath Record Technology (CEHRT). If the data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry needs to be certified to the "capture and export" criteria. In addition, CMS intends to revisit the certification criteria with the Office of the National Coordinator for Health Information Technology (ONC) in the Stage 3 rulemaking to develop a more flexible clinical data registry reporting option and certification criteria for the EHR Incentive Program.

The AMA appreciates the agency's efforts to further recognize registry reporting across its performance programs in how clinical quality measures are captured, and supports the proposal to allow QCDRs to report CQMs for the EHR Incentive Program. This new option has major ramifications for EHR vendors, physicians, and registries. **Therefore, we urge CMS to work with these affected stakeholders to help ensure that data used for calculating quality measure performance is imported, calculated, and submitted in a manner that is standardized, transparent, and achievable over time.** Transparency around this work is critical for physicians as they select new EHRs and engage in relationships and transactions with their vendors and registries.

In response to proposals finalized in the EHR Incentive Program Stage 2 final rule, CMS invites comments on whether there would be sufficient time for EHR technology developers to update their systems and timely distribute the updated CQM versions in a way that would enable EPs to report on the updated versions.

The AMA supports the proposal to require EPs to use the most recent version of the CQM specifications, including the most recent version of the value sets published in the Value Set Authority Center (VSAC), if EPs will submit data directly to CMS. Recognizing that new health care standards may be published in the future, **it is recommended that CMS work with national standards developing organizations before applying new standards to CQMs in a CMS program. Finally, vendors and providers should be given adequate time to implement the standards so they are prepared for a successful transition to a new platform.**

XV. Value-Based Payment Modifier (VBM)

In this rule, CMS is proposing a rapid and risky expansion of the ACA-mandated value based payment modifier (VBM). If finalized, the rule would double the size of potential VBM-related penalties and more than double the number of physicians subject to the modifier in 2016. Some

491,000 physicians—58 percent of those who treat Medicare patients—in groups as small as 10 would face a two percent penalty if they did not meet minimum PQRS reporting requirements in 2014. At the same time, as detailed in the preceding section, CMS is projecting that only 40 percent of physicians will participate in PQRS in 2014 and only 27 percent will meet all the requirements for an incentive payment. Exactly how these predicted results would affect the VBM program depends on a number of variables. **Under any scenario, however, a very large percentage of physicians are likely to see both a two percent PQRS and a two percent VBM penalty in 2016. When added to a potential two percent sequester reduction, and possibly another two percent EHR penalty, this could push some older physicians to retire or close their practices to Medicare beneficiaries**. Also, by the agency's own analysis, the physicians who are most likely to face penalties tend to practice in specialties such as geriatrics and oncology that treat Medicare's sickest patients.

We understand that CMS is under pressure to push the VBM out to more and more physicians in order to meet the Congressional requirement for applying the modifier to all physicians by 2017. But we do not agree that an overly optimistic Congressional deadline is an adequate rationale for putting more than half of the nation's physicians into a giant experiment built on an untested methodology with no pause between phases to analyze results and make necessary refinements. We are concerned that this rule discounts the difficulties associated with educating hundreds of thousands of physicians about such a complex requirement and fails to appreciate the potential impact on patient care of a policy that by CMS' own projections would expose hundreds of thousands of physicians to payment cuts of four percent at a minimum. We are also troubled by the decision to expand the program before the agency has completed the refinements it is undertaking in the development of an episode grouper and risk adjustment improvements and before its proposed cost measures have ever been tested in the ambulatory setting.

The administration wisely chose to delay the ACA's employer mandate for a year rather than proceed without adequate structure and outreach. We strongly urge that the same cautionary approach be employed in the roll-out of the value modifier. **Specifically, we are opposed to: increasing the VBM penalty from one percent to two percent; mandating participation in the tiering option; and making Medicare Spending Per Beneficiary an additional cost measure. We also recommend that the modifier be required only for groups of 50 or more.** Our answer to the question of whether the VBM should be extended to solo and groups of fewer than ten physicians in 2017, based on performance in 2015, is an unequivocal "no." In fact, we are not convinced that it will ever be possible to develop a methodology that can accurately judge performance at the individual physician level for all specialties.

Size of Groups Subject to VBM: CMS proposes to expand a requirement now applicable to about 1,100 groups with a total of 216,000 physicians, to 17,000 groups with a total 491,000 physicians. There has been no time to collect, let alone assess, data on the VBM's impact on individual plans and physicians covered in the 2013 performance year. As detailed below, there are major methodological questions that have not been resolved. CMS' finding that it could attribute only 808 Medicare beneficiaries to the smallest of its 54 multi-specialty GPRO plans raises significant questions about whether even all of the groups that are currently subject to the VBM have enough Medicare patients

to ensure that cost and quality variation is truly measuring differences in performance rather than random risk. To now rush nearly 16,000 additional groups, more than half of which have fewer than 25 practitioners, into the VBM defies logic and will overwhelm CMS' ability to administer the requirement. We note, for example, that more than 10,500 groups will be eight or nine months into their first performance year before they ever see one of the confidential feedback reports that are the key ingredient in the agency's VBM outreach and education campaign. In addition, experience with prototype feedback reports released in nine states earlier this year indicates that only about a third of the reports were ever opened and in some states, the open rate was as low as 10 percent. Moving the VBM threshold down to 50 practitioners still would substantially increase the number of groups that CMS has to reach and stretch the agency's outreach efforts, but it is more reasonable than the ten practitioner threshold envisioned in the proposed rule.

Maximum VBM-Related Penalty: We understand that CMS feels the need to respond to critics who argue that the current one percent payment reduction is not large enough to force physicians to participate in PQRS and other "value-based-payment" Medicare incentives. However, we do not agree that the size of PQRS and VBM penalties is the driving factor in physicians' decisions on whether to participate in these incentive programs. Nor is it a justification for raising the maximum penalty to two percent after less than one year of experience and without the needed analysis to ensure that the VBM can meet the "first do no harm" standard. After ten years of SGR-triggered payment constraints, many physicians have neither the time nor the resources to adopt the changes required to avoid either the VBM or other penalties. **In addition, as noted above, it also is likely under the current CMS proposal that many of the practices incurring penalties based upon 2014 performance will not even know that they were subject to the program until the pay cuts occur.** It is neither fair nor fruitful to add an even higher VBM penalty to the mix when many physicians are already struggling to keep up both financially and mentally with the vast array of other new burdens such as new ICD-10 diagnosis codes, resource-intensive new EHR systems, and escalating quality measurement activities that have been imposed in recent years.

Mandatory Quality Tiering: Despite the fact that no one yet knows how a voluntary quality tiering option affected the groups included in the first phase of the modifier, CMS also is proposing to make quality tiering mandatory for all groups of ten or more practitioners. Those with fewer than 100 practitioners would be held harmless from any penalties in the 2014 performance year. However, the groups of 100+ that are already subject to VBM could incur penalties of up to two percent, suggesting that the best the newly-subject plans can expect is a one-year grace period before they too will be forced into the tiering process. By necessity, rules for the value modifier are being developed with little time for careful reflection on the validity and equity of the methodology itself nor the ultimate effects upon physician payments.

While we agree that a voluntary version of the quality tiering mechanism is a reasonable place to start, there are a variety of thorny questions that should be evaluated before it becomes mandatory. These include the use of rigid cut-off points versus a graduated scale for judging performance, as well as the application of uniform versus stratified penalties based upon size and/or other group characteristics. The need for additional refinements has also prompted a number of methodological "work-arounds" to compensate for holes in the data for some groups. For example, under the

proposed process and methodology, CMS will not have group-specific cost and/or quality data for some practices. In these cases, the practice with missing data would be placed in the "average" category (or categories) for tiering purposes and that in turn could determine whether or not the practice receives a penalty or a bonus. **We understand the circumstances that have prompted these decisions and agree they warrant trial implementation, so long as this is voluntary rather than mandatory.**

Gap Between Performance and Adjustment Years: The AMA does not believe that shortening the gap between the performance year and the adjustment year by three months is a significant improvement.

Aligning VBM with PQRS: In general, the AMA continues to support alignment between Medicare's various value-based payment incentives. As detailed in the PQRS section of these comments, however, we believe that the scope of the PQRS changes called for in the proposed rule is too drastic, especially when combined with the overly-ambitious VBM expansion that is also under consideration. On specific issues related to the intersection of PQRS and the VBM, the AMA's view is that:

- The **administrative claims measures**, as stated previously **should be retained for the purposes of avoiding a PQRS and a VBM pay cut.**

- **CMS' proposal to allow groups of physicians to avoid the VBM penalty if 70 percent of the PQRS-eligible professionals in the group participate as individuals should be extended to PQRS reporting and the threshold should be lower than 70 percent** so more groups can qualify through reporting at the individual level.

- CMS needs to provide more detail on how it plans to compare quality for the VBM based on PQRS data collected through different reporting modalities. For example, if a registry reports three PQRS measures and six non-PQRS measures, would quality for physicians participating through the registry be based only on the three PQRS measures because the measures could not be benchmarked against other participation methods? Also, how will CMS include the denominator from a measure collected by a registry for benchmarking, when the measure is being reported on all patients, not just Medicare?

- **Additional analysis and evaluation on the impact and appropriateness of combining data from various reporting modalities and measures should be conducted prior to mandating participation in the tiering option for any physicians**.

Cost and Outcome Measures: As we commented for the CY 2013 PFS proposed rule, **the AMA opposes CMS' persistent reliance on measures that were never developed for and tested in physician practices**, especially in the absence of any CMS analysis of how these measures affect different types of practices and in the context of a mandatory, rather than an optional, tiering process.

On the quality side of the VBM equation, the agency is proposing to retain three claims-based outcome measures (All Cause Hospital Readmissions and the Acute and Chronic Preventive Quality Indicator composites) that were developed for application at the community level. In the CY 2013 PFS final rule, CMS said it has re-specified the measures for use in medical groups and that it adopted them because "a substantial number of commenters from the consumer and physician value community" supported the measures. We do not agree that this meets the necessary standards for measures that have been developed with significant and transparent input from the physician community and tested for use in physician offices. **The Measures Application Partnership, whose recommendations CMS has cited elsewhere in the rule, also has recommended against including these three measures in the calculation of the value modifier** because they have not "been tested and endorsed for clinician level reporting."

For calculating costs, CMS plans to keep the five current measures (total aggregate costs and total costs for each of four conditions) and add a sixth. The new measure, with a somewhat confusing title of Medicare Spending Per Beneficiary, includes costs from three days before to 30 days after a hospital admission. CMS is proposing to use an attribution method that would include the full costs of care during the period to every group where any practitioner submitted a Medicare claim during the covered time frame. While the rule promotes this measure as a method of addressing geographic variation in the use of long term care services, the use of this measure also would enable CMS to produce cost measures for a larger number of groups. **As of the publication of the proposed rule, neither the MAP nor NQF had approved the use of this measure in the physician setting. There is a very real possibility that absent a more reliable adjustment for specialty mix, this proposal could routinely penalize certain physicians whose practices are focused on nursing home or home care or those patients who generally require some time in rehabilitation.**

Specialty Adjustment: We whole-heartedly agree with CMS' conclusion that cost data must be adjusted to account for differences in specialty mix. We appreciate the agency's effort to develop a method for making this adjustment and its acknowledgement of the concerns that the AMA and others have raised regarding the need for more granular specialty designations that would better recognize cost differences at the sub-specialty level. Unfortunately, the specialty impact table included in the discussion of this issue indicates that even with the proposed specialty adjustment, VBM penalties are likely to be concentrated in certain specialties that treat patients with multiple and/or costly conditions. **The fact that about 15 percent of geriatricians, geriatric psychiatrists, neurosurgeons and medical and surgical oncologists would be designated as "high cost" on the total aggregate costs measure suggests a systemic problem in the methodology**. As pointed out in the rule, CMS does have a process for designating additional specialties, which might lead to more sensitive and accurate adjustments. However, for a variety of reasons, a number of physicians, such as hospitalists, may not meet the current requirements for a separately designated specialty, which suggests that CMS also needs to identify other ways to recognize legitimate variation in practices even within the same specialty.

Needed Analysis and Refinements: Throughout the VBM discussion, CMS refers to the reliability of its measures and methodologies, by which it appears to mean that the measures will produce consistent results over time. What we do not know is whether the combined effect of all the measures

and methodological choices leads to a reliable and valid picture of care within an individual physician group. For example, CMS asks for comments on alternative attribution methods for the Medicare Spending Per Beneficiary measure and on proposals to designate groups without attributed costs or quality as "average." It is impossible to determine the appropriate response to these and other questions without additional information on the impact of these proposals on different specialties, geographic regions and types of practice.

Also, although we are pleased that CMS has begun testing prototype episode groupers and a modified risk adjuster with the 54 large GPRO groups, the VBM discussion glosses over the weaknesses in the current risk adjuster. Two-thirds of beneficiaries have multiple chronic conditions, and as illustrated in CMS' Chronic Conditions Chart Book, these beneficiaries have more hospitalizations, more readmissions, more physician visits and more post-acute care than those with a single condition. As currently constituted, the VBM does not recognize the impact of multiple chronic illnesses and co-morbidities and will systematically penalize physicians who tend to attract these beneficiaries due to their expertise, specialty or location.

XVI. Physician Feedback Program

The AMA greatly appreciates the efforts by CMS staff to obtain physician input on the design of the Quality and Resource Use Reports (QRURs) that will serve as the principle tool in CMS' effort to make physicians aware of the VBM and help them understand how the program is likely to affect them. We are especially pleased that the next round of reports will include additional information, including patient names, which are key to evaluating and responding to the reports' findings. We look forward to further collaboration when the new and revised reports are distributed in mid-September. However, we do want to emphasize the need for realistic expectations regarding the dissemination and uptake of the reports.

XVII. Updating Existing Standards for E-Prescribing Under Medicare Part D

The AMA supports CMS' proposal to upgrade electronic prescribing (e-prescribing) standards for the Medicare Part D prescription drug benefit program by retiring NCPDP Formulary and Benefit Standard 1.0 and adopting NCPDP Formulary Benefit Standard 3.0. The formulary and benefits standard is challenging for many physicians due to the complex and variable nature of this information. Upgrading this standard will assist physicians and help enable new e-prescribing functionalities.

While the AMA supports efforts to incentivize e-prescribing, we are concerned that certain physicians are unfairly penalized by the program. In particular, we believe that physicians who provide care to military patients, where paper prescriptions are at times required, and physicians close to retirement, may be unable to successfully participate. **We urge CMS to provide exemptions or otherwise factor in these limitations when determining successful participation in the e-prescribing program.**

XVIII. Modifier 25 Edits For Childhood Immunization and Wellness Visits

The AMA strongly urges CMS to deactivate the edits associated with the use of Modifier 25 for billing childhood immunizations and wellness visits. The AMA has a longstanding commitment to ensuring that children nationwide are immunized on schedule. This is a critical aspect of preventive health care. At the June 2013 annual meeting, the AMA House of Delegates adopted new policy (Resolution 121) supporting the deactivation of coding edits adopted by CMS under the National Correct Coding Initiative (NCCI). These edits are linked to a decrease in immunization rates among children. We urge CMS to deactivate these edits retroactive to January 1, 2013, the date on which the edits took effect. Medical societies whose members treat patients most affected by these edits, particularly pediatricians and family physicians, are extremely concerned.

Specifically, CMS released procedure-to-procedure edits on all evaluation and management (E/M) service codes (including the preventive medicine service codes, 99381-99395) when reported with all immunization administration codes (90460 and 90461 and 90471-90474). The edits have caused significant billing problems for affected physicians when billed in conjunction with well child visits even when the proper 25 modifier is included. Consequently, this is impeding access to care for children covered by Medicaid.

Physicians are particularly concerned given the attention the Office of the Inspector General has placed on the overuse of modifier 25 in the past. If CMS continues to insist that physicians use modifier 25 on claims which contain codes for both a preventive service and an immunization, affected physicians could be unduly targeted for audits. CMS has communicated to physicians that the agency will defer to states on whether the edits should be deactivated. While 13 states have said they will deactivate these edits, at least one state has said it will not.

The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with CMS to achieve resolution in each of the foregoing matters.

Sincerely,

James L. Madara, MD

Attachments

APPENDIX A: Comments on CMS Table 29 / Proposed New Measures Beginning 2014

PQRS# / NQF#	Measure Title	Measure Description	Comment
N/A / N/A	Atopic Dermatitis: Overuse: Role of Antihistamine	Percentage of patients aged 25 years or younger seen at one or more visits within a 12-month period with a diagnosis of atopic dermatitis, who did not have a diagnosis of allergic rhinitis or urticaria, who were prescribed oral nonsedating antihistamines	The AMA-PCPI does not support inclusion of this measure in the PQRS program. This measure was dropped from the measurement set after public comment, prior to the finalization of the measures. There are no current specifications for this measure.
N/A / N/A	Maternity Care: Elective Delivery or Early Induction Without Medical Indication at >= 37 and < 39 Weeks	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at =37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication	The AMA-PCPI supports inclusion of this measure in the PQRS program and would like to propose that it be adopted for EHR reporting in future program years.
N/A / N/A	Maternity Care: Post-Partum Follow-Up and Communication and Care Coordination	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning	The AMA-PCPI supports inclusion of this measure in the PQRS program and would like to propose that it be adopted for EHR reporting in future program years.
N/A / N/A	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy	Percentage of patients undergoing a total knee replacement with documented shared decision making with discussion of conservative (non-surgical) therapy (e.g., NSAIDs, analgesics, exercise, injections) prior to the procedure	These measures were developed under the PCPI's independent process. The PCPI is not a co-steward and we request to have the measure steward field updated for all of these measures to be solely "AAHKS".
N/A / N/A	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation	Percentage of patients undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	
N/A / N/A	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet	Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	
N/A / N/A	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report	Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications, including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	

N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description	Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institutions computer systems	The AMA-PCPI agrees with the inclusion of this measures group for the PQRS 2014 program. We believe this measures group will allow for reporting by radiologists who otherwise have limited measures to report on, while also addressing an important safety aspect of care.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies	Percentage of Computed Tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study	
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry	Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes	Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive	Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed	

N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	
N/A / N/A	Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis Access is a Catheter at the Time Maintenance Hemodialysis is Initiated	Percentage of patients aged 18 years and older with a diagnosis of ESRD who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is via a catheter at the time maintenance hemodialysis is initiated	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / N/A	Adult Kidney Disease: Catheter Use for Greater than or Equal to 90 Days	Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / N/A	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use)	Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / N/A	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Acute Bacterial Sinusitis (Appropriate Use)	Percentage of patients, aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, without clavulanate, as a first line antibiotic at the time of diagnosis	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / N/A	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)	Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / N/A	Adult Sinusitis: More than 1 Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse)	Percentage of patients, aged 18 years and older, with a diagnosis of chronic sinusitis who had more than one computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within a 90 day period after date of diagnosis	The AMA-PCPI agrees with the proposed addition of this measure to the 2014 PQRS program.
N/A / 1365	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk	The AMA-PCPI agrees with the proposed addition of this measure, which is also a part of the 2014 eCQMs for CMS' EHR Incentive Program, for EHR reporting in the PQRS program.

APPENDIX B: Comments on CMS Table 30 / Measures Proposed for Removal Beginning 2014

PQRS # / NQF #	Measure Title	Measure Description	Comment
86 / N/A	Hepatitis C: Antiviral Treatment Prescribed	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period	The AMA-PCPI supports the removal of this measure as it has since been retired from our measurement set. In light of the changing landscape of treatment for patients with hepatitis C and the move away from interferon-based treatment to include the use of new anti-HCV agents, the work group ultimately decided against moving forward with a measure addressing antiviral treatment.
89 / N/A	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12 months	The AMA-PCPI supports the removal of this measure as it has since been retired from our measurement set in favor of a broader measure which the AMA has put forward for consideration in CMS' Call for Measures: *Preventive Care & Screening: Unhealthy Alcohol Use: Screening & Brief Counseling* measure.
90 / N/A	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy	Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment	The AMA-PCPI supports the removal of this measure as it has since been retired from our measurement set.
173 / AQA adopted	Preventive Care and Screening: Unhealthy Alcohol Use – Screening	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	The AMA-PCPI does not agree with the proposed removal of this measure because CMS has not proposed adding a replacement measure. We urge CMS to adopt the more comprehensive measure, *Unhealthy Alcohol Use: Screening & Brief Counseling*, which we developed with the Substance Abuse & Mental Health Services Administration (SAMHSA) for the 2014 Call For Measures. The current measure should not be removed without a measure to take its place.
184 / N/A	Hepatitis C: Hepatitis B Vaccination in Patients with HCV	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	The AMA-PCPI does not agree with the proposed removal and asks CMS to reconsider. This measure is paired with PQRS #183 which remains in the program. More importantly, this measure still addresses an important aspect of care for patients with hepatitis C and should remain in PQRS.

200 / N/A	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation	Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy	The AMA-PCPI supports the removal of this measure as it was retired by the PCPI work group.
237 / 0013	Hypertension (HTN): Blood Pressure Measurement	Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded	The AMA-PCPI supports the removal of this measure as it was retired by the PCPI work group.
244 / N/A	Hypertension: Blood Pressure Management	Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12-month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more antihypertensive medications during the most recent office visit	The AMA-PCPI does not support the removal of this measure and asks CMS to reconsider, as this measure combines two important aspects of care that were previously covered by two measures since retired from PQRS.
306 / 0012	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV)	Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit	The AMA-PCPI supports the removal of this measure as it was retired by the PCPI work group.
307 / 0014	Prenatal Care: Anti-D Immune Globulin	Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation	The AMA-PCPI supports the removal of this measure as it was retired by the PCPI work group.
N/A / N/A	Chronic Wound Care: Patient Education Regarding Long-Term Compression Therapy	Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12-month reporting period	The AMA-PCPI disagrees with the proposed removal of this new measure for PQRS 2014. We believe that the addition of this measure, proposed in CY 2013 PFS final rule, adds an important aspect of care related to the other two Chronic Wound Care measures currently in the PQRS program.

APPENDIX C: Comments on Measures Proposed for Removal of Claims-Based Reporting Option

The AMA-PCPI would like to recommend that in future publications, **this list be formatted in a table similar to Tables 29 and 30.** It is more challenging to read in paragraph form due, in part, to the fact that the measure steward is not specified, nor is there consistent information provided for each measure. More importantly, however, **there appears to be a difference between the measures identified to have the claims reporting option which CMS proposes removing in the NPRM, compared with those identified during an AMA briefing call with CMS staff on August 1, 2013**. The AMA-PCPI is unable to comment on the specifics of these measures given the contradictory information provided within the NPRM and by CMS staff. We are especially concerned there may be proposals not included in the published version of the NPRM.

The AMA encourages CMS to keep a variety of reporting options available, especially due to the fact that the majority of EPs still report via claims, despite CMS' indication that claims-based reporting allows for the most errors. The claims reporting option for PQRS 2013 offers many EPs an opportunity to avoid incurring additional costs of implementing a registry or EHR. **This is a very important option for small and rural physicians, who may not have the resources to adopt either of those capabilities.** Some of the measures CMS has proposed for the removal of claims reporting (namely, PQRS #130: Documentation of Current Medications in the Medical Record) can be more broadly used by EPs who otherwise have limited measures on which to report. By removing the claims reporting option, the EP is essentially forced to adopt a new form of reporting in order to meet the requirements of reporting satisfactorily for the PQRS program.

Therefore, the AMA urges CMS to keep the reporting modality options as expanded as possible for these "broad" measures that can be reported on by the majority of physicians. We encourage CMS to be transparent about a phase-out approach for claims-based reporting, if that is the intent for the future state of PQRS, and allow EPs at least a one-year look-ahead time so they can allocate resources accordingly to implement a registry, knowing if the measures they report on will have limited reporting modalities.

Where Identified	PQRS # / NQF #	Measure Title	Measure Description	Comment
Call ONLY	6 / 0067	Coronary Artery Disease (CAD): Antiplatelet Therapy	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who were prescribed aspirin or clopidogrel	This measure was not listed in the published version of the rule. The AMA-PCPI would request additional information detailing what exactly is proposed to be changing regarding the reporting methods for this measure.
Proposed Rule & Call	53 / 0041	Asthma: Pharmacologic Therapy for Persistent Asthma – Ambulatory Care Setting	Percentage of patients aged 5 through 50 years with a diagnosis of persistent asthma and at least one medical encounter for asthma during the measurement year who were prescribed long-term control medication	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting, otherwise this increases the likelihood of reporting errors.

Proposed Rule & Call	64 / 0001	Asthma: Assessment of Asthma Control – Ambulatory Care Setting	Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk)	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting; otherwise this increases the likelihood of reporting errors.
Call ONLY	84 / 0395	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom qualitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	This measure was not listed in the published version of the rule as proposed to end the claims reporting option. The AMA-PCPI requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure. While we understand and support the agency's goal of encouraging registry and EHR reporting, we believe that the EP should retain the option of reporting on the hepatitis C measures via claims.
Call ONLY	85 / 0396	Hepatitis C: HCV Genotype Testing Prior to Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment	This measure was not listed in the published version of the rule as proposed to end the claims reporting option. The AMA-PCPI requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure. While we understand and support the agency's goal of encouraging registry and EHR reporting; we believe that the EP should retain the option of reporting on the hepatitis C measures via claims.
Proposed Rule & Call	87 / 0398	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	While we understand and support the agency's goal of encouraging registry and EHR reporting, we believe that the EP should retain the option of reporting on the hepatitis C measures via claims.
Proposed Rule ONLY	89 / 0401	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12 months	This measure is proposed for removal from PQRS 2014. The AMA-PCPI supports the removal of the measure. Therefore, it seems unnecessary to remove the claims reporting option.

Proposed Rule ONLY	90 / 0394	Hepatitis C: Counseling Regarding use of Contraception Prior to Antiviral Therapy	Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment	This measure is proposed for removal from PQRS in 2014. The AMA-PCPI supports the removal of the measure. Therefore, it seems unnecessary to remove the claims reporting option.
Call ONLY	107 / 0104	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified	This measure was not listed in the published version of the rule as proposed to end the claims reporting option. The AMA-PCPI requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure.
Proposed Rule & Call	176 / AQA Adopted	Rheumatoid Arthritis (RA): Tuberculosis Screening	Percentage of patients aged 18 years and older with a diagnosis of RA who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease modifying anti-rheumatic drug (DMARD)	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting; otherwise this increases the likelihood of reporting errors.
Proposed Rule & Call	177 / AQA Adopted	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting; otherwise this increases the likelihood of reporting errors.
Proposed Rule & Call	178 / AQA Adopted	Rheumatoid Arthritis (RA): Functional Status Assessment	Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting; otherwise this increases the likelihood of reporting errors.

Proposed Rule & Call	179 / AQA Adopted	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis	Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	The AMA is concerned that limiting the reporting modalities by removing the claims option, without detailing a phase-out approach, will put undue burden on EPs who have not adopted an alternative reporting method. We believe CMS needs to be transparent and allow for a look-ahead period so physicians can allocate resources to adopt a new form of reporting; otherwise this increases the likelihood of reporting errors.
Call ONLY	180 / AQA Adopted	Rheumatoid Arthritis (RA): Glucocorticoid Management	Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone $\geq$ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	This measure was not listed in the published version of the rule as proposed to end the claims reporting option. The AMA-PCPI requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure.
Call ONLY	183 / 0399	Hepatitis C: Hepatitis A Vaccination in Patients with HCV	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	This measure was not listed in the published version of the rule as proposed to end the claims reporting option. The AMA-PCPI requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure.
Call ONLY	197 / 0074	Coronary Artery Disease (CAD): Lipid Control	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result $\geq$ 100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin	This measure is not currently reportable via claims. Therefore, the AMA-PCPI is unsure why this was cited as having a change in reporting modalities, and requests additional information detailing what exactly is proposed to change regarding the reporting methods for this measure.

APPENDIX D: Comments on Measure Title and Description Updates from PQRS CY 2013

Below is a table comprised of the AMA-PCPI stewarded measures which we believe CMS plans to include in the 2014 PQRS program (based upon the published version of the NPRM) *and also* received updates to the measure title, description, or both. The comments below reflect the most current language for the measure, as we provided to the CMS contractor for updates from the current, 2013 PQRS program.

PQRS # / NQF #	Measure Title	Measure Description	Comment
21 / 0268	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
30 / 0269	Perioperative Care: Timing of Prophylactic Antibiotic – Administering Physician	Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures with the indications for prophylactic parenteral antibiotics for whom administration of a prophylactic parenteral antibiotic ordered has been initiated within one hour (if fluoroquinolone or vancomycin, two hours) prior to the surgical incision (or start of procedure when no incision is required)	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
31 / 0240	Stroke and Stroke Rehabilitation: Venous Thromboembolism (VTE) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage	Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered venous thromboembolism (VTE) prophylaxis the day of or the day after hospital admission	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
52 / 0102	Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy	Percentage of patients aged 18 years and older with a diagnosis of COPD who have an FEV1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator	The measure title has been updated from 2013 PQRS. The new title is listed in this table.
53 / 0047	Asthma: Pharmacologic Therapy for Persistent Asthma	Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
56 / 0232	Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Vital Signs	Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with vital signs documented and reviewed	The measure title has been updated from 2013 PQRS. The new title is listed in this table.
59 / 0096	Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Empiric Antibiotic	Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with an appropriate empiric antibiotic prescribed	The measure title has been updated from 2013 PQRS. The new title is listed in this table.
64 / 0001	Asthma: Assessment of Asthma Control	Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period for asthma control (comprising asthma impairment and asthma risk)	The measure description has been updated from 2013 PQRS. The new description is listed in this table.

81 / 0323	Adult Kidney Disease: Hemodialysis Adequacy: Solute	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥ 90 days have a spKt/V ≥ 1.2	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
83 / 0393	Hepatitis C: Confirmation of Hepatitis C Viremia	Percentage of patients aged 18 years and older who are hepatitis C antibody positive seen for an initial evaluation for whom hepatitis C virus (HCV) RNA testing was ordered or previously performed	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
84 / 0395	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12-month reporting period for whom quantitative hepatitis C virus (HCV) RNA testing was performed within 12 months prior to initiation of antiviral treatment	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
85 / 0396	Hepatitis C: HCV Genotype Testing Prior to Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12-month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
87 / 0398	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4-12 weeks after the initiation of antiviral treatment	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
102 / 0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	The measure title has been updated from 2013 PQRS. The new title is listed in this table.
104 / 0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence, receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist)	The measure title has been updated from 2013 PQRS. The new title is listed in this table.
106 / 0103	Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity	Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of major depressive disorder (MDD) with evidence that they met the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV-TR criteria for MDD AND for whom there is an assessment of depression severity during the visit in which a new diagnosis or recurrent episode was identified	The measure description has been updated from 2013 PQRS. The new description is listed in this table.

107 / 0104	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
118 / 0066	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
123 / N/A	Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL	Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy and have a hemoglobin level > 12.0 g/dL	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
173 / N/A	Preventive Care and Screening: Unhealthy Alcohol Use – Screening	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use at least once within 24 months using a systematic screening method	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
183 / 0399	Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV)	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
184 / 0400	Hepatitis C: Hepatitis B Vaccination in Patients with Hepatitis C Virus (HCV)	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B	The measure title and description have been updated from 2013 PQRS. The new title and description are listed in this table.
185 / 0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
231 / N/A	Asthma: Tobacco Use: Screening – Ambulatory Care Setting	Percentage of patients aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
232 / N/A	Asthma: Tobacco Use: Intervention - - Ambulatory Care Setting	Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were identified as tobacco users (or their primary caregiver) who received tobacco cessation intervention at least once during the one-year measurement period	The measure description has been updated from 2013 PQRS. The new description is listed in this table.

242 / N/A	Coronary Artery Disease (CAD): Symptom Management	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12-month period	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
276 / N/A	Sleep Apnea: Assessment of Sleep Symptoms	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
281 / N/A	Dementia: Cognitive Assessment	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
325 / N/A	Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions	Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
326 / 1525	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy	Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism	The measure description has been updated from 2013 PQRS. The new description is listed in this table.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description	Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems	The measure title and description have been updated from what is published in the 2014 NPRM. The new title and description are listed in this table.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies	Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study	The measure title and description have been updated from what is published in the 2014 NPRM. The new title and description are listed in this table.

N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes	Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	The measure title and description have been updated from what is published in the 2014 NPRM. The new title and description are listed in this table.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive	Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media-free, shared archive prior to an imaging study being performed	The measure title and description have been updated from what is published in the 2014 NPRM. The new title and description are listed in this table.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (eg, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	The measure title and description have been updated from what is published in the 2014 NPRM. The new title and description are listed in this table.
N/A / N/A	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry	Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements	The measure title has been updated from what is published in the 2014 NPRM. The new title is listed in this table.
N/A / N/A	Maternity Care: Elective Delivery or Early Induction Without Medical Indication at $\geq$ 37 and < 39 Weeks	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at $\geq$ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication	The measure title has been updated from what is published in the 2014 NPRM. The new title is listed in this table.
N/A / N/A	Maternity Care: Post-Partum Follow-Up and Care Coordination	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning	The measure title has been updated from what is published in the 2014 NPRM. The new title is listed in this table.