



August 24, 2010

Submitted Electronically

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule; CMS-1503-P

Dear Administrator Berwick:

The American College of Radiology (ACR), representing more than 37,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed changes to the 2011 Medicare Physician Fee Schedule (MPFS) on the Physician Quality Reporting Initiative (PQRI), the physician feedback program, maintenance of certification program (MOCP) and electronic health record (EHR) reporting.

The American College of Radiology (ACR) remains committed to quality care for Medicare beneficiaries and welcomes the opportunity to work with CMS on the Physician Quality Reporting Initiative (PQRI) and any future Pay for Performance (P4P) initiatives mandated by Congress and enacted by the Agency. This commitment is an extension of existing ACR programs including: Appropriateness Criteria, Modality Accreditation Programs, educational resources and a strong relationship with the American Board of Radiology (ABR), a member of the American Board of Medical Specialties (ABMS).

It is our sincere hope that the important role of radiologists and imaging in patient care will be recognized through the PQRI program. Specifically, we wish to work with CMS to ensure that appropriate measures are available for radiology services through claims-based, registry-based and MOC-based reporting. We also look forward to working with CMS to make certain that radiology's role is acknowledged in future payment models

including those involving bundled episodes of care and the application of the proposed budget neutral payment modifier.

Section V. B.: Provisions of the Affordable Care Act (ACA) Section 3003: Improvements to Physician Feedback Program (RUR) and Section 3007, Value-Based Payment Modifier under the PFS (pg 268 of MPFS PR)

Physician Resource Use Measurement and Reporting Program (RUR)

Phased implementation continues

- Future phases of the feedback reports will include distribution to increasing numbers of groups/physicians, such that every Medicare practitioner will receive a report prior to implementation of the payment modifier.
- ACA requires, in addition to confidential feedback reports to physicians on resource use (RU), in 2012 to provide reports comparing patterns of RU of individual physicians. ACA also requires
 - Application of a separate, budget-neutral payment modifier to FFS schedule, phased in 2015 through 2017,
 - Modifier provides differential payment to a physician or groups of physicians based on relative quality and cost of services to beneficiaries.
 - CMS goal is to have Medicare physicians receive a confidential feedback report prior to implementation of value payment modifier.

ACR Comment: CMS states it has a goal of providing every Medicare practitioner with a “feedback” report prior to implementation of the payment modifier. CMS also states that it will begin an effort to gain widespread stakeholder involvement in expanding the confidential feedback (RUR) program and transition to a payment modifier, emphasizing the collaborative nature needed in this process. CMS plans include involving both internal and external stakeholders, holding a public listening session, outreach through physician groups and specialty societies, and e-mail communications. Physician collaboration in developing meaningful “feedback” reports for consultant or hospital-based specialties such as radiology, pathology, anesthesiology, and infectious disease is essential. Attribution to these physician types in the current structure and focus of the reports does not make sense. Are these physicians the decision makers who could control volume of resources used? Perhaps other platforms can better assess control over use of resources. For example, the Medicare Imaging Demonstration may be informative for determining the appropriateness of services in relation to established criteria and physician peers.

- Phase II of the RUR will include quality measures in combination with resource use measurement. CMS proposes use of claims-based measures developed for the CMS Generating Medicare Physician Quality Performance Measurement Results (GEM)

project. GEM is a core set of 12 measures that can be calculated from claims data. In future, CMS is looking at linking RUR to the HITECH Meaningful Use program and the group practice reporting option in PQRI. CMS believes that both offer measures and measure sets which may be useful in physician peer comparison.

ACR Comment: A combination of quality and resource use measures is important. Focusing solely on cost could create negative incentives to reduce level of care provided. Yet there is a lack of claims based quality measures that are relevant to all physicians in any one specialty, making comparison difficult within the context of beneficiary population and resources used.

Few radiologists would be able to report the GEM, HITECH Meaningful Use or the group practice reporting option in PQRI measures with meaningful data. (Reporting these measures to demonstrate meaningful use capability would in almost all cases result in a denominator of zero).

Additionally, measuring quality outcomes is extremely challenging in diagnostic imaging because it is difficult to differentiate the radiologists' contribution from that of many other members of the clinical team.

- With respect to the RUR, CMS seeks input on a) risk adjustment, b) attribution, c) benchmarking, d) peer groups, e) minimum case sizes, f) cost and quality measures, and g) composite measures. No formal proposals on these in this PR. Discussion with questions on each area seeking input.

ACR Comment: In general, the proposed statistical methods seem reasonable in the current construct of evaluation.

Risk adjustment: Building a risk model on just the patient characteristics and excluding county level socioeconomics is appropriate. Counties are often large areas with diverse populations in terms of income and area socioeconomics do not accurately capture individual characteristics. Besides, individual socioeconomics may be influenced by a patient's health status, and not really be a predictor. To that end, it might be worth excluding Medicaid participation from the risk estimation and considering an instrument or some other alternative.

It does seem appropriate to not risk adjust process measures; the justification provided seems reasonable.

Attribution: Attribution is tricky. Multiple-proportional attribution seems more reasonable because it assigns responsibility to a wider range of physicians, and is more inclusive in its comparisons. Could a survey be performed to determine if the attribution logic finds the actual decision makers? Without a reliable sense of who

the decision makers are, any policy prescriptions based on incorrect attribution may deliver unintended consequences. To the extent that the plurality-minimum method of attribution will be used, the described methods seem careful, but may still attribute costs to incorrect physicians. For instance, a primary care physician may meet the minimum criteria and may refer a patient to a specialist. The specialist may initiate a large amount of care in a small number of E&M visits, and the costs would all be assigned to the primary care physician.

Benchmarking: A minimum of 20 beneficiaries seems reasonable and data will reveal if this continues to be a reasonable cutoff. Further sensitivity analysis around this minimum should be performed. We may not need a minimum number of peers, but the number of peers should be made explicit in any comparisons. 99th percentile with 5 peers may represent a very different physician from someone who is at the 99th percentile among 500.

Section VI. F. 1.: MIPPA Section 131 Physician Payment, Efficiency, and Quality Improvements – PQRI, with relevant provisions from the Affordable Care Act (ACA)

2011 PQRI Individual Measures

- One new measure potentially reportable by radiologists has been proposed by CMS for 2011 reporting: *Reminder System for Mammograms*.

ACR Comment: The ACR is pleased that CMS has proposed inclusion of *Reminder System for Mammograms*. Inclusion of this measure will provide greater opportunity for radiologist participation in PQRI and potentially the ability for more radiologists to avail themselves of registry reporting.

Reporting Mechanisms

- Because of the limitations of claims-based reporting, CMS proposes that it will continue to consider significantly limiting the claims-based mechanism in future program years (beyond 2011). Potentially, claims-based reporting after 2011 may be limited to reporting structural measures or when claims-based reporting is the only available mechanism for some eligible professionals (EPs) to report measures.

ACR Comment: The ACR agrees with CMS that reducing reliance on claims-based reporting of PQRI data will allow more sophisticated and timely reporting of data and may reduce the burden of reporting. However, even if there are a sufficient number of qualified registries by 2011, CMS should not totally discontinue claims-based reporting for several reasons. A common radiologist practice pattern is to practice at numerous locations where the data is controlled by the institutions, not the group or individual. Having access to the data to send to a registry may be

problematic. Lastly, because many radiologists specialize their practice by modality or body system, few can report three measures, making them ineligible for registry reporting.

The ACR again urges CMS to remove the restriction on registry reporting for those EPs that cannot report 3 measures. CMS has previously responded to this request indicating that it does not have the analytic capability to determine whether or not an EP reporting less than 3 measures through a registry will pass the Measure Applicability Validation process. It seems that the existing analytics could still be used for validation if a registry submits less than 3 measures for an EP, following that submission.

Reporting Requirements for Individual Measures

Claims-based

- Sample size requirement for individual measures reduced from 80% of measure-applicable claims to 50% sample size. Based on experience from 2007 and 2008, CMS believes this will substantially increase the number of EPs who qualify for the PQRI incentive. Only about half of EPs participating through claims based reporting satisfied reporting criteria.

ACR Comments: The ACR applauds CMS for reducing the sample size for claims based reporting from 80% to 50% with the goal of increasing the success rate for EPs who participated in PQRI using the claims-based mechanism. Although this may not lessen the burden of participation, the likelihood of achieving success and obtaining the incentive bonus (or avoiding penalty in future years) is much greater. This is also important as CMS begins to publicly report whether an EP was successful and qualified for a PQRI incentive payment. Beneficiaries or patients may equate qualification for an incentive payment with higher quality care, which is not necessarily the case.

Requirements for PQRI Qualified Registries

- CMS proposes to disregard and not count measures reported through registries (or EHRs) that have a 0% performance rate (clinical quality action is not performed on at least 1 patient). CMS assumes in this situation that the measure was likely reported from data mining and was unintentionally submitted.

ACR Comments: The ACR understands the CMS rationale for excluding measures with a 0% performance rate. However, if this same methodology were used to assess compliance with HITECH Meaningful Use measures, then many physicians would be deemed “not capable” when attempting to demonstrate reporting

capability of quality data. This is because EPs are allowed the flexibility to demonstrate compliance with meaningful use capability when reporting clinical quality measures by reporting a zero denominator.

- For 2011 PQRI, CMS proposes that current or new registries will be required to use a CMS-provided measure calculation algorithm. CMS also proposes requiring registries to submit to CMS individual measure data elements and beneficiary level data vs. aggregated data. CMS states that differences have been found in measure performance rates when comparing registry rates to rates calculated by CMS using claims data for the same EP. CMS believes this makes physician comparison difficult and inconsistent.

ACR Comments: The ACR recognizes the importance of consistent comparison, especially when the data is publicly reported. However, we are concerned that a CMS-developed algorithm might not accurately calculate measure reporting or performance rates in all instances for all EPs. Currently, a situation exists in the CMS calculation algorithms for claims based submission wherein CMS uses any CPT and ICD-9 combinations from any dates of service in the measurement period. This causes many services to be counted as eligible for PQRI reporting when they actually are not. In 2008 CMS assessed PQRI reporting issues and identified situations where claims were split and not counted toward satisfactory reporting. CMS subsequently modified analytics to look at all diagnoses submitted on a base claim as well as a line-item diagnosis. CMS stated in the *Physician Quality Reporting Initiative 2007 Reporting Experience* that this modification might “result in QDCs [quality data codes] being considered valid based on including all diagnoses on the claim rather than limiting analysis to only line-item diagnoses”. Several radiology practices determined that there was a difference in results when comparing detailed claims data from CMS used for evaluation of PQRI reporting success with internal practice claims data for the same time period. The practice claims data was re-run using CMS methodology and results were the same as CMS. This indicates that the modified CMS analytics “cross-pollination” of ICD-9 and CPT dates of service on the entire body of a claim identifies missed opportunities for reporting erroneously. This resulted in a lost opportunity to qualify for PQRI incentive payments for a number of radiologists, with no recourse.

CMS states that the rationale for requiring registries to use a CMS algorithm is that CMS found differences in measure performance rates when comparing registry rates to rates calculated by CMS using claims data for the same EP. Potentially, the reason for this could be that the CMS adjudication logic used base claim data where a registry did not. If CMS should decide to require use of a CMS algorithm, CMS should make that available to registries and the public prior to use as well as conduct a comment period to gather input regarding the validity or faults of the algorithm.

The benefit of requiring registries to submit individual measure data elements and beneficiary level data vs. aggregated data is unclear. It would seem to defeat part of the purpose of a registry. Does CMS intend to require submission of individual data elements only for registries subject to validation?

Public Reporting of PQRI Data

- Specifically, CMS proposes to post the names of EPs and group practices that:
 - Submit data on the 2011 PQRI quality measures through one of the reporting mechanisms available for the 2011 PQRI;
 - Meet one of the proposed satisfactory reporting criteria of individual measures or measures groups; and
 - Qualify to earn a PQRI incentive payment for covered professional services furnished during the applicable 2011 PQRI reporting period.

ACR Comments: The ACR encourages CMS to be specific and clear in posting the information that successful reporting is just that – successful reporting – and does not necessarily indicate higher quality care was or will be provided by those individuals who earned PQRI incentive payments, particularly since success is dependent on accurate analysis of claims by CMS.

Maintenance of Certification Program (MOCP) in the Physician Quality Reporting System (pg 552)

Section 3002 of the Affordable Care Act (ACA) requires an option for a physician or other EP to provide CMS with data on quality measures through an MOCP operated by an ABMS specialty body. The statute authorizes an additional incentive of 0.5 percent for 2011 – 2014, when requirements are met. Beyond 2014, participation in MOCP and successful completion of a MOCP practice assessment may be incorporated into the “composite of measures” of quality furnished under the physician fee schedule value-based payment modifier.

- CMS proposed requirements for an EP to qualify for an additional incentive payment of .5% through MOCP participation:
 - EP must meet basic proposed requirements for satisfactory reporting under PQRI for 2011, based on 12 month reporting (not the 6 month reporting option). The EP can report individual PQRI measures or measures groups. Method of reporting PQRI measures is not specific (can use claims-based or any registry available). Alternatively, EPs may satisfactorily report under PQRI based on submission of PQRI data by an MOCP, provided that the MOCP has qualified as a PQRI registry for 2011.



- The EP's MOCP practice assessment must include a survey of patient experience with care.

ACR Comments: Many specialty boards do not require a survey of patient experience with care in order to satisfy practice assessment or MOC requirements. Could CMS clarify why this has been included in the PQRI MOCP option?

- Boards may also participate as registries for PQRI data provided that they meet the registry requirements.

ACR Comments: The ACR recommends that CMS allow boards who participate as registries for PQRI data to submit measure information for EPs reporting less than 3 measures.

Integration of PQRI and EHR Reporting (Section 3002(d) of ACA)

- CMS proposes to include American Recovery and Reinvestment Act (ARRA) core clinical quality measures in the PQRI program. CMS plans to make available by January 1, 2012, a plan to integrate reporting on quality measures with EHR reporting. CMS solicits comments on how the plan for integration will optimally improve quality care for individuals and provide meaningful use of EHRs.
- In addition to the 10 measures available for EHR-based reporting in 2010 PQRI, CMS is proposing to include 12 additional measures for EHR-based reporting in 2011 PQRI that overlap with the clinical quality measures used in the ARRA EHR incentive program. These measures are related to primary care/preventive services.

ACR Comments: As stated above, the ACR is concerned that if CMS uses the same proposed methodology for excluding measures with a 0% performance rate in the PQRI program that it does for assessing compliance with HITECH Meaningful Use measures then many physicians will be deemed "not capable" when attempting to demonstrate reporting capability of quality data. This is because EPs are allowed the flexibility to demonstrate compliance with meaningful use capability when reporting clinical quality measures by reporting a zero denominator.

Section 3002(e) of ACA: Feedback Reports

- Section 3002(e) of the ACA requires CMS to provide timely feedback to EPs on the performance of the EP with respect to satisfactorily submitting data on quality measures. CMS believes the requirement for "timely" feedback reports is met by providing the feedback reports on or about the time of issuance of the incentive

payments. Thus, CMS proposes to provide 2011 feedback reports on or about the time of issuance of the 2011 incentive payments, consistent with current practice.

ACR Comments: Receiving feedback reports at about the same time as issuance (or non-issuance) of incentive payments may be timely for attempting to understand the payment decision, but it is not timely as far as adjusting processes for the reporting year following that payment (i.e. reports for 2009 received in October 2010 will not provide information in a timely manner to adjust 2010 reporting as necessary). Further, these feedback reports would be of no value to EPs intent on learning whether their current PQRI data submission practices need to be adjusted in order to qualify for PQRI incentive payments. For example, truly “timely” feedback would allow an EP to correct errors and perhaps at least qualify for PQRI incentives for the last 6 months of the year. We also address this issue below in discussing the proposed “interim” feedback reports.

- CMS also proposes to provide interim feedback reports for EPs reporting 2011 measures groups through the claims-based reporting mechanism. CMS expects to make these interim feedback reports available to EPs in June 2011 based on claims for services from January 1, 2011 through February 28, 2011.
- Additionally, CMS is considering a process for responding to interim feedback report requests at the individual level for claims-based reporting, based upon first quarter claims data for the program year. This would provide the EP with information on errors in submission prior to the start of the 6 month reporting period in July.

ACR Comments: ACR believes that both of the above proposed interim reports will assist EPs in making adjustments in order to successfully participate. In fact, such “interim” reports would be of much greater value than the “timely” feedback reports proposed by CMS. Having said this, we urge CMS to ensure that all EPs using the claims-based reporting option can receive “interim” feedback reports, not just those submitting data for measures groups. We also urge CMS to consider requiring qualified PQRI registries to provide a similar feedback opportunity to EPs using registry-based reporting. We note, too, that for the PQRI to truly improve patient care, it should provide timely and actionable clinical information to physicians in as near to real-time as possible.

Section 3002(f) – Appeals

- Section 3002(f)(2) of the ACA requires CMS to have in place no later than January 1, 2011, an informal review process for EPs to seek a review of the determination that an EP did not satisfactorily submit data on quality measures under the PQRI.

ACR Comments: Providing for a review and appeal process is a much-needed addition to the PQRI program. The lack of transparency in CMS methodology for calculating metrics and its validation process combined with the current lack of recourse for EPs has



contributed to a lack of interest in, and even skepticism about, the program. An appeal process is ever more important as the amount of PQRI data that is publicly reported increases. CMS must also implement a procedure whereby publicly reported information is updated for any EP who is considered “successful” following a review and appeal.

Conclusion

Thank you for the opportunity to comment on the important issues discussed in this proposed rule. The ACR remains committed to the PQRI program and quality patient care. The ACR looks forward to continued work with CMS on these important efforts. If you have any questions about our comments please feel free to contact Judy Burleson at 800-227-5463 ext. 4787 or via email at jburluson@acr-arrs.org.

Respectfully Submitted,

A handwritten signature in black ink that reads "Harvey L. Neiman, MD". The signature is written in a cursive style.

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Executive Director

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