



**American Hospital
Association**

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Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1524-P, Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2012; Proposed Rule; July 1, 2011

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2012.

While we support a number of the proposed rule's provisions, including the modifications to Medicare Telehealth "Category 2" approvals, we have concerns about the expansion of the multiple procedure payment reduction, the narrowing of the definition of group practice and changes to the three physician incentive programs. In addition, we are deeply concerned that physician payments will decline by an estimated 29.5 percent on January 1, 2012 due to the flawed sustainable growth rate formula. Cuts of this magnitude are unsustainable. **We urge CMS to work with Congress to fix the physician payment formula, and to do so in a manner that does not result in reduced payments to other providers.**

MULTIPLE PROCEDURE PAYMENT REDUCTION (MPPR) FOR IMAGING SERVICES

The AHA urges CMS to withdraw its unjustified application of a MPPR to the professional component of advanced imaging services.

Beginning January 1, 2012, CMS proposes to apply a 50 percent MPPR to the professional component of advanced imaging services (computed tomography (CT) scans, magnetic



resonance imaging (MRI) and ultrasound) provided by the same practitioner to the same patient in the same session. Currently, CMS applies a 50 percent MPPR to the *technical* component for advanced diagnostic imaging services performed in a single session. The payment reduction for the professional component would affect all settings where advanced imaging services are provided, including those in hospital inpatient and outpatient departments. CMS estimates its proposal would redistribute approximately \$100 million in payments, through a small increase in the conversion factor and a small adjustment to all practice expense (PE) relative value units (RVU), and that the change would primarily reduce payments to the specialties of radiology and interventional radiology.

CMS fails to provide any data or statistical analysis supporting the expansion of the MPPR policy to the professional component of imaging services. CMS states that there are “expected efficiencies in furnishing multiple services in the same session due to duplication of physician work—primarily in the pre- and post-service periods, with smaller efficiencies in the intra-service period.” Yet CMS does not provide any data or statistical analysis to support this statement. The agency does not identify the various services physicians provide in the pre-, post- and intra-service periods, nor does it identify discrete areas of duplication. To support its proposal, CMS vaguely references the work of the American Medical Association’s (AMA) Resource Use Committee (RUC), which reviews code pairs to account for efficiencies in a bundle of services; a July 2009 Government Accountability Office report that recommended expanding the imaging MPPR policy to reflect efficiencies in physician work for certain imaging services; and a March 2010 Medicare Payment Advisory Commission (MedPAC) report that recommended exploring whether expanding the unit of payment through packaging or bundling would improve payment accuracy.

While we agree that there are efficiencies within the technical component of advanced diagnostic imaging services, it is unclear that there are significant efficiencies to be gained within the professional component. The technical component pays for staff time and equipment use. It includes such activities as greeting and gowning the patient, providing patient education, setting up an intravenous infusion and preparing and cleaning the room. It is reasonable to believe there are efficiencies involved in these services when they are delivered to the same patient in the same session. However, the professional component pays a physician to interpret the results of the diagnostic imaging test and write a report of his or her findings. It would seem reasonable that a physician would spend the same amount of time reading and interpreting, for example, a CT of a patient’s head or a CT of their abdomen. These are unique images, requiring the full concentration, analysis and expertise of the physician. It is questionable whether there are considerable cost savings and efficiencies when a radiologist interprets successive imaging studies during a single patient visit.

The professional component may have already been deliberately reduced during the AMA RUC process to take into account any efficiencies related to physician work. Last year the AMA RUC examined the work values for a series of CT codes that describe

combined services, and demonstrated that the new recommended relative values reflected the expected efficiencies gained. CMS states in the rule that it accepted the AMA RUC recommended work values for these codes, and that the values “reflected an expected efficiency for the typical combined service that paralleled the reductions that would typically result from a MPPR adjustment.” Thus, a reduction in RVUs may have already been made for certain imaging services during the RUC process to avoid duplication. An additional MPPR would significantly undervalue these services. Rather than applying a blunt 50 percent MPPR to all advanced imaging services, CMS should request that the RUC continue to review carefully services that are frequently billed together to ensure the relative values reflect any expected efficiencies.

The AHA opposes expansion of the MPPR policy to the professional component of advanced imaging services given the complete lack of data and analysis to support such a significant policy change. CMS does not explain what professional services it believes are duplicative, and fails to provide any data or analysis that identifies or justifies the actual amount of duplicability. Last year CMS proposed a 50 percent MPPR to the technical component of outpatient therapy services but adopted a 25 percent reduction in the final rule (with Congress later reducing the payment reduction to 20 percent for therapy services delivered in outpatient settings). The agency itself has acknowledged that a 50 percent MPPR may not be accurate or appropriate in all circumstances. Until the agency better justifies how a 50 percent reduction would capture the duplicate inputs it suggests are present when multiple professional services are performed on a single patient in a single session, it should drop its proposal.

In addition, CMS states that it will be aggressively exploring further expansion of the MPPR policy in CY 2013, including expanding the MPPR policy to the technical component of all imaging services, the technical component of all diagnostic tests and/or the professional component of all imaging services. **The AHA urges CMS not to expand this policy further until it performs a rigorous data analysis that supports its expansion, including determining an appropriate percentage reduction based on the percentage of efficiencies gained.**

MEDICARE TELEHEALTH SERVICES

The AHA supports CMS’s proposal to cover smoking cessation counseling via telehealth services. Currently, new telehealth services may be approved on two bases: Category 1, where the new service is similar to services currently on the telehealth list, or Category 2, where the new service is not similar to those currently on the list, but where there is evidence that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the service. CMS proposes to add smoking cessation counseling (CPT codes 99406 and 99407, HCPCS codes G0436 and G0437) to the list of approved telehealth services for CY 2012 on a Category 1 basis. CMS reasons that smoking cessation counseling is similar to the education, assessment and counseling elements of kidney disease education and medical nutrition therapy, which are currently covered telehealth services.

Beginning CY 2013, CMS proposes to change its criteria for adding services to the Medicare telehealth list. Specifically, the agency proposes to modify Category 2 so that telehealth services that meet a new “clinical benefit standard,” rather than the current “comparability standard,” may be approved. This more flexible clinical benefit standard would allow CMS to add a service to the list if the service results in a clinical benefit to the patient.

The AHA strongly supports CMS’s modification of its Category 2 approval process, which should result in an expanded list of telehealth services and better medical care for beneficiaries who might otherwise not have access to certain diagnostic or treatment services. Since the agency adopted its telehealth policy in CY 2003, only 35 services have been added to the approved Medicare telehealth list and all on a Category 1 basis. Providers have had difficulty demonstrating that the clinical outcomes of a service delivered via telehealth are comparable to the outcomes of the in-person service. Also it is not necessarily appropriate to compare a telehealth services with an in-person service, given that the alternative to the in-person service is frequently no service at all. Using a new “clinical benefit standard” rather than the current “comparability standard” should result in necessary telehealth services receiving coverage under Medicare.

BUNDLING/THREE-DAY PAYMENT WINDOW

The Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 requires that outpatient diagnostic and non-diagnostic services, other than ambulance and maintenance renal dialysis services, provided by a hospital within three days of a hospital admission be deemed related to the admission and, thus, bundled with the hospital inpatient bill unless the hospital attests that the service is unrelated to the hospital stay.

CMS clarifies in its August 1, 2011 Inpatient Prospective Payment System (IPPS) final rule that this provision also is applicable to services delivered in physician offices or clinics that are not provider-based but that are wholly owned or wholly operated by the hospital receiving the admission. The agency continues to define an entity as wholly owned by the hospital if “the hospital is the sole owner of the entity” and wholly operated by the hospital if “the hospital has exclusive responsibility for conducting and overseeing the entity’s routine operations, regardless of whether the hospital also has policymaking authority over the entity.”

In the PFS rule, CMS proposes that Medicare payments for physicians’ services subject to the three-day payment window delivered in a hospital’s wholly owned or operated physician practice would be made at the lower facility rate (rather than non-facility) beginning January 1, 2012. A new Medicare HCPCS modifier would be established through sub-regulatory guidance to identify those services to be paid at the facility rate. CMS states that the physician practice would need to manage its billing processes to ensure that it bills for its physician services appropriately when a related inpatient admission has occurred. The hospital also would be responsible for notifying the physician practice of the inpatient stay.

The AHA requests that CMS identify the hospitals and physician offices affected by this provision and make this information known and available to providers. CMS suggests that it does not know how many physician offices meet this definition of wholly owned or wholly operated, but believes it to be very few. Yet, CMS states that physician practices self-designate whether they are owned or operated by a hospital during the Medicare enrollment process on CMS form 855B. Given the financial – and potential legal – implications of this policy, it will be critical to ensure CMS’s information is as accurate and up-to-date as possible. We urge CMS to set up as quickly as possible a mechanism, website or other avenue to identify whether a physician practice is wholly owned or wholly operated by a hospital, and to associate the practice with its affiliated hospital. In addition, hospitals and physicians must have the opportunity to review and validate these data prior to CMS implementing payment adjustments based on this information.

We urge CMS to extend the start date of this provision by one year to January 1, 2013. The AHA is concerned that hospitals and physician practices will not be able to implement this provision by January 1. Currently, most hospitals and physicians billing systems are not interconnected and, thus, do not “talk” to one another or share patient information. Hospitals do not have the appropriate communications systems in place to easily identify whether a patient was seen at a physician’s office (even if it is one wholly owned or wholly operated by the hospital) prior to a hospital admission and, importantly, whether that visit was indeed related to the patient’s inpatient stay. It will be challenging, if not impossible, for hospitals to set up the registration and billing systems necessary to appropriately comply with this provision. In addition, we question whether CMS will be able to correctly identify those physicians and hospitals to which this provision would apply by January 1, 2012.

PHYSICIAN QUALITY REPORTING SYSTEM (PQRS)

When CMS established a national quality reporting system for physicians, it chose to test many different reporting mechanisms and offer a variety of measures from which eligible professionals (EPs) could choose. Now that CMS is moving into the fifth year of the program and intends to use PQRS as the basis for physician value-based purchasing (VBP), it is no longer appropriate to use this approach and it must make strides to move toward a more comprehensive method of standard data collection.

We support CMS’s proposal toward establishing a core measure set for EPs, and we urge CMS to move more rapidly down this path. Because CMS is intending to use the data submitted from PQRS in the physician value-based modifier or physician VBP program, it is advantageous to require more robust core measure reporting. We urge CMS to learn from the process that has allowed for seamless transition from a pay-for-reporting program into hospital value-based purchasing. From the outset of the hospital pay-for-reporting program, core measures were required and have facilitated the transition to a VBP program, this October. We encourage CMS to consider a core measure set that is required for reporting by *all* EPs. CMS must articulate a clear vision and measurement framework

that will ease the transition from the current disjointed “choice” approach into a comprehensive database of quality measures that can produce statistically reliable differentiations that will be used to adjust payment in the physician VBP program.

As a first step toward a core measure set, CMS has proposed reporting one cardiovascular prevention measure from among a core set of seven measures that must be reported by four medical specialties – internal medicine, family practice, general practice and cardiology. Though the seven measures that CMS has proposed within this core measure set may need to be altered over time, this is a step in the right direction. As such, **we support CMS’s proposal to require submission of one cardiovascular prevention core measure** for the specialties included above.

Definition of Group Practice. **The AHA does not support CMS’s proposed change to the definition of group practice.** According to CMS data, of the four options available to EPs submitting measures into the PQRS, the group reporting option yields the fewest errors and is the most user-friendly method of data submission. For the CY 2011 PQRS program, CMS recognized two different types of group practices; those with 2-199 EPs and those with 200 or more EPs. Both types of group practices were eligible to use the group reporting option to participate in PQRS. For the CY 2012 PQRS program, CMS is proposing a new definition of group practices, using only one definition of a group practice that includes 25 or more EPs.

In proposing this new definition of group practice, CMS will put group practices with two-24 EPs at a distinct disadvantage by forcing those EPs into the more complicated reporting alternative. CMS does not demonstrate any empirical evidence to justify this definitional change. We urge CMS to allow any group practice with two or more EPs the option to report to PQRS through the group practice reporting tool. If CMS still intends to remove the group practice reporting option for group practices with fewer than 25 EPs, we urge CMS to exercise maximum transparency by estimating the impact of removing the option because we believe it will increase the burden placed on these EPs by forcing them into claims-based or registry reporting.

Eligible Professionals Primarily Practicing in Hospital Settings. **We encourage CMS to form a technical expert panel of practicing hospital-based EPs to seek advice on how PQRS can be more responsive to the non-surgical medical care delivered in inpatient hospitals.** According to the AHA annual survey, more than 200,000 thousand EPs are employed by hospitals and therefore primarily deliver medical care within an inpatient or hospital setting. These 200,000 EPs represent more than 25 percent of professionals eligible to participate in PQRS, and we urge CMS to pursue options on how PQRS can be tailored to these EPs. Despite the fact that there are more than 200 measures that EPs can choose from, the available measures fail to address the critical steps in care, such as management of airway passages, that are provided in the inpatient setting by EPs, such as hospitalists or intensivists. A technical expert panel of hospital-based EPs can work with CMS to identify the critical steps in inpatient care and help to align existing measures or create new measures. The technical expert panel also should consider how the current

measures used in the Inpatient Quality Reporting (IQR) program can be used as a proxy for the performance of hospital-based EPs.

PHYSICIAN COMPARE

Aligning eligible professionals with hospitals and health systems is important to the success of our members and an essential strategy to enhance seamless clinical integration. As such, we are eager for quality tools such as *Physician Compare* to enhance hospital and physician integration. We urge CMS to clarify how the group practice data displayed on *Physician Compare* will reflect the performance of the more than 200,000 EPs who are employed in hospitals and health systems. It is important for both consumers and providers to have easy access to information that illustrates the affiliations that EPs have with hospitals and health systems. *Physician Compare* is a tool that can provide such information.

PHYSICIAN FEEDBACK PROGRAM

In the Physician Feedback Program, CMS is working with a contractor to develop confidential feedback reports for EPs that illustrate the performance on both cost of care and quality measures. CMS has sent sample reports to a select number of group practices (36) and the individual EPs within each group practice. CMS intends to distribute additional feedback reports in the fall of this year and will be using data from the group practice reporting option in the PQRS program (as discussed above). For the reports that CMS is planning to send out this fall, CMS is targeting 28 quality measures, of which 26 are endorsed by the National Quality Forum (NQF). For 2011 and all future years of the feedback program, **we urge CMS to use only NQF-endorsed measures.**

In addition, CMS is including five Medicare spending per beneficiary efficiency measures in this report. None of these measures is NQF-endorsed. We encourage CMS to closely monitor the current endorsement project NQF has opened for efficiency measures. **We urge CMS to submit its efficiency measures to the NQF.** It is likely that NQF will produce several endorsed efficiency measures under this project by the end of 2011. As a result of this pending endorsement, CMS may find itself using efficiency measures in a national program that are not endorsed when several other viable candidate measures are endorsed and available. In order to avoid this potential situation, we provide additional information on the NQF and the efficiency measure endorsement project.

Government Funding of the NQF. *The Medicare Improvements for Patients and Providers Act* (MIPPA) directs the Secretary of Health and Human Services (HHS) to identify and have in effect a contract with a consensus-based entity, such as the NQF, to provide for the endorsement of standardized health care performance measures. In response to MIPPA, the Department of HHS entered into a four-year, \$40 million contract with NQF to endorse measures. In consultation with CMS, HHS had NQF launch a steering committee of experts to achieve consensus around endorsing an inaugural set of efficiency measures.

Because CMS has been a noticeably absent stakeholder during the work of the efficiency committee, we have summarized the progress of the committee below.

NQF Steering Committee on Efficiency Measures. In December 2009, NQF called for nominations for a Resource Use Steering Committee. Since endorsing efficiency measures is a new effort for the NQF, the steering committee developed a [white paper](#) to establish principles on what is necessary for measuring the cost of care. The steering committee also created an alternative set of criteria by which to evaluate efficiency measures, recognizing the difference between these measures from the traditional quality measures that NQF more routinely reviews.

Once the broad evaluation aspects were established, the NQF recognized that the steering committee would need additional support reviewing the initial set of 38 per capita and episode-based efficiency measures. Therefore, the NQF established four detailed Technical Advisory Panels (TAPs) for cardiovascular/diabetes, cancer, bone/joint and pulmonary clinical areas. These TAPs have extensively reviewed efficiency measures pertaining to each condition and made detailed recommendations to inform the steering committee's review. In the future, NQF intends to launch additional condition-specific TAPs in relevant clinical areas.

The steering committee has reviewed the following five per capita efficiency measures:

1. Relative Resource Use for People with Diabetes – Measure Developer: National Committee for Quality Assurance (NCQA)
2. Relative Resource Use for People with Cardiovascular Disease – Measure Developer: NCQA
3. Total Cost of Care and Resource Use Population Per Member Per Month (PMPM) Index – Measure Developer: Health Partners
4. Total Cost of Care PMPM Index – Measure Developer: Health Partners
5. Episode Treatment Group (ETG) Based non-Condition Specific Resource Use – Measure Developer: Ingenix

As we noted above, if CMS continues to use its proposed per capita measures CMS may find itself using efficiency measures in a national program that are not endorsed when several other viable candidate measures are endorsed and available. **Using non-endorsed measures is not a viable option and, therefore, CMS must choose between using the measures listed above or submitting its measures to the NQF for review.**

Minimum Sample of Patients for Efficiency Measure Attribution. **We urge CMS to provide empirical justification, by publicly releasing analytic results, for the minimum threshold of cases needed to derive a consistent rate of reliability for all measures used in VBP programs.** In the proposed rule, CMS states that it includes an efficiency measure in both the group practice and individual reports if the measure is able to be populated for 30 or more patients. CMS also states that: “this threshold is commonly used for attribution purposes.”

We ask CMS to provide references that empirically support this minimum. Further, it is incumbent upon CMS to harmonize methodologies, such as the establishment of minimum thresholds, across its various VBP programs. One way in which CMS can do this is to establish a rate of reliability that a measure must achieve in order to ensure the measure is statistically accurate. There is a variety of conflicting research on what rate of reliability is needed. Therefore, it is incumbent upon CMS to consult experts and then obtain comment from the public prior to finalizing a rate of reliability. Once a rate is established, then CMS must conduct further research on what minimum threshold of cases (whether it be patients or claims) is appropriate in order to attain the rate. **It is incumbent upon CMS to make all of this research available to the public for review.** Currently, CMS has established the following minimum thresholds for measures used in its VBP programs:

- 30 patients for efficiency measures in the physician feedback program;
- 25 patients for the public reporting of quality measures reported on *Hospital Compare*;
- 11 patients for the ESRD Quality Incentive Program (*proposed*);
- 10 patients for clinical process of care measures in hospital VBP;
- Three patients for the patient safety composites in hospital VBP (*proposed*);
- One claim for the hospital-acquired conditions rates in hospital VBP (*proposed*).

While these measures are currently tied to payment now, or soon will be, CMS has not done its due diligence to ensure these measures are producing statistically reliable information. CMS must rectify this immediately. In the absence of disclosing its research results on reliability rates, we are unable to assess the appropriate number for a minimum sample of patients for efficiency measure attribution.

PHYSICIAN VALUE-BASED MODIFIER (VALUE-BASED PURCHASING)

The Patient Protection and Affordable Care Act (ACA) requires CMS to adopt a budget-neutral value-based payment modifier for physicians by January 2015. In advance of the beginning of this physician VBP program, CMS also is required to finalize a list of measures it intends to use in the program by January 2012. CMS has proposed 62 quality measures and five efficiency measures for the physician VBP program. Among the 62 quality measures proposed, 56 are NQF-endorsed. Among the five efficiency measures proposed, none is NQF-endorsed. **We urge CMS to only use NQF-endorsed measures in the physician VBP program.**

Timeliness of Data Submission. **We urge CMS to assign beneficiaries to group practices on a quarterly basis.** The majority of the quality measures proposed are the same measures that eligible professionals will be submitting through the group practice reporting option under the PQRS program. This reporting option relies upon retrospective data submission that occurs more than a full calendar year after care has been delivered. The time lag between care delivery and measure submission is excessive. The majority of the time lag is due to CMS assigning beneficiaries to group practices only once per year.

Rather than waiting until the end of the calendar year to assign beneficiaries, quarterly assignment would facilitate the submission and tracking of beneficiaries and allow group practices to manage care rather than simply audit care delivery on an annual basis.

Full Calendar Year Per Capita Measures. **We urge CMS to consider how per capita measures should be applied to hospital-based professionals as a separate and distinct measurement population.** All of the proposed per capita efficiency measures include a full calendar year of data for each assigned beneficiary. As we note above, more than 25 percent of eligible professionals deliver medical care in an inpatient or hospital setting. Additionally, we urge CMS to align any hospital-based EP per capita measures with the per capita measure recently finalized in CMS's inpatient quality reporting program. It is incumbent upon CMS to ensure measure alignment across its various VBP programs. Specifically, the number of days used in the hospital per capita measure should be consistent with the number of days used in hospital-based EP per capita measures. **Since CMS has finalized a 30-day per capita measure for hospitals, we urge CMS to include a similar 30-day per capita measure for hospital-based EPs.** Further, we have previously urged CMS to consider per capita measures that end no later than 15 days post-discharge for hospitals and we continue to support this timeframe. We also note that these comments on measure alignment are also applicable to CMS's request for comments on how the physician VBP program can be responsive to "system-based care."

Hospital-based Physician Notification of Unscheduled Admissions. CMS did not make any measure proposals that specifically address coordination of care for the physician VBP program, but it did solicit comments on a measure concept that aims to bridge what it defines as a gap in coordination between hospital-based EP management of care and non-hospital-based management of care. From CMS's description, it appears that this concept would require a hospital-based EP to notify a patient's primary care provider when an unscheduled admission has occurred. We encourage CMS to make the detailed measure specification for this concept available, so we can confirm that we are interpreting CMS's intent properly.

Though we fully support the use of care coordination measures, this concept requires a level of coordination that may only be found in highly integrated care systems such as accountable care organizations (ACO) or comprehensive medical homes. Therefore, this measure concept is inappropriate for the physician VBP program. This concept assumes that the majority of patients have a primary care provider, which unfortunately is not an accurate assumption. Because patients often do not have a primary care provider, we are having difficulty conceptualizing how this concept will operate in practice. In order for a hospital-based EP to be able to notify a primary care provider of an unscheduled admission, the hospital-based EP would need to know who the primary care provider is and how to contact him/her.

Further, only an entity with access to significant data would be able to coordinate this level of care. The only entities that have such access to data are private health insurance plans and CMS. Since CMS has identified this concept as an important gap in care, we urge

CMS to implement a system where it notifies providers about unscheduled admissions. We have recommended that CMS create such a notification system for providers, such as ACOs. We note that several large insurance companies have fairly sophisticated notification systems in place, which demonstrates proof of concept.

Implementation of physician VBP. We urge CMS to implement physician VBP for non-hospital-based eligible professionals in the early phases of implementation. In the proposed rule, CMS states:

Section 1848(p)(4)(B)(iii) of the Act requires that the Secretary apply the value modifier for items and services furnished beginning on January 1, 2015, with respect to specified physicians and groups of physicians, and not later than January 1, 2017, with respect to all physicians and groups of physicians.

This provision permits CMS to implement physician VBP in phases. Because CMS is allowed this flexibility, it has a critical decision to make on which group of EPs should be included in the early phases of implementation. **Given that CMS has proposed to base physician VBP largely on the existing PQRS program and we have noted that the current PQRS program is not responsive to the non-surgical medical care delivered in inpatient hospitals by hospitalists and intensivists, we urge CMS to include hospital-based EPs into physician VBP in the later phases of implementation.** Only after CMS is able to seek feedback from a technical expert panel of practicing hospital-based EPs (as mentioned in the PQRS section above) will it be appropriate to include hospital-based EPs in physician VBP.

MEDICARE ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM

CMS proposes changes to the regulations governing the Medicare and Medicaid EHR Incentive Programs for 2012, particularly requirements for physicians and other EPs to report on specific clinical quality measures (CQMs). The AHA has concerns about automated quality reporting under Stage 1 of Meaningful Use, as well as specific comments on the proposed pilot.

Automated Quality Reporting. Automated quality reporting has clear benefits, including efficient measurement, real-time results and the potential to include whole populations in measure calculations, as well as the ability to easily look at sub-groups. To be useable, however, automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Early experience in Stage 1 of meaningful use indicates that the current approach to automated quality reporting will not deliver on that promise. Providers and vendors have encountered significant issues with the e-specifications, which contain known errors and were never field tested. In addition, the existing CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than the Stage 1 requirements and not in common use. Further, the certification process for EHRs specifically does *not* include testing the accuracy of the embedded measure calculations.

The AHA urges CMS to conduct a pilot program to field-test the measures used in the EHR incentive program and the ability of vendors and providers to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR. In addition, CMS should establish a clear process to manage updates to specifications for quality measures, and a mechanism for vendors and providers to provide feedback on problematic or unclear measures. Our comment letter on the Proposed Rule for the 2012 Outpatient PPS provides additional detailed information on how such a pilot might be conducted and the process needed to ensure the success of automated quality reporting.

Comments on the Proposed Electronic Reporting Pilot. For those physicians and other EPs voluntarily participating in the Medicare EHR Incentive Program, CMS proposes to have in 2012, EPs continue to use a web-based attestation to report CQM data generated by a certified EHR, rather than reporting the CQMs to CMS electronically directly from the EHR. The six required measures would not change.

In addition, CMS proposes to begin a voluntary PQRS-Medicare EHR Incentive Pilot in 2012 to test automated reporting of CQM using certified EHR technology. The same quality measures would be used in the pilot. However, the actual data submitted to CMS would be different. CMS proposes that rather than submitting summary data (numerator, denominator and exclusions), as currently required, EPs participating in the pilot would submit a full year of Medicare patient-level data from which CMS would calculate the CQM results itself using a uniform calculation process. CMS proposes that EPs can fulfill their CQM reporting requirements under meaningful use by participating in the pilot. Participation could delay when EPs receive their incentive payment if they are in their first payment year for meaningful use, because CMS proposes to collect 12 months of CQM data from those participating in the pilot, rather than the 90 days of data required for the first year of meaningful use.

The pilot test also would involve use of data transmission standards other than those currently supported by certified EHRs because CMS has concluded that “it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry content exchange standards as required for certified EHR technology.” CMS anticipates that the pilot will instead test use of the Health Level Seven (HL7) standard Level 1 Quality Report Document Architecture (QRDA), which has been developed to support reporting on quality data from EHRs. **We ask CMS to work with the Office of the National Coordinator for Health Information Technology to remove the PQRI 2009 Registry content exchange standards from the certification requirements, as they will not be used.**

The AHA appreciates and supports the proposed pilot project to test a new standard for transmission of automated clinical quality data from EHRs. However, we urge CMS to give eligible professionals a choice of how to meet their meaningful use quality reporting requirements - through attestation, through participation in the pilot or both attestation and

participation in the pilot. We note that the pilot proposed for eligible hospitals allows these choices. This policy is especially important in 2012, when almost all eligible professionals who attest will be in their first year of participation in the EHR incentive program, with a 90-day reporting period. A pilot program that required EPs in their first year of the program to report a full-year of data for the quality measures would delay their receipt of incentive payments by up to nine months and significantly discourage participation in the pilot. The agency may, in fact, want to consider going one step further, and allow EPs to participate in the pilot program even if they are not ready to attest to meaningful use in 2012.

While the AHA supports the pilot concept, we have significant concerns about the proposal presented. The pilot, as described, would collect large volumes of Medicare patient-level data from EPs, rather than collecting measure data (e.g., numerators, denominators and exclusions). This approach breaks from a number of principles for quality measurement.

First, we urge CMS to structure any quality reporting pilot in a manner that focuses on the ability of EHRs to provide real-time measurement data to hospitals and physicians. We are concerned that the pilot program puts forward an approach that takes away a key benefit of quality measurement through EHRs – real-time data on performance. If quality measures are calculated by the individual EP using an EHR, then results can be presented to clinicians immediately, tracked on an ongoing basis and used to support quality improvement activities. If instead the EP sends patient-level data to CMS for measure calculation and then waits for the agency to provide feedback on performance, the data become much less timely and less useful for ongoing quality improvement efforts.

Second, we recommend that CMS focus on the collection of measure data (numerator, denominator and exclusions), not patient-level data. We are concerned about the volume of data that CMS is proposing to collect, particularly if it is brought to a national scale after the conclusion of the pilot. Creating an analytic file that has the full patient records for all of those patients who are to be included in a given quality measure, such as all patients age 18 to 75 with diabetes, will take considerable resources to generate. We also question whether CMS has the capacity to receive and analyze the full set of these large data files across hundreds of thousands of EPs. Providers, however, should have the choice to work with private-sector intermediaries to generate measure data elements if they choose to work with third-party vendors to abstract information from electronic data sources.

CMS has not previously received such large amounts of protected health information from providers, and we are concerned about the potential risks to the security of patient data. In fact, under current quality reporting programs for hospitals, CMS does not receive any patient-level data. Under the Inpatient Quality Reporting program, hospitals submit data to a Quality Improvement Organization (QIO) clinical data warehouse. The QIO warehouse serves as a third-party vendor to transmit performance on quality measures to CMS. QIO data are protected by law and therefore CMS does not directly access any patient-level data.

ELECTRONIC PRESCRIBING (eRx) INCENTIVE PROGRAM

In 2008, Congress established an electronic prescribing (e-Rx) incentive program to reward EPs, including qualifying physicians and group practices, for generating and transmitting prescriptions and prescription-related information electronically. Successful e-prescribers may earn an incentive payment of 1.0 percent of their total allowed charges for Medicare Part B PFS services for 2011 and 2012. This incentive payment drops to 0.5 percent in 2013. Beginning in 2012, eligible professionals who do not successfully participate in the eRx program will receive a payment penalty of 1.0 percent. This penalty increases to 1.5 percent in 2013 and 2.0 percent in 2014. No eRx incentive payments are authorized beyond 2014.

Eligibility. As in prior years, CMS proposes to allow EPs to participate in the eRx program as an individual eligible professional or as part of a group practice (eRx GPRO). Group practices must “self-nominate” for each year they wish to participate in the eRx GPRO, and identify which reporting mechanism they will use (claims, qualified registry or qualified EHR). Beginning January 1, 2012, CMS proposes to modify its definition of “group practice” for the eRx GPRO to be consistent with the modification it proposes for the 2012 PQRS, specifically to define group practices as those with at least 25 or more eligible professionals. **The AHA is concerned that this change in the definition of group practice may result in fewer EPs participating in the eRx GPRO.** About half of all physicians practicing in a group do so in one that has between three and 25 physicians. This change will require the vast number of physicians to participate in the eRx program as individual EPs, which may result in fewer physicians participating in the eRx program.

“Qualified” e-Prescribing Systems. In order to meet the requirements of the e-Prescribing Incentive Program, EPs must have a “qualified” e-prescribing system that meets four functionalities:

- Generates a complete active medication list, incorporating data received from applicable pharmacies and pharmacy benefit managers;
- Allows EPs to select medications, print prescriptions, electronically transmit prescriptions and conduct alerts (such as drug-drug interactions);
- Provides information related to lower cost, therapeutically appropriate alternatives if they exist; and
- Provides information on formulary or tiered formulary medications, patient eligibility and authorization requirements received electronically from the patient’s drug plan.

On July 1, 2011, CMS published a proposed rule with changes to the 2011 eRx Incentive Program. In that rule, CMS proposed to expand its definition of a “qualified” e-prescribing system to recognize adoption of certified EHR technology as a “qualified” system under the eRx program for the 2011 payment incentive. Thus, CMS proposed that

EPs would either have a qualified e-prescribing system that meets the four functionalities above or have a certified EHR.

In this rule, CMS proposes to include certified EHR technology as a qualified system for the 2012 and 2013 reporting periods. **The AHA supports greater alignment between the e-Prescribing and EHR incentive programs. We strongly support CMS's proposals to revise the 2011, 2012 and 2013 e-prescribing measure to allow EPs to meet the requirements for a qualified e-prescribing system if the e-prescribing component is part of a certified EHR.**

Reporting Periods. CMS proposes to use the 12-month period of January 1, 2012 – December 31, 2012 to determine the 2012 eRx incentive, and the 12-month period of January 1, 2013 – December 31, 2013 to determine the 2013 eRx incentive. **The AHA supports using the entire calendar year period to determine that year's payment incentive.**

For the 2012 payment penalty, CMS proposes to use the six-month period of January 1, 2011 – June 30, 2011 to determine the 2012 eRx payment adjustment. **The AHA urges CMS to determine the eRx payment adjustment based on a full year of 2011 data, which would allow more EPs to meet the requirement.** We are perplexed as to why CMS would allow EPs the entire year to qualify for the bonus payment, yet only half the year to avoid the payment penalty. We urge CMS to review all 2011 e-prescribing activity before assessing any penalties in 2012.

For the 2013 and 2014 payment penalty, CMS proposes two different reporting periods. For 2013, in addition to the 12-month reporting period of CY 2011 that CMS finalized in its 2011 PFS final rule, CMS proposes an additional six-month reporting period of January 1, 2012 – June 30, 2012. For 2014, CMS proposes only the six-month reporting option of January 1, 2013 – June 30, 2013. **The AHA appreciates the additional six-month time period, but continues to urge CMS to review all CY 2012 and CY 2013 e-prescribing activity (not just the first six-months) before assessing penalties in 2012 and 2013.**

Establishing two separate reporting periods makes the program more complex and administratively burdensome. We recommend that CMS streamline and simplify its reporting periods so that a full year of data is used to calculate both the payment incentive and the payment penalty. For example, CMS would examine the e-prescribing activity for January 1, 2012 – December 30, 2012 to determine whether EPs would receive an e-prescribing 2012 incentive payment or would be subject to a 2012 payment penalty.

Significant Hardship Exemptions. For the purposes of the 2013 and 2014 payment adjustment, CMS proposes to provide significant hardship exemption categories for professionals who:

- Practice in a rural area with limited high-speed Internet access;
- Practice in an area with limited available pharmacies for e-prescribing;
- Are unable to electronically prescribe due to local, state or federal law; or

- Prescribe fewer than 100 prescriptions during a six-month, payment adjustment reporting period.

The AHA urges CMS to include a significant hardship exemption to eligible professionals who are in the process of adopting EHR technology and who will have an EHR in place by October 2012 or 2013 for purposes of the 2013 and 2014 payment adjustment. In its July 1, 2011 proposed rule with changes to the 2011 eRx Incentive Program, CMS proposed a hardship exemption category for the 2012 e-prescribing payment adjustment for EPs who register to participate in the Medicare or Medicaid EHR incentive programs and adopt certified EHR technology. We urge CMS to continue to allow this hardship exemption category. Thus, EPs who register for either the Medicare or Medicaid EHR incentive program and provide identifying information for the certified EHR technology that has been adopted for use by October 1, 2012 or October 1, 2013 would be eligible to apply and be exempt from the 2013 and 2014 e-prescribing penalty, even if they have not yet reported the required e-prescribing events. Note that under the Medicare EHR program, EPs have until October 1, 2014 to adopt EHR technology and still receive incentive payments.

HOSPITAL DISCHARGE CARE COORDINATION

While CMS is not proposing any changes at this time, the agency solicits broad public comment on how to improve physician care coordination within the statutory structure for physician payment and quality reporting, particularly for a beneficiary's transition from the hospital to the community. The AHA applauds CMS for acknowledging the critical importance of care transitions, especially from the hospital back into the community, as a means of achieving better health, better health care and greater efficiency. This is also a topic of great interest to our members given that hospitals will be penalized for higher-than-expected readmission rates beginning October 1, 2012.

The AHA urges CMS to examine care coordination comprehensively, and consider whether all payment systems need to be adjusted to better reflect the extra resources required to ensure smooth care transitions for patients. As the average hospital stay decreases, the role of the hospital discharge planning process has become more critical and complex. In fact, hospital discharge planning now begins the day the patient is admitted to the hospital, and for many elective admissions it actually begins well before the patient is hospitalized. While physicians have an important role in discharge planning, so do the nurses, clinical nurse specialists, case managers, social workers and others who work in hospitals and other provider settings. Nurses and other care providers have substantially increased the number of tasks they perform to ensure safer, more effective patient transitions between care settings.

Discharge planning is the work of an interdisciplinary team, including physicians and members of the hospital staff, who together perform the following critical functions:

- Risk screen patients/identify discharge barriers;

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- Establish communication with the primary care physician, family and home care;
- Educate patient/caregiver about his/her diagnosis and care;
- Coordinate patient care across the multidisciplinary care team;
- Implement comprehensive discharge planning, including identification of alternative care settings, such as post acute care, nursing home, or home care;
- Promote patient self-management;
- Perform medication reconciliation;
- Teach “red flags” of the patient’s respective disease;
- Fax discharge orders and other information to the community physician if known;
- Schedule and prepare a patient’s follow-up appointment with the community physician or hospital clinic;
- Facilitate discharge to post acute care, nursing home or home care, with detailed discharge instructions;
- Follow-up with the patient via telephone; and
- Reach out to community services for the patient if needed.

These important tasks contribute enormously to a patient’s successful recovery, and are deserving of recognition in CMS’s various provider payment systems. We urge CMS to take a comprehensive view of what is involved in successful care transitions as the agency considers appropriate changes in payment for all providers.

If you have any questions, please feel free to contact me or Ashley Thompson, director of policy, at (202) 626-2688 or athompson@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President