



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

July 28, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Berwick:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents over 94,700 physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed rule regarding payment policies under the Medicare physician fee schedule and other revisions to Medicare Part B for calendar year 2011. The Centers for Medicare and Medicaid Services (CMS) published the proposed rule in the *Federal Register* on July 13, 2010, and invited comments on various issues. Our comments on issues of relevance to family medicine generally follow the order of the issues as presented in the proposed rule.

Before addressing specifics of the proposed rule, we do want to recognize the effort that CMS is making to address primary care issues within the parameters permitted by the current statute. For instance, we want to reaffirm CMS's decision to eliminate Medicare payment for the consultation codes in 2010 and to redistribute the work values for those codes to other evaluation and management services, which are commonly provided by primary care physicians. We find further examples of this effort at specific points throughout the proposed rule. These include CMS's attention to potentially misvalued codes, proposed improvements in the relative value of intranasal/oral immunization administration codes, and proposed changes in the e-prescribing incentive program. In short, publication of the proposed rule demonstrates CMS's continued recognition that a high quality, efficient health care system must rest on a foundation of primary medical care. We thank CMS for all of its efforts in this regard.

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

CMS is not proposing any broad changes in its PE RVU methodology, and CMS is not proposing any broad PE data collection efforts. CMS does propose a variety of narrow technical PE changes, including its intent to use a 75% equipment utilization rate (rather than the current 90%) for certain expensive diagnostic imaging equipment, as mandated by the Patient Protection and Affordable Care Act (PPACA).

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Additionally, CMS proposes to act on public requests to update equipment and supply price inputs annually through rule making. Specifically, CMS proposes to use the annual physician fee schedule proposed rule released in the summer and the final rule released on or about November 1 each year as the vehicle for making these changes. In particular, CMS proposes to accept requests for updating the price inputs for supplies and equipment on an ongoing basis; requests must be received no later than December 31 of each calendar year to be considered for inclusion in the next proposed rule. In that next proposed rule, CMS would present its review of submitted requests to update price inputs for specific equipment or supplies and its proposals for the subsequent calendar year. CMS would then finalize changes in the final rule for the upcoming calendar year.

To facilitate its review and preparation of issues for the proposed rule, CMS would, at a minimum, expect that requesters would provide multiple invoices from different suppliers/manufacturers, recognizing that, in some cases, multiple sources may not be available. In those situations, CMS would expect a detailed explanation to support the request. When furnishing invoices, CMS believes that requestors should take into consideration the following parameters:

- May be either print or electronic but should be on supplier and/or manufacturer stationery (for example, letterhead, billing statement, etc.)
- Should be for the typical, common, and customary version of the supply or equipment that is used to furnish the services.
- Price should be net of typical rebates and/or any discounts available, including information regarding the magnitude and rationale for such rebates or discounts.
- If multiple items are presented on the same invoice, relevant item(s) should be clearly identified.

With respect to the Medicare physician fee schedule, AAFP policy supports practice expense RVUs that are based on the actual resources, both direct and indirect, which physicians use to provide services and that are adjusted in a timely and understandable manner. Accordingly, we are supportive of CMS's proposal to establish a regular and more transparent process for considering public requests for changes in its PE database as it relates to price inputs for supplies and equipment used in existing codes.

Malpractice RVUs

As with its PE RVUs, CMS is proposing no broad methodological changes or data collection efforts in conjunction with its malpractice RVUs. CMS does state its intent to publish in each year's final rule the analytic crosswalk(s) used to determine the malpractice RVUs for new and revised codes, which it has not previously done. We support this move toward greater transparency in CMS's malpractice RVU methodology and look forward to seeing the analytic crosswalk(s) for the malpractice RVUs of new and revised codes for 2011 in the final rule to be published this fall.

Potentially Misvalued Codes Under the Physician Fee Schedule

Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(K) of the Social Security Act (as added by section 3134 of the PPACA) requires the Secretary to periodically review and identify potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. It further specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services, as well as conduct surveys or implement other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment of the relative values of potentially misvalued codes. Finally, section 1848(c)(2)(L) of the Social Security Act (as added by section 3134 of the PPACA) provides that the Secretary shall establish a process to validate RVUs under the physician fee schedule.

This is a critical issue as several recent studies show that the widening income gap between cognitive and procedural physician specialties is dramatically reshaping the physician workforce by influencing both career choice by students and graduate medical education build-up by teaching hospitals. There is a direct tie between payment policy and a growing threat to access for primary care services for Medicare beneficiaries.

Effectively revaluing primary care and other cognitive codes will be essential to correcting this problem. You may recall that an effort was made to do this during the last five-year review of the Medicare physician fee schedule. That effort resulted in an increase in the work RVUs of evaluation and management (E/M) codes in 2007. However, the recommended RVUs for these services reflected a significant compromise on the part of primary care, and due to the statutory requirement for budget neutrality, which CMS chose to apply using a "work adjuster" in that instance, the accepted increase was effectively reduced in a drastic manner. Accordingly, we are concerned that primary care services in general and E/M services in particular continue to be undervalued. Because health care reform in general has consumed so much of our time and other resources during the past year, we chose not to make E/M services part of the current five-year review of the Medicare physician fee schedule. CMS should not, however, take that as an acceptance of the current values for those services, and we would encourage the agency to include E/M services in its ongoing efforts to identify, review, and validate potentially misvalued codes (which the AAFP believes remain undervalued).

In the proposed rule, CMS notes that over the past several years, it has been working with the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) to identify approaches to addressing the issue of potentially misvalued services. Further, CMS describes the progress that it has made in conjunction with the RUC in identifying and reviewing potentially misvalued codes in each of seven categories:

1. Codes and families of codes for which there has been the fastest growth.
2. Codes or families of codes that have experienced substantial changes in practice expenses.
3. Codes that are recently established for new technologies or services.
4. Multiple codes that are frequently billed in conjunction with furnishing a single service.
5. Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
6. Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes').
7. Other codes determined to be appropriate by the Secretary.

Beyond these current efforts, CMS notes that it intends to establish a more extensive validation process of RVUs in the future in accordance with the requirements of section 1848(c)(2)(L) (as added by section 3134 of the PPACA). Accordingly, CMS is soliciting public comments on possible approaches and methodologies that it should consider for a validation process. CMS is especially interested in public comments regarding approaches, including the use of time and motion studies, to validate estimates of physician time and intensity that are factored into the work RVUs for services with rapid growth in Medicare expenditures, which is one of the categories that the statute specifically directs CMS to examine. CMS plans to discuss the validation process in a future physician fee schedule rule once it has considered the matter further in conjunction with any public comments and other input from stakeholders.

The AAFP acknowledges the efforts that CMS and the RUC have made to date in identifying and reviewing potentially misvalued codes, and we would encourage CMS to continue its efforts, consistent with the direction of section 3134 of the PPACA. Later in this letter, we offer suggestions on changes to this process to better accomplish what CMS and MEDPAC have recommended in this regard.

As regards future RVU validation efforts and CMS's call for comments on possible approaches and methodologies for a validation process, especially as it relates to estimates of physician time and intensity, we would offer the following suggestions for CMS's consideration.

First, services with 10 and 90-day global periods typically include a number and level of post-service hospital (where appropriate) and office visits, the time and value of which are assumed to be included in the total value of the global period. To the best of our knowledge, CMS has never validated this post-service work in services with 10 and 90 day global periods. It might be instructive for CMS to review a statistically valid sample of associated medical records for selected high volume 10 and 90-day global services to validate whether or not the post-service visits assumed to be included in the RVUs of the global service are, in fact, typically provided at the frequency and level assumed. This may be especially important given CMS's emphasis on use of the building block methodology in the proposed rule.

On a related note, Cromwell, et. al. (Cromwell, Jerry, et. al., "Missing Productivity Gains in the Medicare Physician Fee Schedule: Where Are They?," *Medical Care Research and Review*, published online June 16, 2010), present an empirical study showing more post-surgery handoffs by surgeons. That study suggests that surgeons are increasingly delegating postsurgical visits to other physicians, nurse practitioners, and physician assistants. Thus, in addition to validating the number and level of post-service visits, the time and value of which is assumed to be included in the value of the global service, CMS may also want to validate that the physician or group receiving those RVUs is, in fact, providing the post-service visits.

Second, physician service times, particularly intra-service times, are captured in other venues besides the RUC survey process. For example, hospital operating room logs often record surgical times, and there is peer-reviewed literature on the times of other physician services (e.g., colonoscopy). The Cromwell article noted above also discusses this phenomenon and documents that physician time estimates used by CMS are statistically significantly longer than actual documented times in the clinical setting. CMS might want to investigate and utilize such extant data sources in its validation of physician time used in establishing RVUs.

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While the basic principles of the relative value system have been proved to value codes over the past 20 years, newer, scientific approaches would allow refinement of estimates of work intensity, just as the RUC has refined other elements of work values. The Academy, along with other specialty societies, is supporting research being performed independently at the University of Cincinnati to investigate physician work intensity using more modern techniques. Two initial papers showing preliminary results have been accepted for publications in peer-reviewed journals. The Academy encourages CMS to investigate and support further methods of measuring work intensity fairly. For more information, CMS may contact Ronnie D. Horner, PhD, Principal Investigator, by phone at (513) 558-2756 or by email at ronnie.horner@uc.edu.

Finally, in reviewing this section of the proposed rule, we were struck by how much CMS seems to rely on the RUC in this area. Like CMS, we acknowledge that the RUC has extensive expertise and a unique infrastructure and perspective that facilitate the valuation of codes. However, we remain concerned that CMS continues to put all of its eggs in the same basket in this regard. The dangers in doing so are illustrated by CMS's critique of the RUC's handling of codes with site-of-service anomalies.

The Medicare Payment Advisory Commission (MedPAC) has previously recommended that CMS establish a group of experts, separate from the AMA RUC, to help the agency review RVUs. AAFP strongly supports MedPAC's recommendation that CMS establish a group of experts (including consumer and employers), separate from the AMA RUC, to help the agency review and validate RVUs. Although the RUC provides valuable expertise, the review process would benefit if CMS had an additional means of identifying misvalued services and validating RVUs and if supporting evidence was collected and analyzed not only by specialty societies but also by experts who were less invested financially in the outcome. In medicine, we call this "getting a second opinion."

Like MedPAC, we believe that such a panel would not supplant the RUC, but would augment it, and like MedPAC, we believe that such a panel would assist CMS by using the results of data analyses to identify potentially misvalued services and validate RVUs. We anticipate that the RUC would be allowed to comment on any recommendations or findings of such a group. In any case, we urge CMS to establish such an expert panel as part of its plans to implement the RVU validation process required by section 3134 of the PPACA.

Identification and Review of Potentially Misvalued Services in 2011

In the proposed rule, CMS discusses five types of codes which it is asking the RUC to target as potentially misvalued codes in 2011. These include:

- Codes on the multi-specialty points of comparison list;
- Codes with low work RVUs commonly billed in multiple units per single encounter;
- Codes with high volume and low work RVUs;
- Codes with site-of-service anomalies; and
- Codes that qualify as "23-hour stay" outpatient services.

Site-of-Service Anomalies

In general, we are supportive of CMS's intent to ask the RUC to review the identified codes in each of these areas. With respect to the codes with site-of-service anomalies, in particular, we share CMS's concern that "the majority of the codes with site-of-service anomalies continue to be overvalued under the AMA RUC's most recent recommendations." As CMS noted in the proposed rule on the 2010 Medicare physician fee schedule, the AMA RUC has previously made recommendations to CMS to change the components of codes with site-of-service anomalies, which included changing the pre- and post-service physician time and mix of post-service evaluation and management services. However, in many cases, there was no corresponding change in the work RVUs assigned to those services as a result. To the extent that services have had a change in their resource inputs without a corresponding change in the relative values assigned to them, AAFP supports CMS's decision to take a critical look at their current relative values, as suggested in this proposed rule.

23-Hour Stays

As noted, we support CMS's intent to ask the RUC to review codes with "23-hour" stays and to apply a more uniform approach the valuation of these services. However, in fairness to the RUC and the specialties who have previously attempted to value these services, we would like to challenge an implicit assumption that we observe in CMS's proposed approach to these codes.

Specifically, CMS states in the proposed rule:

We believe that the 23-hour stay issue encompasses several scenarios. The typical patient is commonly in the hospital for less than 24 hours, which often means the patient may indeed stay overnight in the hospital. On occasion, the patient may stay longer than a single night in the hospital; however, in both cases, the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient, and our claims data support that the typical 23-hour stay service is billed as an outpatient service. Accordingly, we believe that the valuation of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service.

The implicit assumption that we observe in CMS's proposal is that a patient's status (i.e., outpatient versus inpatient) in the hospital is a function of patient acuity, such that "outpatients," by definition require less work than "inpatients." The flaw that we observe in this assumption is that patient status in the hospital is as often a function of payment policy as it is patient acuity. That is, hospitals not infrequently declare a patient's status as "inpatient" or "outpatient" based on what they calculate will be most financially advantageous (e.g., based on a comparison of what Medicare will pay under the outpatient versus inpatient prospective payment systems), which does not necessarily equate to patient acuity. Thus, a patient kept in observation as an outpatient for 23 hours may be as sick or sicker, and require as much or more physician work, than a patient admitted as an inpatient for the same time period.

To this point, CMS Acting Administrator and Chief Operating Officer, Marilyn Tavenner, wrote to the President and Chief Executive Officer of the American Hospital Association on July 7, 2010. In her letter, she noted that CMS:

. . . has become increasingly concerned that Medicare beneficiaries are remaining in observation care for longer periods of time, sometimes exceeding 48 hours. Our claims data indicate a modest trend toward proportionally more observation services extending beyond 48 hours, from approximately 3 percent in 2006 to nearly 6 percent in 2008.

Ms. Tavenner goes on to state that CMS is unaware of any policies that would cause a hospital to extend observation care for Medicare patients, and she indicates that CMS is interested in learning more about why this trend is occurring. We would suggest that, in fact, CMS payment policy may be a cause of the observed behavior on the part of hospitals and evidence that hospitals are substituting "outpatient" status for "inpatient" status without regard to the patient's acuity, as discussed above.

We agree with CMS that, "Currently, the valuation of 23-hour stay services is conducted in a nonuniform manner by the AMA RUC." However, we would also observe that, currently, the payment to hospitals of 23-hour stays is conducted in a nonuniform manner by CMS, and CMS needs to critically review its own policies in this regard when asking the RUC to do the same. The two issues are connected and cannot be resolved in isolation.

Geographic Practice Cost Indices (GPCIs)

Updates to the GPCIs

Section 1848(e)(1)(A) of the Social Security Act requires CMS to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice). While requiring that the PE and malpractice GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) sets a permanent 1.5 work GPCI floor in Alaska for services furnished beginning January 1, 2009. Section 1848(e)(1)(C) requires CMS to review and, if necessary, adjust the GPCIs at least every three years. This section also specifies that if more than one year has elapsed since the last GPCI revision, the agency must phase in the adjustment over two years, applying only one-half of any adjustment in each year. The 2009 adjustment to the GPCIs reflected the fully implemented fifth comprehensive GPCI update. Calendar year 2010 would have typically included no adjustments to the GPCIs.

However, section 3102(a) of the PPACA amends section 1848(e)(1)(E) of the Social Security Act to extend the 1.0 work GPCI floor for services furnished through December 31, 2010. Additionally, section 3102(b) of the PPACA adds a new subparagraph 1848(e)(1)(H), which specifies that for 2010 and 2011, the employee compensation and rent portions of the PE GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average. The new subparagraph also includes a "hold harmless" provision for 2010 and 2011 for any locality that would otherwise receive a reduction to its PE GPCI resulting from the limited recognition of cost differences. Additionally, section 1848(e)(1)(I) (as added by section 10324(c) of PPACA) establishes a 1.0 PE GPCI floor for services furnished in frontier States effective January 1, 2011.

The PPACA and other statutory provisions impacting rule making pertaining to GPCIs can be summarized as follows:

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- Work GPCI has a floor of 1.0 through 2010 then reverts to previous values;
- In 2010 and 2011, the employee compensation and rent portions of the PE GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average;
- a "hold harmless" provision for 2010 and 2011 for any PFS locality that would otherwise receive a reduction to its PE GPCI resulting from the limited recognition of cost differences;
- a permanent 1.5 work GPCI floor in Alaska for services furnished beginning January 1, 2009;
- a permanent 1.0 PE GPCI floor for frontier States (North Dakota, South Dakota, Montana, Nevada, Wyoming) effective January 1, 2011;
- the PPACA requires CMS to complete an analysis of the data sources used and cost share weights assigned to the PE GPCIs;
- Work GPCIs are required to be updated.

The GPCIs were last updated in 2008 using professional earnings data from the 2000 Census. Because wage and earnings data are no longer available from the Census long form and the 2000 data are outdated, CMS, for this proposed (sixth) GPCI update, used the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data as a replacement for the 2000 Census data.

CMS proposes to implement changes in PE data sources and cost share weights beginning in 2011. In particular, CMS is proposing that the weight for the office rent component of PE be revised from 12.209 percent to 8.410 percent to reflect a more detailed breakout of the types of office expenses that are determined in local markets instead of national markets. For example, for previous GPCI updates, CMS used the office expenses cost category as the cost share weight for office rent and, therefore, all individual components previously included in the office expenses category were adjusted for local area cost differences by the GPCIs. CMS is proposing to disaggregate the broader office expenses component into nine new cost categories as part of the proposed 2011 Medicare Economic Index (MEI) rebasing discussed elsewhere in the proposed rule. The disaggregation of the office expenses category indicates that the fixed capital cost category, for which the consumer price index (CPI) for owner's equivalent rent is the price proxy, is the office expense category applicable to the office rent component of the PE GPCI. Therefore, the fixed capital cost category is the only component of office expenses that CMS is proposing to adjust for local area cost differences beginning in 2011.

CMS is also proposing to assign other newly defined components of the office expenses category (for example, utilities, chemicals, paper, rubber and plastics, telephone, postage, and moveable capital) to the medical equipment, supplies, and other miscellaneous expenses cost component of the PE GPCIs. The medical equipment, supplies, and other miscellaneous expenses component of the PE GPCIs is assumed to have a national market and, therefore, this component is not adjusted for local area cost differences.

CMS does not believe there is a national data source better than the Housing and Urban Development (HUD) data for determining the relative cost differences in office rents. Therefore, the agency is proposing to use the 2010 apartment rental data produced by HUD at the 50th percentile as a proxy for the relative cost difference in physician office rents.

AAFP long-established policy supports:

- a) practice expense RVUs that are based on the actual resources, both direct and indirect, which physicians use to provide services and that are adjusted in a timely and understandable manner;
- b) work RVUs which appropriately value evaluation and management services relative to procedural services; and
- c) the elimination of all geographic adjustment factors from the Medicare Fee Schedule except for those designed to achieve a specific public policy goal (e.g., to encourage physicians to practice in underserved areas).

Accordingly, AAFP urges CMS to utilize the most broadly applicable methodology to reduce geographic payment disparity that it has legally available.

AAFP agrees with the findings of the GAO's March 2005 Report entitled, "MEDICARE PHYSICIAN FEES: Geographic Adjustment Indices Are Valid in Design, but Data and Methods Need Refinement" (GAO-05-119). That GAO report focused on the data sources used by CMS stating, in particular, that the wage data used for the PE GPCIs are not current. We would encourage CMS to follow the GAO's recommendation that the Secretary of Health and Human Services seek to improve the GPCIs' data and methods by taking the following six actions:

- develop a plan for transitioning from the Census Bureau's decennial census to the annual American Community Survey (ACS) for earnings and wage data, pending resolution by the Census Bureau of key outstanding issues regarding the implementation of the ACS;
- add data on physician assistants' wages to improve the measurement of the practice expense GPCI;
- consider the feasibility of replacing the practice expense GPCI's current rent index with a commercial rent index; if using a commercial rent index is not feasible, consider a residential rent index directly based on ACS data;
- collect malpractice premium data from all states;
- collect data from insurers that account for at least half of malpractice business in a state; and
- standardize collection of malpractice premium data (e.g., by using data from Physician Insurer's Association of America).

As noted, CMS proposes to implement changes in PE data sources and cost share weights beginning in 2011. AAFP appreciates this modification but is not convinced that this is a reasonable and accurate response to the findings of the GAO, as HUD apartment rental data is not considered an accurate proxy for office rent. This is particularly true in rural areas where primary care physicians must locate their offices strategically to accommodate traffic patterns and convenient access, which means on commercially viable and valuable real estate.

Consideration of Alternative Payment Localities

Section 1848(e) of the Social Security Act requires CMS to establish the GPCI as part of the Resource-Based Relative Value Scale method for paying physicians. Like the RVUs, the GPCI is split into three components: the physician work GPCI, the practice expense GPCI, and the malpractice insurance GPCI. The three GPCIs can be summarized into one Geographic Adjustment Factor (GAF).

The GPCIs attempt to adjust payments for geographic variation in the costs of providing services, and the data used to generate the GPCIs are intended to be proxies for the costs of providing care in the existing payment localities.

The value for each U.S. county is normed to a national index value, so that a GPCI of 1.0 is equal to the national average. GPCIs for a given region or "locality" are then calculated as RVU-weighted averages of the counties included in the locality. Defined in 1996, there are currently 89 payment localities with an average of 36 counties per locality. Since 1996, many of these localities have experienced shifts in population and economic development. In some localities, areas that were once rural may now be suburban or urban, resulting in changes to the cost structure of rents and wages. CMS contracted with Acumen LLC to develop a report which considers four potential alternative scenarios for redefining the existing 2009 Fully Implemented GPCI locality configuration. The agency then accepted public comments on the interim report through November 3, 2008.

The alternative locality configurations discussed in the report are described briefly in the NPRM:

Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration

This option uses the Office of Management and Budget (OMB's) Metropolitan Statistical Area (MSA) designations for the payment locality configuration. MSAs would be considered as urban CBSAs. Micropolitan Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of State) CBSAs. This approach would be consistent with the inpatient prospective payment system pre-reclassification CBSA assignments and with the geographic payment adjustments used in other Medicare payment systems. This option would increase the number of physician fee schedule localities from 89 to 439. (The Acumen report indicates this scenario creates 523 payment localities with an average of 6 counties per locality).

Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties)

Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of physician fee schedule localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties. (The Acumen report indicates this scenario creates 267 payment localities with an average of 12 counties per locality).

Option 3: Separate MSAs from Statewide Localities (Separate MSAs)

This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of physician fee schedule localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs. (The Acumen report indicates this scenario creates 203 payment localities with an average of 16 counties per locality).

Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers)

This option creates tiers of counties (within each State) that may or may not be contiguous but share similar practice costs. This option would increase the number of physician fee schedule localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers. (The 140 payment localities would have an average of 23 counties per locality).

As stated by CMS in the proposed rule, "This option was designated by CMS as "Option 3" in its Proposed Rule (72 FR 38141) of July 12, 2007."

CMS goes on to state in the proposed rule, "As a result, payments to urban areas would increase, while rural areas would see a decrease in payment because they would no longer be grouped with higher cost 'urbanized' areas." Additionally, the agency notes, "A number of public commenters on the draft report expressed support for Option 3 (separate MSAs from Statewide localities) because the commenters believed this alternative would improve payment accuracy over the current locality configuration and could mitigate possible payment reductions to rural areas as compared to Option 1 (CMS CBSAs)."

Notwithstanding the agency's confusing reference to the numbered options, it appears that commenters who indicated preference for "option 3" (which is really option 4 in the current proposed rule) are expressing sentiment that it does the least harm to rural areas; thus, it is the lesser of four evils. CMS indicates that "Acumen is conducting a more in-depth analysis of the dollar impacts that would result from the application of Option 3."

The tables and maps included in the Acumen report illustrate the distribution effects of the four scenarios compared to the current 89 payment localities. Based on the report and the information in the proposed rule, the AAFP notes that the positive effects are concentrated in metropolitan, urban or suburban areas. This creates further geographic disparity negatively impacting rural areas and, in some cases, predominantly rural states. Further, AAFP analysis of all of the options shows that, depending on the scenario implemented, between 41 and 85% of practicing family physicians would face a decrease in their GAF. Consequently, the AAFP cannot support any of the four scenarios discussed in the Acumen report and urges CMS to take steps to mitigate, not enhance, geographic payment disparity.

We also have an overarching concern about Acumen's proposals. In that proposal, it was clear to us that they had made adjustments in urban areas using data and claimed that they lacked data from rural areas. The result was that their proposals gave to urban areas and reciprocally took from rural areas. We see nothing in this proposed rule to suggest that either they or CMS has corrected this problem. We strongly encourage CMS to further review Acumen's methods before taking any action in this area.

Code Specific Issues: Diabetes Self-Management Training (DSMT) Services

Medicare covers DSMT services and pays for them using two codes: G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes). To date, CMS has not assigned any work RVUs to these services, because CMS believed training would typically be performed by individuals other than a physician, such as a registered nurse.

However, for 2011, based on comments received from a number of stakeholders, CMS proposes to include physician work in valuing DSMT services. Specifically, CMS is proposing that code G0108 for 30 minutes of individual DSMT services would be crosswalked to code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes) for

purposes of assigning work RVUs, with the physician work RVUs for code 97803 multiplied by two to account for the greater time associated with code G0108 (that is, 30 minutes). CMS is also proposing that code G0109 for 30 minutes of group DSMT services would be crosswalked to code 97804 (Medical nutrition therapy; group (2 or more individuals(s)), each 30 minutes) for purposes of assigning work RVUs. The proposed work RVUs for codes G0108 and G0109 are 0.90 and 0.25, respectively. The rationale for the proposed work RVUs for the DSMT codes is based on the similarity of DSMT services to medical nutrition therapy (MNT) services in the individual and group setting.

Concurrent with its proposal to add work RVUs to codes G0108 and G0109, CMS is proposing to modify the PE inputs for DSMT services to reflect the current equipment and supplies for the kidney disease education (KDE) G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour) and G0421 (Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour)), based on the similarity in the equipment and supplies necessary for DSMT and KDE services. CMS has made adjustments to some of the equipment times for the 30 minute DSMT individual and group services as compared to the 1 hour individual and group KDE services, and CMS is also including a diabetic educator curriculum and data tracking software in the PE inputs for DSMT services. With respect to clinical labor, CMS is removing all of the clinical labor from the group DSMT code and most of the clinical labor from the individual DSMT code, given that it is proposing work RVUs for both codes. As a result of these changes, the PE RVUs for G0108 will increase slightly from 0.64 in 2010 to 0.66 in 2011, while the PE RVUs for G0109 will decrease slightly from 0.35 in 2010 to 0.28 in 2011.

We support the appropriate valuation of DSMT services and concur that DSMT and MNT services are relatively similar with respect to the physician work involved. We appreciate that CMS is finally recognizing that there is physician work involved in DSMT services.

Code Specific Issues: Intranasal/Oral Immunization Codes

To ensure that the PE RVUs are consistent between the intranasal/oral and injectable immunization administration codes that describe services that utilize similar PE resources, CMS is proposing to crosswalk the PE values for code 90471 (Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)) to the following codes:

- **90467** (Immunization administration younger than age 8 years (includes intranasal or oral routes of administration) when the physician counsels the patient/family; first administration (single or combination vaccine/toxoid), per day)
- **90473** (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid))

Similarly, CMS is proposing to crosswalk the PE values for code 90472 (Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)) to the following codes:

- **90468** (Immunization administration younger than age 8 years (includes intranasal or oral routes of administration) when the physician counsels the patient/family; each additional administration (single or combination vaccine/toxoid), per day (List separately in addition to code for primary procedure))
- **90474** (Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure))

This would increase the PE RVUs of 90467 and 90473 from 0.22 to 0.49 and would increase the PE RVUs of 90468 and 90474 from 0.13 to 0.18.

The AAFP fully supports adequate payment for immunization administration, and we appreciate CMS's desire to ensure that its payment policy does not create any financial incentives that inappropriately favor one method of immunization administration over another. However, the PE RVUs, like the rest of the fee schedule, are supposed to be resource-based, and CMS's proposal does not address what, if any, adjustments CMS is making to the PE resource inputs for codes 90467, 90468, 90473, and 90474 to yield these PE RVU changes. If CMS is not making PE input changes, either to these codes or to codes 90471 and 90472, then we have concerns that CMS is arbitrarily playing with PE RVUs in a way that lessens the resource-based nature of the fee schedule. We would encourage the agency to provide a more thorough and defensible rationale for the changes that is consistent with the resource-based nature of the fee schedule.

Refinement Panel Process

Historically, CMS has used a refinement panel process to assist it in reviewing the public comments on interim physician work RVUs for codes with that status (i.e., "interim") in each year and developing final work values for the subsequent year. Since 1992, the refinement panels' recommendation to change a work value or to retain the interim value has hinged solely on the outcome of a statistical test on the ratings (an F-test) provided by the panel members. For refinement panels beginning in 2011 (that is, for those codes with 2011 interim values that would be subject to refinement during 2011), CMS is proposing to eliminate the use of the F-test and instead base revised RVUs on the median work value of the panel members' ratings. CMS believes this approach will simplify the refinement process administratively, while resulting in a final panel recommendation that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values.

Members of the AAFP have frequently served on CMS refinement panels, and we appreciate CMS's intent to continue the refinement panels with representatives that include primary care physicians. With respect to CMS's proposal to eliminate the use of the F-test and instead base revised RVUs on the median work value of the panel members' ratings, we have no objections.

Medicare Telehealth Services for the Physician Fee Schedule

As part of its annual process of reviewing and acting upon requests to add services to the list of approved Medicare telehealth services, CMS proposes to add the following services to that list in 2011:

- Individual kidney disease education (KDE)
- Individual diabetes self-management training (DSMT) (provided the eligible beneficiary receives a minimum of one hour of in-person instruction in the self-administration of injectable drugs)
- Group KDE, group medical nutrition therapy, group health and behavior assessment and intervention services, and group DSMT (provided the eligible beneficiaries receiving group DSMT also receive a minimum of one hour of in-person instruction in the self-administration of injectable drugs)
- Subsequent hospital care (subject to a frequency limit of once every three days for subsequent hospital care provided through telehealth)
- Subsequent nursing facility care (subject to a frequency limit of once every 30 days for subsequent nursing facility care provided through telehealth and conditioned on the fact that the encounter is not a federally-mandated periodic visit)

For a variety of reasons, CMS is not proposing to add the following requested services:

- Initial hospital care
- Hospital discharge day management
- Initial nursing facility care
- Nursing facility discharge day management
- Neuropsychological testing
- Speech-language pathology services
- Home wound care services

It is the position of the AAFP that the delivery of healthcare services via telemedicine should be consistent with the principles of ethical medical practice and that regulation should not unduly restrict accessibility of telemedicine services. By creating ready access to information, telemedicine can provide physicians with current medical information that may not otherwise be available in a given setting. The AAFP believes that payment should be made for physician services that are reasonable and necessary, safe and effective, medically appropriate and provided in accordance with accepted standards of medical practice. The technology used to deliver the services should not be the primary consideration; the critical test is whether the service is medically reasonable and necessary.

In light of this policy, we are pleased to see CMS's list of additions to approved Medicare telehealth services. In this proposed rule, CMS has shown a willingness to be much more open-minded with respect to telehealth services than it has in the past, and we want to congratulate the agency for its willingness to reconsider past decisions and expand Medicare coverage of telehealth services in ways that we hope will facilitate beneficiary access to care. While the proposed expansion might not be everything for which we and our rural members might have hoped, we do believe that it represents a step in the right direction, for which we commend CMS.

Provisions of the Patient Protection and Affordable Care Act of 2010 (PPACA): Section 3003 (Improvements to the Physician Feedback and Program) and Section 3007 (Value-based payment modifier under the physician fee schedule)

As required by law, CMS has established and implemented the Physician Resource Use Measurement and Reporting (RUR) Program for purposes of providing confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. CMS has completed Phase I of the RUR program and is proceeding with Phase II. In the proposed rule, CMS discusses the changes that it proposes to make in Phase II. These changes include:

- Including quality measures in the form of claims-based measures developed by CMS in the Generating Medicare Physician Quality Performance Measurement Results (GEM) project
- Including reporting to group practices
- Discontinuing use of commercially-available proprietary episode grouping software in favor of a Medicare-specific episode grouper, as required by section 3003 of PPACA
- Distributing reports electronically by leveraging the infrastructure used to distribute PQRI feedback reports

Until a Medicare-specific episode grouping software is developed, CMS plans to produce reports for Phase II that contain per capita cost information. More specifically, instead of episode-specific cost information, CMS plans to provide overall per capita cost information, as well as per capita cost information for those beneficiaries with five common chronic diseases:

1. diabetes
2. congestive heart failure
3. coronary artery disease
4. chronic obstructive pulmonary disease
5. prostate cancer

This information will not be specific to the cost of treating the disease itself, but will provide total Part A/B per capita cost information, as well as service category breakdowns, for treating the subset of attributed beneficiaries with that disease. CMS intends to risk adjust the cost data using the Hierarchical Condition Categories model, but it does not intend to risk adjust the quality data in Phase II.

Additionally, CMS discusses the impact of two provisions in PPACA on the RUR program. First, section 3003 requires the Secretary, beginning in 2012, to provide reports that compare patterns of resource use of individual physicians to other physicians. In addition, section 3007 requires the Secretary to apply a separate, budget-neutral payment modifier to the physician fee schedule payment formula. The payment modifier, which will be phased in beginning January 1, 2015 through January 1, 2017, will provide for differential payment under the fee schedule to a physician or groups of physicians, and later, possibly to other eligible professionals, based upon the relative quality and cost of care of their Medicare beneficiaries. With respect to these two provisions, CMS solicits comments on specific statistical issues, including, but not limited to:

- Risk adjustment
- Attribution
- Benchmarking and peer groups
- Cost and quality measures and compositing methods

Assuming adequate sample size, we believe that group reporting is most useful for public reporting. While individual reporting should not be used for public reporting unless the sample size is large enough to assure validity and reliability, there is value in having individual data available to individual physicians and those managing physician groups, even if it is not statistically valid for public reporting purposes. Group leaders can use this information to direct interventions with individuals by adding other information that may only be available internally.

Public reporting for individual (i.e., solo) or small group practice settings will continue to be problematic because of the small numbers problem. This is especially true if the reports are condition specific rather than an aggregate of measures across a number of conditions treated by the practice. Therefore, the AAFP recommends against public reporting of individual small practices unless it can be demonstrated that it meets adequate statistical and case-mix reliability standards.

As noted, CMS plans to make electronic reports available in Phase II using the infrastructure to distribute PQRI feedback reports. One of the most common complaints about the PQRI program is the difficulty of getting meaningful and timely feedback about the quality data. The ideal would be to have the data available for any participant to view at any time (i.e., real time data) where any physician or group would be able to assess their own performance against aggregated, de-identified peer data. The CMS proposal sounds like the participants would be able to look at reports that are produced and approved before being available for viewing. CMS does not have a good track record here. The data are old, sometimes as much as two years and it is not presented in a way that suggests a clear path to improvement. Data feedback for quality improvement must come with enough detail to help suggest strategies for improvement.

Regarding attribution methods, we would observe that they vary and are somewhat arbitrary. In Phase II, CMS plans to use the "plurality minimum" method, in which a beneficiary's entire cost was attributed to the physician who performed the plurality of the evaluation and management services, subject to a minimum percentage (i.e., 20 percent for individual physicians and 30 percent at the physician group level). Although this is an accepted method, it is not as accurate as some more sophisticated models. We are also concerned that it will penalize primary care by holding the primary care physician accountable for all the care a person receives, even though the primary care physician is providing only a subset of the patient's care. Once again, the problem of small numbers may make it difficult to fairly assess the costs at the individual physician level.

Regarding benchmarking and peer groups, CMS proposes to require 30 patients as a minimum sample size. This is fairly common, but to some degree arbitrary. In actual fact, the number of patients required for a certain level of precision might vary based on the actual measure under consideration. It would be better to require a measure of the precision, such as confidence interval. Also, individual physician level data may be useful even if there are less than 30 patients. Reports to a group should include data on individuals even when there are less than 30 patients, so that the managers of the group can combine that information with other internal information to help change physician behavior or design more reliable processes.

Lastly, we would observe that it is not clear how CMS intends to use cost and quality to measure "value." Value is generally considered to be lower cost for a given level of quality or conversely higher quality for a given level of cost. In Phase I, CMS only used cost measures. In Phase II, CMS plans to

use both per capita cost measures and selected quality measures, but how CMS intends to corollate both sets of measures for purposes of “value based purchasing” is unclear. It is critical that this process is validated and transparent before CMS implements the mandated payment modifier beginning in 2015.

Provisions of the PPACA: Section 3111 (Payment for Bone Density Tests)

Section 1848(b) of the Social Security Act (as amended by section 3111 of the PPACA) changes the payment calculation for dual-energy x-ray absorptiometry (DXA) services described by two specified DXA codes for 2010 and 2011. The codes in question are:

- **77080** (Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine))
- **77082** (Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; vertebral fracture assessment)

Specifically, this provision requires payment for these services at 70% of the product of the 2006 RVUs for these services, the 2006 conversion factor, and the geographic adjustment for the relevant payment year.

CMS has provided payment in 2010 under the physician fee schedule for codes 77080 and 77082 at the specified rates. In Addendum B to the proposed rule, CMS has published for these two codes the RVUs that result from application of this statutory provision and the proposed 2011 conversion factor of \$26.6574. Because the statute specifies a payment amount for these services as described above, CMS imputed RVUs for 2011 that would provide the specified payment amount for these services when multiplied by the 2011 conversion factor. Specifically, CMS divided the payment amount based on the statutory requirements by the 2011 conversion factor for this proposed rule, and distributed the imputed total RVUs across the work, PE, and malpractice components proportionately to their 2006 distribution.

According to 2008 Medicare claims data, family physicians provide approximately 10% of the volume of these services, so they are of interest to us. The mandated change in payment appears as though it will increase payment for these services, which should make it more feasible for family physicians to provide them. We do note that the proposed 2011 conversion factor used by CMS is based on current law, which assumes a significant decrease in the conversion factor in 2011. If Congress intervenes, as it has in the past, to avoid such a decrease, we trust that CMS will recalculate the imputed RVUs for these services based on the actual conversion factor in effect for 2011.

Provisions of the PPACA: Section 4103 (Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan)

PPACA expanded Medicare coverage under Part B to include an annual wellness visit, effective January 1, 2011. CMS proposes to implement PPACA section 4103 principally by adding 42 CFR 410.15 to the Medicare regulations. Proposed 42 CFR 410.15(a) provides definitions for key terms, while 42 CFR 410.15(b) and (c) describe conditions of coverage and limitations on coverage, respectively. Finally, CMS discusses its proposals for coding and payment of the new annual wellness

visit service. We will comment on some of CMS's proposed definitions and its proposed coding and payment policy for this service.

Definitions

Eligible beneficiary

The first definition on which we would like to comment is the one for "eligible beneficiary." According to the proposed rule, "Eligible beneficiary for purposes of this section means an individual who is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and who has not received either an initial preventive physical examination or an annual wellness visit providing a personalized prevention plan within the past 12 months."

This definition is apparently based on the language in PPACA section 4103 that states:

(G)(i) A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary's coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period.

We would argue that CMS has misinterpreted the statute with respect to patient eligibility. First, CMS's definition precludes a beneficiary from being eligible for an annual wellness visit within the first 12 months of his or her coverage under Part B. However, (G)(ii) of PPACA section 4103, which immediately follows the language quoted above states:

(ii) The Secretary shall establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12 months after the date that a beneficiary's coverage begins under part B, which shall include information regarding any relevant differences between such services.

This language clearly states that Congress intended for Medicare beneficiaries to be eligible for either an initial preventive physical examination (IPPE) (also known as the "Welcome to Medicare" visit) or an annual wellness visit or during their first 12 months of coverage under part B. Contrary to CMS's definition, Congress did not intend to exclude coverage of the annual wellness visit during those first 12 months. The fact that (G)(i) states "A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary's coverage begins under part B . . ." only reiterates the limitation on coverage of the IPPE; it is not intended to preclude coverage of the annual wellness visit during the same period.

Second, CMS's definition incorrectly ties the frequency of eligibility to a prior occurrence of the IPPE or annual wellness visit. However, as noted above, (G)(i) of PPACA section 4103 states, "A beneficiary . . . shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period." In this context, we would argue that "such services" refers to "personalized prevention plan services" only, not an

IPPE. Accordingly, we believe that a definition of “eligible beneficiary” more consistent with the statute would read:

Eligible beneficiary for purposes of this section means an individual who has not otherwise received an initial preventive physical examination within the first 12 months after the effective date of his or her first Medicare Part B coverage period or who has not received an annual wellness visit providing a personalized prevention plan within the past 12 months.

First annual wellness visit providing personalized prevention plan services

According to the proposed rule, CMS proposes that the first annual wellness visit for purposes of this benefit include the following:

- Establishment of the individual’s medical and family history;
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual;
- Measurement of the individual’s height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the individual’s medical and family history;
- Detection of any cognitive impairment that the individual may have;
- Review of the individual’s potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations;
- Review of the individual’s functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations;
- Establishment of the following:
 - A written screening schedule, such as a checklist, for the next 5 to 10 years as appropriate, based on recommendations of the USPSTF and the Advisory Committee on Immunization Practices, and the individual’s health status, screening history, and age-appropriate preventive services covered by Medicare; and
 - A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under §410.16), and a list of treatment options and their associated risks and benefits;
- Furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks

and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition; and

- Any other element determined appropriate by the Secretary through the National Coverage Determination process.

As noted, the “first annual wellness visit providing personalized prevention plan services” includes, among other things, “Establishment of an individual’s medical and family history” and “Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.”

This definition assumes that the physician does not already know the patient’s medical and family history or other providers and suppliers involved in the patient’s care. The reality is that primary care physicians, such as family physicians, who are most likely to provide these services already have an established relationship with their Medicare patients and therefore already know the patient’s medical and family history and other providers and suppliers involved in the patient’s care. This is consistent with comprehensive and continuity of care that primary care physicians in general and family physicians in particular provide to their patients.

Accordingly, we would recommend that CMS change “Establishment of an individual’s medical and family history” and “Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual” to “Establishment of or update to . . .” in both instances. We note that CMS has one definition that covers both “establishment of, and an update to the individual’s medical and family history,” so this change should be easy to make within the current construct of CMS’s proposal.

Health risk assessment

Interestingly, CMS offers no definition for “health risk assessment.” In fact, CMS has not included any requirements related to the health risk assessment in this proposed rule. Instead, CMS states, “When HRA [health risk assessment] guidelines and standards have been established, and a model HRA instrument is available and determined by the Secretary to be appropriate for the Medicare population, we will revise these regulations to include the HRA as an element in the definition of the annual wellness visit.”

What makes this interesting is that section 4103 of the PPACA requires that a health risk assessment be included in the new annual wellness visit beginning January 1, 2011. Indeed, section 4103 lists a health risk assessment as the first element of an annual wellness visit.

The health risk assessment allows the visit to be personalized to the specific needs of the patient based in part on the information gathered in his or her health risk assessment. Instead, CMS proposes to take a cookie cutter approach to the annual wellness visit and require the same elements to be performed, regardless of the patient’s need. However, for example, not every Medicare patient needs to be screened for functional ability and safety, and many will have already had such tests performed outside the annual wellness visit.

The purpose for creating this visit was to provide an annual, Medicare-covered encounter dedicated to prevention. Because not everyone's prevention needs are the same, the idea was to create a personalized experience, the ultimate product of which is a customized plan that identifies key risk factors and then provides an appropriate set of instructions, referrals, and guidance for what the patient needs to do over the course of time to address modifiable risk factors, stay healthy, and get screened. The key to the personalized nature of the visit is the health risk assessment, which is why it is bundled with the visit. Together, the health risk assessment and the encounter comprise the prevention plan services. The content of the encounter was meant to be driven in large part by the results of the health risk assessment, thus leading to a more personalized experience, in sharp contrast to the standardized, "one size fits all" approach embodied by the Initial Preventive Physical Examination (i.e., Welcome to Medicare Visit).

We fail to understand how CMS can properly define an annual wellness visit as anticipated by section 4103 without defining what is involved with health risk assessment. The health risk assessment is a fundamental component of establishing the personalized prevention plan, and the visit cannot be defined adequately in the absence of a model for how the health risk assessment will be incorporated into the design of the visit. It is like trying to define the ingredients of bread and neglecting to mention the flour. As a consequence, CMS's proposal appears incomplete, and we would encourage the agency to get about the business of defining "health risk assessment," so that its proposal can be evaluated appropriately.

Coding and payment

To allow for Medicare reporting and payment of the annual wellness visit, CMS is proposing to create two new HCPCS G-codes for reporting the first wellness visit and creation of the PPPS and the subsequent visits available to the beneficiary every 12 months. CMS proposes to value the work of the code for the first wellness visit equivalent to an IPPE, which is valued equivalent to a 99204 with 2.43 work RVUs. CMS is also assigning similar PE inputs and malpractice RVUs to this code. For the code for the subsequent annual wellness visit, CMS proposes to value the code similar to a 99214, which has 1.50 work RVUs.

CMS proposes to allow a medically necessary, problem-oriented evaluation and management (E/M) service to be separately reported (using modifier 25) when provided at the same encounter as an annual wellness visit. However, CMS states that it expects this scenario would be "uncommon," and it expects that the components of the annual wellness visit would not be used in determining the level of the separately reported E/M visit.

As noted, the annual wellness visit is not yet fully defined, because a central element, application of the health risk assessment, is not yet defined. Consequently, it is difficult for us to evaluate the relative values that CMS proposes to assign to these two new codes.

That said, we are disturbed at what CMS is requiring the now covered annual wellness visit to include relative to the proposed payment allowance. For instance, it seems a bit harsh to include assessment and documentation of the presence (or not) of cognitive impairment as an element when this alone might justify a comparable level of service due to the time it requires and the accompanying time spent in counseling and coordination of care with the patient and family. CMS also proposes to require a

preventive screening schedule for the next five to ten years, which is a good idea in theory but one that will take much more time than for which CMS is proposing to pay! Based on CMS's proposed requirements for the first and subsequent wellness visits, we would suggest that they should more appropriately be valued equivalent to a 99205 and 99215, respectively.

CMS's proposed undervaluation of this service may lead many physicians to otherwise provide a preventive medicine service as described by Current Procedural Terminology (CPT) codes 99381-99397 in lieu of the new "annual wellness visit." Because CMS excludes coverage of those CPT codes and makes the beneficiary liable for any associated physician charges, physicians can use them to provide an age-appropriate annual wellness visit as envisioned in the legislation and still receive an appropriate level of compensation for their time and effort. Unfortunately, CMS's proposed valuation of its new G codes will not achieve the same end.

We do appreciate CMS's willingness to allow a medically necessary, problem-oriented E/M service to be separately reported (using modifier 25) when provided at the same encounter as an annual wellness visit. However, we believe that CMS should disabuse itself of the notion that this will be an "uncommon" scenario. In our members' experience, it is common for patients to present for a preventive medicine visit and then say, "Oh, by the way . . ." and proceed to engage the physician in a problem-oriented E/M service. This is true whether the patients are Medicare beneficiaries or not. In addition, a substantial number of Medicare beneficiaries have chronic medical problems. It makes sense, and is more efficient of the patient's time, to address assessment and changes to chronic medical conditions at the same visit as a comprehensive wellness evaluation, as comorbid conditions will influence a physician's recommendations for the patient's personal prevention plan. Patients without significant comorbid conditions would be less likely to need a separate E/M service.

Provisions of the PPACA: Section 4104 (Removal of Barriers to Preventive Services in Medicare)

Section 4104 of PPACA revises the Social Security Act by defining the term "preventive services." It also waives coinsurance and deductible for the IPPE and for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate to the individual. CMS proposes to modify its regulations to conform to these statutory changes.

We have reviewed CMS's proposed regulatory revisions and agree that they accurately represent what is described and intended by section 4104 of PPACA. Table 38 in the proposed rule, which clearly outlined, by code, the proposed coinsurance and deductible status of preventive services under Medicare, was especially helpful in this regard, and we would encourage CMS to make some form of this table available on its web site after it publishes the final rule on the 2011 physician fee schedule this fall.

We also appreciate CMS's interpretation of the statute with respect to vaccines and their administration covered under Medicare Part B (i.e., influenza, pneumococcal, and hepatitis B vaccines). We agree with CMS that these immunization services meet the requirements (and the intent) of the statute for the waiver of coinsurance and deductible based on the most recent USPSTF grades for these services.

Provisions of the PPACA: Section 5501(a) (Incentive Payment Program for Primary Care Services)

Section 5501(a) of the PPACA provides for incentive payments equal to 10 percent of a primary care practitioner's allowed charges for primary care services under Part B between January 1, 2011, and before January 1, 2016. Payments would be made on a quarterly basis. The law defined primary care services as those services identified by the following codes as of January 1, 2009, listed in the table below from the proposed rule. The table appears as Table 39 in the proposed rule and consists of office visits, nursing home visits and home health care visits.

CPT Codes	Description
99201	Level 1 new patient office or other outpatient visit
99202	Level 2 new patient office or other outpatient visit
99203	Level 3 new patient office or other outpatient visit
99204	Level 4 new patient office or other outpatient visit
99205	Level 5 new patient office or other outpatient visit
99211	Level 1 established patient office or other outpatient visit
99212	Level 2 established patient office or other outpatient visit
99214	Level 4 established patient office or other outpatient visit
99215	Level 5 established patient office or other outpatient visit
99304	Level 1 initial nursing facility care
99305	Level 2 initial nursing facility care
99306	Level 3 initial nursing facility care
99307	Level 1 subsequent nursing facility care
99308	Level 2 subsequent nursing facility care
99309	Level 3 subsequent nursing facility care
99310	Level 4 subsequent nursing facility care
99315	Nursing facility discharge day management;. 30 minutes
99316	Nursing facility discharge day management; more than 30 minutes
99318	Other nursing facility services; evaluation and management of a patient involving an annual nursing facility assessment.
99324	Level 1 new patient domiciliary, rest home, or custodial care visit
99325	Level 2 new patient domiciliary, rest home, or custodial care visit
99326	Level 3 new patient domiciliary, rest home, or custodial care visit f

CPT Codes	Description
99327	Level 4 new patient domiciliary, rest home, or custodial care visit
99328	Level 5 new patient domiciliary, rest home, or custodial care visit
99334	Level 1 established patient domiciliary, rest home, or custodial care visit
99335	Level 2 established patient domiciliary, rest home, or custodial care visit
99336	Level 3 established patient domiciliary, rest home, or custodial care visit
99337	Level 4 established patient domiciliary, rest home, or custodial care visit
99339	Individual physician supervision of a patient in home, domiciliary or rest home recurring complex and multidisciplinary care modalities; 30 minutes
99340	Individual physician supervision of a patient in home, domiciliary or rest home recurring complex and multidisciplinary care modalities; 30 minutes or more
99341	Level 1 new patient home visit
99342	Level 2 new patient home visit
99343	Level 3 new patient home visit
99344	Level 4 new patient home visit
99345	Level 5 new patient home visit
99347	Level 1 established patient home visit
99348	Level 2 established patient home visit
99349	Level 3 established patient home visit
99350	Level 4 established patient home visit

The primary care practitioners would be identified as the following:

- (1) in the case of physicians, enrolled in Medicare with a primary specialty designation of 08-family practice, 11-internal medicine, 37-pediatrics, or 38-geriatrics; or
- (2) in the case of non-physician practitioners (NPPs), enrolled in Medicare with a primary care specialty designation of 50-nurse practitioner, 89-certified clinical nurse specialist, or 97-physician assistant; and
- (3) for whom the primary care services displayed in Table 39 accounted for at least 60 percent of the allowed charges under Part B for such practitioner during the time period that is specified by the Secretary, and proposed in this section.

CMS proposes to use 2009 data to identify primary care practitioners eligible for the Primary Care Incentive Payment (PCIP) based upon claims data and the practitioner’s national provider identifier (NPI) number. This would include claims processed through June 30, 2010.

Newly enrolled Medicare practitioners would not be eligible for the PCIP until Medicare claims data reflecting the practitioner’s primary care specialty and a percentage of allowed charges for primary care services equals or exceeds the 60 percent. However, CMS stated that it is committed to supporting primary care practitioners and is therefore inviting comments on “alternative approaches for establishing PCIP eligibility for newly enrolled practitioners that would be consistent with the statutory requirement.” CMS also will monitor data to determine whether physicians may be changing their specialty designations in an attempt to take advantage of the PCIP. CMS notes the statute denies

both administrative and judicial review for this program under the assumption that Congress intended implementation as soon as possible.

With respect to CMS's proposed implementation of the PCIP, we would observe the following:

1. *Quarterly payments.* We note that CMS proposes to use the discretion provided in the law to pay the PCIP on a quarterly (rather than on a monthly) basis, and we agree. There are many different types of primary care practices that submit payments on different schedules. A quarterly distribution will minimize the administrative requirements and fit more conveniently with most practice claims schedules.

2. *Definition of primary care services.* While the law defines primary care services for purposes of eligibility for and payment of the primary care bonus as a list of codes, AAFP feels that the list is inadequate for capturing essential primary care services and that CMS has discretionary authority to adjust the list to reflect actual primary care services. We would note that the law includes discretionary authority when it defines primary care services as "services identified as of January 1, 2009, by the following HCPCS codes (*and as subsequently modified by the Secretary*)..." [Emphasis added]. The enclosed table provides the sets of codes that AAFP would like to see added to the numerator used in qualifying primary care physicians for PCIP. We estimate that addition of these codes to the "numerator" in CMS's calculations would permit almost 3,000 (4%) more family physicians to qualify for the PCIP at the current 60% threshold. Absent some change like this in the proposed calculation of eligibility for the bonus, we believe that the current formula approved by Congress will leave out many of the physicians that Congress otherwise intended to help.

We are also concerned that this definition is biased against rural physicians. The Robert Graham Center studies referenced below suggest that less than half of rural primary care physicians will be eligible. In rural areas, primary care physicians must offer a broader array of services, especially inpatient and emergency care, which is consistent with the definition of primary care accepted by the Institute of Medicine (IOM) and the World Health Organization (WHO). CMS should consider a rural physician exemption or modification. We suggest that all rural physicians be included unless 50% or more of their claims come from inpatient or emergency services.

A similar bias may exist against physicians that are practicing in a patient-centered medical home (PCMH). To the extent that they provide comprehensive services to their patients, they will offer a broader array of services than what is captured in CMS's proposed definition, but this array of services will likely be consistent with other definitions of primary care, such as those accepted by the IOM and WHO. As with rural physicians, we suggest that CMS make some allowance for physicians who are practicing in a PCMH in its calculation of the PCIP.

In any case, the calculation needs to be fixed, and CMS should try and use its 'interpretive' power as suggested above to do this to the extent possible.

3. *Identification of primary care practitioner.* To determine who is a primary care physician or provider, CMS proposes to use the primary specialty designation provided by the physician,

nurse practitioner or physician assistant in billings submitted for services provided in the most current full year of claims data (i.e., 2009 for bonus payments to be distributed in 2011). CMS notes that the specialty designation is applied to each claim by the claims processing system. We agree with this initial identification process, since it is administratively simple and non-burdensome. However, we are concerned that, as CMS has noted, there will be opportunity for physicians or providers to change their specialty designation, and we support the subsequent proposal of CMS to monitor this switching process carefully. We agree that it will be appropriate to review the designation every year, based on the previous year's claims.

4. *Newly enrolled Medicare providers.* Since CMS is proposing to use a year of data to verify eligibility for the PCIP, newly enrolled Medicare providers will essentially have to wait a year before they could be eligible. We would suggest, as an alternative, that for newly enrolled primary care physicians and providers CMS consider using a six-month period of data. This could be a pre-defined six month period (e.g., January through June) or a six month period particular to the provider (e.g., his or her first six months of claims data). We note that CMS has six-month reporting periods as an option for determining PQRI payments, and it seems reasonable to offer that as an option for PCIP for newly enrolled primary care physicians and providers, too.

As another alternative, CMS might simply presume that newly enrolled Medicare providers in the designated specialties will meet the bonus threshold until proven otherwise after the first year. It is otherwise a disincentive to start taking Medicare patients. It is in CMS' best interest to tell newly enrolled Medicare providers in the designated specialties up front that they will receive the bonus in good faith and then tell them how to remain eligible.

We note that, in the discussion about getting newly enrolled Medicare physicians and providers into the PCIP cycle as quickly as possible, CMS says: "...given our general interest in supporting primary care practitioners and entry into primary care practice by new physicians and NPPs in order to ensure that Medicare beneficiaries have access to these important services,..." CMS can support this interest by addressing the numerator and denominator issues relative to the PCIP, which we are highlighting elsewhere in our comments on the PCIP.

5. *Monitoring specialty designation of primary care physicians and providers.* We strongly agree that CMS needs to review the designation of primary care physicians and providers to make sure there is no gaming the system. The Robert Graham Center found specific discrepancies by matching National Provider Identifier declared specialty with claims self-designation and AMA training history. Comparisons of two or more of these files could be routinely used to identify potential mis-designation and fraud.

6. *No administrative or judicial review.* We agree with CMS that Congress has specifically emphasized the importance of distributing the PCIP in a timely way by eliminating administrative and judicial review of the agency's decisions. We share the Congressional sense of urgency. We further agree with CMS's conclusion that this provision does not preclude CMS from correcting errors made from clerical or mathematical mistakes. We appreciate the willingness of CMS to accept information from physicians who believe the decision on their eligibility was based on such an error.

7. *PCIP payment regardless of other payments.* We agree that Congress has been clear that eligibility for the PCIP has no relation to any other payment that Congress has authorized. In other words, Congress has authorized a 10-percent bonus payment for physicians and providers who practice in Health Professionals Shortage Areas. Neither payment should affect eligibility for the other, since they are designed for different purposes.

8. *Eligibility threshold of 60 percent of allowed Part B charges.* Congress designed this eligibility threshold to ensure that the bonus payment was directed to primary care physicians and providers who were engaged in offering mostly primary care services. However, when calculating the percentage, CMS considers all Part B allowed charges, including laboratory and other ancillary services, to be in the denominator. We are concerned that including these non-office based services will greatly reduce the number of primary care physicians and providers who will be eligible for this bonus payment. In a May 2009 White Paper, entitled "Effects of Proposed Primary Care Incentive Payments on Average Physician Medicare Revenue and Total Medicare Allowed Charges," the Robert Graham Center estimates that only 59 percent of family physicians and general practitioners would be eligible. They further estimated that only 38 percent of internists, 23 percent of pediatricians, and 63 percent of geriatricians would be eligible.

Under contract to Health Resources and Services Administration (Office of Rural Health Planning), the Graham Center has further demonstrated that there is a significant bias in the bonus payment calculation against rural primary care physicians, due to the fact that they must have a broader scope of practice to serve rural Medicare beneficiaries. Rural physicians are more likely to deliver care in the emergency room and hospital and to perform minor surgical procedures. As it stands, the threshold calculation may have the unintended consequence of narrowing scope of practice for rural physicians and of limiting access for rural Medicare beneficiaries. Under the same contract, the Graham Center has used data on scope of practice from the American Board of Family Medicine and from the Dartmouth Atlas to do ecological analyses and found a strong association between broader scope of practice in primary care and reduced Medicare costs. So, the bias against rural physicians and broad scope of practice in the bonus threshold calculations may ultimately work against Medicare's interest in lowering costs and securing access for beneficiaries. We strongly believe that CMS should investigate ways within its authority that may avoid these potentially harmful biases.

Provisions of the PPACA: Section 6404 (Maximum Period for Submission of Medicare Claims Reduced to Not More Than 12 Months)

Historically, as authorized by statute and CMS, physicians had a minimum time limit for filing Part B claims of 15 months and a potential maximum of 27 months after the service was furnished, depending on what month of the year the service was furnished. PPACA changes that by requiring that all claims for services furnished on or after January 1, 2010, must be filed within 1 calendar year after the date of service, while claims for services furnished before January 1, 2010, must be filed on or before December 31, 2010. CMS proposes to amend its regulations to be consistent with the statutory changes imposed by the PPACA.

Historically, CMS also had one exception to the timely filing limit. That exception applied when the failure to file "...was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority." Consistent with the authority provided in Section 6404 of the PPACA, CMS also proposes to create two new exceptions. The first new exception would apply when CMS or one of its contractors determines that the following conditions have been met:

- At the time the service was furnished the beneficiary was not entitled to Medicare; and
- The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

The second new exception would apply when CMS or one of its contractors determines that all of the following conditions have been met:

- At the time the service was furnished the beneficiary was not entitled to Medicare;
- The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service; and
- A State Medicaid agency recovered the Medicaid payment for the furnished service from the provider or supplier 11 months or more after the date of service.

In the case of the first new exception, the time to file a claim would be extended through the last day of the 6th calendar month following the month in which the beneficiary received notification of Medicare entitlement effective retroactively to or before the date of the furnished service. In the case of the second new exception, the time to file a claim would be extended through the last day of the 6th calendar month following the month in which the State Medicaid agency recovered the Medicaid payment for the furnished service from the provider or supplier.

For the existing exception, the extension of time is the last day of the 6th calendar month following the month in which the error or misrepresentation is corrected. However, no extension of time will be granted when the request for this particular exception is made to CMS or one of its contractors more than four years after the date of service, consistent with current CMS policy. CMS does not propose to define "date of service" and instead intends to provide "sub-regulatory" guidance on what constitutes the date of service for different services.

We have reviewed CMS's proposed regulatory changes in response to section 6404 of the PPACA and are generally content that they are consistent with the statute. We also appreciate CMS's proposal to add two new exceptions to the corresponding timely filing limits.

Regarding the extended time limit that CMS proposes for each exception, we question why CMS is only granting six months. The PPACA provision essentially provides physicians and others with a 12 month period in which to file claims for services for which they have reason to believe Medicare may be responsible. However, in the exceptions graciously provided by Medicare, the physician only has 6 months to file a claim after he or she becomes aware of Medicare's responsibility. We believe, consistent with PPACA, that the time to file a claim under each exception should be extended through the last day of the 12th month following the month in which the exception applies.

Also, as regards the exception due to error or misrepresentation on the part of Medicare, we think the extended time limit should be based on the month in which the error or misrepresentation is corrected and the physician has been notified of that fact. As proposed, the extended time limit begins when the error or misrepresentation is corrected, without apparent regard to whether or not the physician is aware of that fact. Recognizing that there may be some time between when the error or misrepresentation is corrected and when the physician is notified of this fact, we think that it is at the latter point (i.e., the point at which the physician becomes aware of the correction) that the extended time limit should begin.

Accordingly, we would recommend that 42 CFR 424.44(a)(4) be revised to read as follows:

(4) Extension of time. (i) The time to file a claim will be extended through the last day of the 12th calendar month following the month in which the provider or supplier has been notified that the error or misrepresentation referenced in paragraph (b)(1) of this section, is corrected. However, no extension of time will be granted for paragraph (b)(1) when the request for that exception is made to CMS or one of its contractors more than 4 years after the date of service.

(ii) If CMS or one of its contractors determines that both of the conditions are met in paragraph (b)(2) of this section but that all of the conditions in paragraph (b)(3) are not satisfied, the time to file a claim will be extended through the last day of the 12th calendar month following the month in which the beneficiary received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) If CMS or one of its contractors determines that all of the conditions are met in paragraph (b)(3) of this section, the time to file a claim will be extended through the last day of the 12th calendar month following the month in which the State Medicaid agency recovered the Medicaid payment for the furnished service from the provider or supplier.

Finally, with respect to 42 CFR 424.44(a)(4)(ii), we have a question that we hope CMS will address in the final rule. Namely, the extended time limit commences with notification of the Medicare beneficiary regarding his or her retroactive entitlement effective date. If the beneficiary does not, in turn, notify the physician of the retroactive entitlement until after the extended claims filing time limit expires, does the beneficiary remain responsible for payment of the service? From our perspective, we believe the beneficiary remains responsible, since the notice of retroactive entitlement goes to the beneficiary, not the physician, and the beneficiary's failure to notify the physician in a timely fashion precludes the physician from filing a timely claim. Some confirmation of this view in the final rule would be appreciated.

Other Provisions of the Proposed Regulation: Clinical Laboratory Fee Schedule – Signature on Requisition

The AAFP recommends that CMS not change current policy regarding signatures for laboratory requisitions. CMS's current policy is that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the clinical laboratory fee schedule. However, it must be evident, in accordance with CMS's regulations at 42 CFR 410.32(d)(2) and (3), that the physician ordered the services.

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In this proposed rule, CMS is proposing to require a physician's or non-physician provider's (NPP's) signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the clinical laboratory fee schedule. CMS believes that this policy would result in a less confusing process, because a physician's signature would then be required for all requisitions and orders. This, in turn, would eliminate uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature.

CMS also believes that this proposal would not increase the burden on physicians. It is CMS's understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the "order"), as well as providing a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the "requisition") as a matter of course. Further, CMS contends that this policy would make it easier for reference laboratory technicians to know whether a test is appropriately requested. Finally, CMS argues that potential compliance problems would be minimized for laboratories during the course of a subsequent Medicare audit because a signature would be consistently required.

The AAFP disagrees with this analysis and believes that requiring a signature in all cases will create an excessive burden. In particular, when physicians use electronic ordering in an office EHR (Computer Physician Order Entry, which is a required component of EHR Meaningful Use criteria), having a physical signature would require printing paper (the exact opposite of the intent of EHR).

When CMS raised this issue last year in its proposed rule on the 2010 Medicare physician fee schedule, we noted that CMS's distinction between an "order" and a "requisition" was somewhat convoluted but made sense to us if understood in the following way. An "order," as defined by CMS, represents a physician's (or NPP's) request for a diagnostic test for a beneficiary. As such, it may take multiple forms (i.e., written, verbal, electronic) and be transmitted in different ways. One way to transmit an order is a "requisition," which CMS has defined as physical paperwork that relays an order from a physician (or NPP) to the entity providing the diagnostic test.

With this distinction in mind, we have supported CMS's policy that a written order for diagnostic tests, including those paid under the clinical laboratory fee schedule and those that are not paid under the clinical laboratory fee schedule should be signed by the ordering physician or NPP. The request for a diagnostic test represents part of the physician's plan for the patient, which is part of the patient's medical record. As such, when the request is in writing, a physician signature would be appropriate and likely easily generated, assuming the physician is writing the order.

We have also supported CMS's previous policy that a physician's signature is not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule. To the extent a "requisition" is simply a paper mechanism for transmitting an order and more administrative in nature, it is less likely to be generated or handled by the physician. Thus, to require a physician signature on a requisition for clinical diagnostic laboratory tests paid on the basis of the Clinical Laboratory Fee Schedule, as CMS now proposes to do, would be an added and unnecessary burden on physicians, from our perspective. Accordingly, we urge CMS to maintain its current policy that requires evidence that a physician (or NPP) ordered a clinical diagnostic lab test

paid on the basis of the clinical laboratory fee schedule and does not require a physician's signature on the requisition for such tests.

Physician Quality Reporting Initiative (PQRI)

PQRI has been in existence since 2007 and provides incentive payments for Eligible Physicians (EPs) who report on quality measures. Incentive levels as high as 2% of Medicare physician fee schedule payments have been available through the program. Initially the program required claims based reporting to qualify. In 2008, registry based reporting was added as an option as long as the registry was deemed "CMS qualified." In 2009, CMS began testing programs for Electronic Health Record (EHR) reporting of quality data.

PPACA supports the continuation of the PQRI program with some significant changes in both the operation of the program and the incentive structure over the next few years. Key changes for the program include the following:

- 1) The incentive available is reduced to 1% for 2011, 0.5% for 2012 through 2014 and a penalty for those not reporting by 2015 in the form of a deduction from fee schedule payments.
- 2) EPs who participate in a Maintenance of Certification (MOC) Program that includes a practice assessment will be eligible for an additional bonus of 0.5%. The practice assessment may need to be completed more often than required by the individual specialty Board, probably once per year.

We believe that certain parts of the proposed rule misinterpret the original legislative intent of the statute as it pertains to the American Board of Medical Specialties' (ABMS) MOC provisions surrounding the PQRI. Specifically, the proposed rule requires that eligible physicians participating in MOC programs must "more frequently" participate in MOC. The narrative of the proposed rules indicates that the requirement should be applied both to the elements of the MOC program (Parts II and III, but not Part I) and the requirement to successfully complete a Part IV practice assessment. However, the language in section 1848(m)(7)(B)(ii) of the Social Security Act states, "The eligible professional, more frequently than is required to qualify for or maintain board certification status-- (A) Participates in such a Maintenance of Certification Program for a year; and (B) Successfully completes a qualified Maintenance of Certification Program practice assessment (as defined in paragraph (b) of this section) for such year." We would argue that nothing in this language would imply the "more frequently" requirement applies to anything other than the Part IV requirement, since no mention is made of Parts I, II, or III.

Equally troublesome is the narrative in the proposed rule that provides specific recommendations on how CMS will interpret the phrase "more frequently." The proposed rule indicates that this interpretation will vary depending on the specific MOC requirements for any given specialty board and that the interpretation could even vary between physicians certified by the same specialty board. We do not believe that it was the intent of the legislation to create unequal requirements for physicians to qualify for the incentive payment. We would suggest that CMS create a uniform requirement for all physicians, and specifically, that the March 2009 Standards for ABMS MOC adopted by the ABMS Board of Directors be used as the basis for establishing this requirement. Those standards require that Diplomates of ABMS member boards must complete a Part IV activity every two to five years. We

would suggest that anything that was more frequent than this (e.g., one Part IV activity every 1-4 years) would meet the intent of "more frequently."

We would respectfully make one additional point regarding the practical implementation of the "more frequently" language in the proposed rule. As currently written, it is conceptually impossible to determine how the rule could be applied. Since 2011 will mark the initial year of implementation of the ABMS MOC provisions as they apply to PQRI, how will the Boards or CMS determine what is "more frequently?" Will it be taking into consideration all MOC Part IV activity completed prior to 2011? If not, it would be necessary for Diplomates to complete two Part IV activities in 2011 to meet the "more frequently" requirement and qualify for the bonus for that initial year. From a practical standpoint, this is just not possible for Diplomates to accomplish. We believe the rule needs to provide further clarification with regard to the practical implementation of the "more frequently" requirement.

The proposed rule also requires a qualified MOC practice assessment to include a survey of patient experience of care in order to receive the 0.5% incentive payment. While we are strongly in favor of measuring patients' experience with care, it is important to note that ABMS has not yet adopted a definitive standard with regard to recording and reporting patients' experience with care and will not do so until 2012 at the earliest. Except for the American Board of Family Medicine and one other ABMS member board, all of the remaining 22 ABMS member boards are not collecting this information and would not be able to report it in 2011. Since we believe the intent of this legislation is to encourage participation in PQRI, we would respectfully request that CMS waive this requirement in 2011 and implement it in 2012. This would provide the opportunity for other ABMS member boards to create mechanisms for collecting this information in 2011 and reporting it to CMS in 2012, which consistent with the intent of the legislation to create equal requirements for physicians to qualify for the incentive payment, as noted above.

3) The Secretary is required to develop a Physician Compare Internet web site by January 1, 2011. Participating physicians in Medicare and other EPs under the PQRI program would be listed on the web site, with a notation about successful qualification for the PQRI incentive.

4) EPs will be able to qualify for PQRI bonuses through three mechanisms: Claims Based Reporting (CBR), Registry Based Reporting (RBR) and EHR Based Reporting (EBR). Two reporting periods are available for CBR and RBR, 12 months or the last six months of the year. EBR will only be reported for the full year.

We recommend that the reporting period for EBR be expanded to the same two options as the other methods of reporting. The additional reporting periods were instituted to increase participation rates in a new and evolving program. EPs who implement EBR after January 1 but before July 1 should be able to take advantage of incentives in the same manner as the other reporting methods.

CBR has been problematic from the start of the PQRI program. The claims system was designed and has evolved to support payment and not quality reporting. The complexity of the system makes EP understanding difficult, technical issues taxing, and errors frequent. We recommend that the CBR option be phased out with the expectation that RBR and EHR reporting will be the mainstay of the program. Registries and integrated computer systems facilitate proactive care for chronic illness and

promote ongoing quality improvement in a way that CBR does not. The feedback loop for CBR is inordinately long and of little value for quality improvement or better patient care.

5) EPs who elect to participate by EBR must have a PQRI qualified EHR product and the data must be submitted to a CMS clinical data warehouse in a manner and format specified by CMS.

We recommend that CMS consider accepting measure rates from EHRs rather than just numerator and denominator data. Rates generated within the system will be more readily available for local quality improvement purposes and timely feedback to EPs and office staff. Timely feedback has been and will continue to be a problem for this program. System characteristics that promote and facilitate local improvement efforts should be designed in from the outset.

6) Requirements for CMS qualified registries are detailed, including sponsor participation in mandatory meetings and conference calls. They must be able to report data at the TIN/NPI level, and they must be able to separate out Medicare Part B FFS patients for reporting. Registries will no longer be able to combine both commercial insurance patients and Medicare patients, as was permitted in the past.

It is not clear if reporting needs to be at both the TIN **and** NPI level or the TIN **or** NPI level. We recommend that all quality reporting be required to include NPI information and feedback at that level. Registries are most useful for improved patient care when all patients in the practice with a particular condition are included in the system. This change eliminates any benefit that EPs had for using the registry more broadly than just for Medicare patients.

8) CMS proposes to require all qualified registries to submit data on numerator and denominator results, so CMS could then calculate the rates. The purported reason for this requirement is to reduce the variation that has been observed in comparing information from various registries. The proposed rule also expresses a concern that small practices may not be able to participate in registry reporting.

We believe that the rate calculation from the numerator and denominator data involves simple arithmetic and is unlikely to be the cause of the observed variation. The more likely cause is a variation in how the data is collected or defined within the system. This remedy is not likely to work. RBR is actually ideal for small practices, because data collection can even be done manually, if needed, on the small number of patients required (30). Small practices can also use registries offered by certifying Boards or specialty societies at low cost.

9) CMS has asked for comment on their proposal to lower the rate of successful submissions in the CBR method from 80% to 50%.

CBR has been error prone, complex, and “user unfriendly” from the start for a myriad of reasons. It seems that the proposal to drop the requirement from 80% to 50% is really an acknowledgement of the lack of validity and reliability of the method and system rather than an attempt to discover the true reporting rates by individual EPs. CMS data and individual investigation of complaints show that most of the EPs who failed to qualify actually had fairly high reporting rates at the practice level. The “voltage drop” occurred in the transfer, scrubbing, and analysis of the data.

10) Measures used in the PQRI program must be endorsed by the National Quality Forum (NQF).

We agree with a final common pathway for measure endorsement. The NQF has developed the capability to do this work and should continue. The AQA Alliance is no longer doing measure evaluation work and should not be allowed to approve measures for PQRI as a way to side-step the well-designed and well-executed process of the NQF.

11) CMS proposes to allow qualified maintenance of certification programs (MOCP) to qualify an EP for the PQRI bonus payment. An alternative under consideration is to allow the individual specialty Board to submit data on individual EPs to the American Board of Medical Specialties (ABMS), which would then be able to verify EP qualification.

Although the ABMS has issued guidelines for MOCP, the individual Boards have a fair amount of latitude in how they implement those guidelines. We favor the plan to have individual specialty Boards meet the CMS criteria if they wish to be deemed to verify individual EP qualification for PQRI incentives.

12) The PPACA calls for the Secretary to integrate the PQRI and EHR "Meaningful Use" Reporting. CMS is seeking input on this process of integration.

Although we favor any simplification and alignment of measures between these two programs, the purpose of each is actually different, which will make it difficult to achieve this integration. Quality reporting is only one of the features of meaningful use, and of course, PQRI measures should qualify for that objective. PQRI incentives should not require participation in meaningful use and meaningful use incentives should not specifically require PQRI. The degree to which any of the measures could share a dual purpose would be an added advantage for those who are trying to implement these programs.

13) The proposed rule says that CMS has developed an alternative report distribution method, so each EP could "request and receive a full feedback report."

The current system for PQRI feedback reports has not been timely or helpful. Delays in analysis and payment decisions have pushed reports out so far from the date of service (18 to 24 months) that they are not useful for quality improvement. We recommend that the system be redesigned to automatically generate a report as soon as the requirements for an individual EP have been satisfied. Data collection algorithms can be set up to assure that the data is complete and correct, or it will not be accepted. Once the required data has been submitted, the EP could see immediately on the online data entry screen that the task was complete. This is exactly what most of the registry systems do and why they have such a high level of successful completion.

14) The proposed rule sets up an informal review process for EPs who inquire about failure to receive the PQRI bonus. EPs must "request a review within 90 days of the release of his or her feedback report."

It is unlikely that many EPs will request a review if they are successful in obtaining a bonus. The review for those who are unsuccessful is unlikely to overturn the initial adjudication, since it can only be based on data present in the CMS system as there is no opportunity for evidence submission. EPs

submitting data could easily be given feedback immediately about whether the data set was complete or not both in terms of the individual data points and the number of eligible patients.

The Electronic Prescribing Incentive Program

According to the proposed rule, to qualify for Medicare e-prescribing incentive payments equal to one percent of their total Medicare Part B charges, eligible physicians need to report the e-prescribing measure for at least 25 visits during 2011. Similar to 2010, physicians have several options for reporting e-prescribing information, and certain group practices can participate as well. Physicians who participate in the 2011 Medicare electronic health records incentive program cannot simultaneously participate in the 2011 e-prescribing incentive program. CMS proposes that eligible physicians who fail to participate in the 2011 e-prescribing incentive program and do not qualify for an exemption would be subject to financial penalties starting in 2012.

The AAFP supports CMS's plan to reduce the e-prescribing reporting burden from 50 percent of all applicable services to reporting just 25 times. However, the AAFP urges CMS to revise the penalty program so that financial penalties are based on lack of e-prescribing activity in 2012, not 2011, which is consistent with the law.

The AAFP also recommends that CMS re-examine the entire e-prescribing program in light of the advent of the "meaningful use" initiative, which offers its own incentives and penalties. "Meaningful use" provides an opportunity and penalty that did not exist when the original e-prescribing regulations were put in place, and there is so much overlap between e-prescribing and "meaningful use" that some adjustments should be made. As it is, e-prescribing and "meaningful use" represent a form of "double jeopardy" for physicians. For instance, a physician who gets the first year "meaningful use" subsidy via Medicaid could also be penalized for not using e-prescribing. CMS needs to address these kinds of inconsistencies going forward. .

Closing Comments

In closing, we would like to observe the following. The proposed rule has much to commend it, and CMS has covered a lot of ground within its pages. As CMS moves forward, however, we would encourage the agency to not miss the forest for the trees. Of necessity, CMS has addressed a myriad of particular statutory and regulatory provisions for which it is responsible in the proposed rule, but these do not remedy the basic inequity of our current "doing more is better," "specialty care is more valuable than primary care," and "procedures are more valuable than cognitive services" environment. They are more akin to rearranging deck chairs on the wrong ship.

A fundamental reform of the payment system is needed, rather than a tinkering with our current broken system. Collectively, we need to start cultivating the environment for such fundamental reform, rather than the piecemeal changes that often introduce as many unintended consequences or challenges as improvements. We think that CMS understands that, and we note that, in the discussion about getting newly enrolled Medicare physicians and providers into the Primary Care Bonus Payment cycle as quickly as possible, CMS says: "...given our general interest in supporting primary care practitioners and entry into primary care practice by new physicians and NPPs in order to ensure that Medicare

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beneficiaries have access to these important services,..." We encourage CMS to keep that perspective moving forward.

We appreciate this opportunity to comment on matters related to the Medicare Physician Fee Schedule. As always, the AAFP looks forward to working with CMS in its continued efforts to ensure access to appropriate physician services.

Sincerely,

A handwritten signature in black ink that reads "Ted Epperly M.D." The signature is written in a cursive style and is positioned below a horizontal line.

Ted D. Epperly, M.D.
Board Chair

TDE:kjm

Enclosure



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

The following table provides the sets of codes that AAFP would like to see added to the numerator used in qualifying primary care physicians for the 10% bonus enacted under PPACA.

Code Set	Value proposition
G0402 - Welcome to Medicare physical G0101 – Pelvic and breast exam Q0091 – Pap collection G0328QW – Fecal Occult Blood Test, immunoassay 82270QW – Fecal Occult Blood Test by peroxidase activity, screening G0103QW – Prostate Specific Antigen Test (PSA), screening 99406-07 – Smoking cessation counseling	CMS has encouraged physicians to help ensure that Medicare beneficiaries receive the preventive services they need. ¹ The inclusion of these services that are commonly rendered by primary care physicians in the numerator for this bonus will help physicians further promote these valuable services and would not be expected to expand the bonus beyond primary care physician practices ² .
G0008 – Administration flu vaccine G9141- Influenza A (H1N1) administration 90655, 90656, 90657, 90658, 90660 – Influenza Virus Vaccine G0009 – Administration pneumonia vaccine 90669 – Pneumococcal Conjugate Vaccine 90732 – Pneumococcal Polysaccharide Vaccine G0010 – Administration hepatitis B vaccine 90740, 90743, 90744, 90746, 90747 – Hepatitis B Vaccine	CMS has noted that, “Despite Medicare coverage for influenza, pneumococcal, and hepatitis B vaccinations, the use of these benefits is not optimal.” ³ The primary care physician practice is the ideal setting for patients to be advised about and receive these important preventive services. Inclusion of these services in the numerator for the bonus may facilitate expanded access to these services and would not be expected to expand the bonus beyond primary care physician practices.
G0179 - Re-certification for Medicare-covered home health G0180 - Certification for Medicare-covered home health G0181 - Supervision of home health	Primary care provision of these care coordination services helps ensure that the plan of care for home health and hospice patients is up-to-date and that supplies and services ordered are

¹ <https://www.cms.gov/MLN Matters Articles/downloads/SE0630.pdf>, accessed 0/23/10

² Due to the scope of practice of most non-primary care specialists and higher allowable charges for procedural services, it is unlikely that the addition of the codes on this list would result in 60% of allowed charges.

³ <http://www1.cms.gov/AdultImmunizations/>

<p>services G0182 - Supervision of hospice services G0372 - Documentation of need for power mobility device</p>	<p>appropriate to the patient's condition. Because these services are typically referred to the primary care physician, even after hospitalization overseen by other physicians, it would be appropriate to include these services in the numerator.</p>
<p>36415 – Venipuncture 85610 - Prothrombin time 81002 – Urinalysis, dip stick/tablet reagent, non-automated, w/o microscopy 81003QW - Urinalysis, dip stick/tablet reagent, automated, w/o microscopy 82947QW – Glucose, quantitative, blood 83036QW - Glycosylated hemoglobin test 83037QW - Glycosylated hemoglobin test, by home test kit</p>	<p>Certain laboratory services are common across primary care practices and the Medicare population. Provision of these services in the primary care practice provides for better care management (i.e., immediate action on physician recommendations vs. referral for action). Inclusion of these services in the numerator for the bonus may facilitate continued access and would not be expected to expand the bonus beyond primary care physician practices.</p>
<p>94010 – Spirometry 94060 – Spirometry, pre- and post-bronchodilator admin.</p>	<p>Spirometry, in addition to clinical examination, improves COPD diagnostic accuracy compared to clinical examination alone and it is a useful diagnostic tool in individuals with symptoms suggestive of possible COPD. The primary benefit of spirometry is to identify individuals who might benefit from pharmacologic treatment in order to improve exacerbations. These include adults with symptomatic, severe to very severe airflow obstruction.⁴ AAFP survey data indicates spirometry is provided by 65% of family physician members making addition of this service to the numerator supportive of continued quality care. While this service is also offered by physician other than primary care physicians, it is unlikely that the addition of these codes would expand the bonus beyond primary care.</p>

⁴ <http://www.ahrq.gov/clinic/tp/spirotp.htm>