October 06, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1321-P
P. O. Box 8015
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents more than 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed notice regarding "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B," as published in the *Federal Register* on August 22, 2006.

Discussion of Comments – Background

Regarding budget neutrality; CMS notes that in the proposed notice for the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to Practice Expense Methodology, CMS has proposed to establish a separate budget neutrality adjustor that would be applied to the calculation of work RVU's. I would like to take this opportunity to again comment that we disagree with CMS's proposed approach to budget neutrality. We believe that CMS should implement any statutory budget neutrality adjustments through an adjustment to the conversion factor. An adjustment to the conversion factor reflects the nature of the budget neutrality adjustment which is made for fiscal reasons and not based upon a change in work values. As we previously noted, there are at least five reasons that we disagree:

1. Adjusting the conversion factor does not affect the relativity of services reflected in the total RVU's. Adjusting the work RVU's has the potential to inappropriately affect that relativity.
2. If the RVU's are adjusted as proposed, it will obfuscate the recommended changes and obscure the hard work done by the RUC.
3. An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVU's. We believe that CMS must consider such "ripple effects" as it decides how to adjust for budget neutrality.
4. CMS has attempted this approach in the past and found it to be problematic. Following the first five-year review, CMS implemented a similar work adjustor in 1997. Two years later, CMS eliminated it, noting that:

[W]e did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVU's to determine a payment amount that matched the amount actually paid by Medicare" (*Federal Register*, Vol. 68, No. 216, Pg. 63246).

5. We believe an adjustment to the conversion factor is preferable because it recognizes that budget neutrality is a fiscal issue, not an issue of relativity. Budget neutrality is mandated for monetary reasons. Thus, the conversion factor, as the monetary multiplier in the Medicare payment formula, is the most appropriate place to adjust for budget neutrality.

CMS also notes the expiration of the 1.0% floor of the work GPCI enacted January 01, 2004. Included in the NPRM is a table showing those localities which will have a negative percent change in the Geographic Adjustment Factor. We note that many of the areas indicated in this table are rural locations in which physician recruitment and retention are already difficult. Those localities where the negative change in geographic adjustment factor is greatest, South Dakota, North Dakota, Missouri and Montana, have many regions designated as Health Professional Shortage Areas. This negative adjustment may further exacerbate the difficulty of recruiting physicians to these areas and limit access to care for Medicare beneficiaries in these areas. The AAFP has previously commented regarding the flawed methodology of the GPCI and continues to support 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). We believe that reimbursement of physician services should not be based on the geographic location where the service is provided and that equivalent service should result in equivalent compensation. As noted, a policy of uniform payment should only be modified to achieve explicit policy goals (e.g., targeted adjustments for demonstrated shortfalls in access to care). I would urge CMS to support a legislative extension of the work GPCI floor.

As noted in the Combined CY 2007 Total Allowed Charge Impact table, family medicine as a whole faces another year of flat updates if this proposed fee schedule is enacted without Congressional intervention or action by CMS to administratively adjust the SGR formula. Family medicine physicians effectively lose the gains that resulted from the five-year review of the evaluation and management codes. This combined with the expiration of the 1% floor for the GPCI will result in a negative update for many family medicine physicians in underserved areas. We urge CMS to take action towards preventing this. As we commented one year ago, "Until a complete revision of the reimbursement formula is accomplished, there is an administrative adjustment that CMS can make immediately. Specifically, CMS should immediately remove, retroactive to the inception of the SGR, the physician-administered drugs from the SGR. These in-office medications are not reimbursed under the Medicare physician fee schedule and should never have been part of the formula used to calculate the conversion factor for physician services. Moreover, the Medicare Modernization Act restructured how these medications are paid for. CMS's continued inaction, in the face of a growing Medicare ambulatory care reimbursement crisis, is of great concern."

<u>Discussion of Comments – Provisions – RUC Recommendations</u>

The AMA's Relative Value Update Committee (RUC) established a new committee, the Practice Expense Review Committee (PERC), to assist the RUC in recommending direct practice expense inputs (clinical staff, supplies, and equipment) for new and existing CPT codes. The PERC reviewed the PE

inputs for over 2000 existing codes, some of which were unresolved practice expense issues from the CY 2006 PFS final rule with comment period, at their meetings held in September 2005, February 2006 and April 2006. CMS has reviewed the PERC-submitted recommendations and proposes to adopt all of them. CMS has worked with the AMA staff to make corrections for any typographical errors and to ensure that previously Practice Expense Advisory Committee (now PERC)-accepted standards are incorporated in the recommendations.

The AAFP participated in the PEAC process and supports this proposal.

Standard Supplies and Equipment for 90-Day Global Codes

CMS is proposing to revise the CPEP supply and equipment inputs for those 90-day global procedures for which the RUC has only refined the clinical labor inputs. As recommended by the RUC, for supplies, CMS proposes to include one minimum supply visit package for each postoperative visit assigned to each code and a post-surgical incision care kit (suture, staples, or both) where appropriate, along with additional items recommended by the RUC for certain procedures. CMS indicates that in some cases, the recommendations from the RUC contain additional items in quantities that appear excessive.

We agree that it is likely that CMS is reimbursing physicians for post-operative supplies that are not actually provided in all cases. As indicated in our comments related to the five-year review, we have suggested that CMS redefine the global surgical policy to eliminate the post-operative visits from the global package. This will eliminate the need to define how many post-operative visits are related to a procedure and how many supplies should be input to the practice expense for these visits. Although this would result in an increased number of evaluation and management service claims, it would also eliminate any excessive spending related to over-estimated post-operative visits and the related supplies. This would also hold all physicians to the same standards for the medical necessity and documentation of evaluation and management services.

Discussion of Comments – Provisions - Splint & Cast Supplies

In commenting on CMS's proposal in the NPRM for the 2006 Medicare Physicians Fee Schedule to include casting supplies in the practice expense for fracture care, we noted that inclusion of these supplies in the practice expense would simplify billing of fracture care. However, we agree that CMS should continue to reimburse the HCPCS Q-codes for splint and cast supplies to allow for billing of these items when not related to the care of a fracture. This will negate the need to review the effect of including the expense of these materials into the practice expense of the codes for fracture care.

Discussion of Comments – DRA Proposals – Ultrasound Screening for AAA

Section 5112 of the Deficit Reduction Act of 2005 amended section 1861 of the Act to provide for coverage under Part B of ultrasound screening for AAA's. CMS proposes to amend Section 1861(ww)(2) of the Act (the IPPE benefit) by adding the new ultrasound screening benefit to the list of preventive services for which physicians and other qualified non-physician practitioners must provide "education, counseling and referral" to new beneficiaries who take advantage of the initial preventive physical examination benefit within the first six months after the effective date of their first Part B coverage period.

The AAFP supports the use of evidence-based medicine. The United States Preventive Services Task Force (USPSTF) found good evidence that screening for AAA and surgical repair in men aged 65 to 75 who ever smoked leads to decreased AAA mortality. We support that the benefit is extended to those beneficiaries who have received a referral for an ultrasound screening as part of initial preventive physical examination, have not been previously furnished an ultrasound screening examination under the Medicare program and is included in one of the following risk categories:

- Has a family history of AAA
- a male patient aged 65 to 75 who have smoked at least 100 cigarettes in his lifetime
- is an individual who manifests other risk factors that are described in a benefit category recommended by the USPSTF regarding an AAA that has been determined by the Secretary through the NCD process

However, as addressed in the AAFP comments on the NPRM for the Changes to the 2005 Medicare Physician Fee Schedule, I would again express our disappointment at the devaluing of the work and expense of providing the Initial Preventive Physical Examination service which is assigned 2.57 RVU's (roughly equal to a 99203 visit which is assigned 2.56 RVU's). As is evidenced by the language of section 1861(ww) (2), physicians must provide "education, counseling and referral" in addition to a comprehensive age/gender appropriate history and examination. This work is equal to that of CPT code 99387 which describes this preventive service. I respectfully request that as CMS adds this additional "education, counseling and referral" to this benefit, CMS also reconsiders the value assigned to the service and aligns it's value more appropriately to code 99387 which has been valued at 4.00 RVU's.

Discussion of Comments – DRA Proposals – Colorectal Cancer Screening Tests

Current Medicare policy requires that, with limited exceptions, incurred expenses for covered part B services are subject to, and count toward meeting the Part B annual deductible. Section 5113 of the DRA amended section 1833(b) of the Act to provide for an exception to the application of the Part B deductible with respect to colorectal cancer screening tests. Beginning January 1, 2007, colorectal cancer screening services, as described in section 1861(pp) (1) of the Act, are no longer subject to the Part B deductible. CMS proposes to add an exception to the Part B deductible of colorectal cancer screening tests to section 410.160 to conform to regulations of the Deficit Reduction Act.

We strongly support this proposal which may encourage beneficiaries to undergo these important preventive services.

Discussion of Comments – Reassignment and Physician Self-Referral

CMS proposes to amend §424.80 of the regulations to clarify that any reassignment pursuant to the contractual arrangement exception is subject to program integrity safeguards that relate to the right to payment for diagnostic tests. First, CMS would amend §424.80 to provide that if the technical component of a diagnostic test (other than clinical diagnostic laboratory tests paid under § 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in § 1833(h)(5)(a) of the Act) which is billed by a physician or medical group under a reassignment involving a contractual arrangement with a physician or other supplier who perform the service, the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

- The physician or other supplier's net charge to the billing physician or medical group
- The billing physician or medical group's actual charge
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly

The AAFP recognizes CMS's concerns regarding potential issues of abuse related to contracted services. It is within the AMA Code of Ethics (which the AAFP has adopted as its code of ethics) for charges to be billed by the performing physician when possible. Policy E-6.09 and E-6.10 of the AMA Code of Ethics state:

E-6.09: When it is not possible for the laboratory bill to be sent directly to the patient, the referring physician's bill to the patient should indicate the actual charges for laboratory services, including the name of the laboratory, as well as any separate charges for the physician's own professional services. (II) Issued prior to April 1977.

E-6.10: Each physician engaged in the care of the patient is entitled to compensation commensurate with the value of the service he or she has personally rendered. No physician should bill or be paid for a service which is not performed; mere referral does not constitute a professional service for which a professional charge should be made or for which a fee may be ethically paid or received. When services are provided by more than one physician, each physician should submit his or her own bill to the patient and be compensated separately, if possible. A physician should not charge a markup, commission, or profit on the services rendered by others. It is ethically permissible in certain circumstances, however, for a surgeon to engage other physicians to assist in the performance of a surgical procedure and to pay a reasonable amount for such assistance, provided the nature of the financial arrangement is made known to the patient. This principle applies whether regardless of the assisting physician is the referring physician. (II) Issued prior to April 1977; Updated June 1994.

Second, CMS would also require that in order to bill for the technical component, the billing entity would be required to perform the interpretation.

CMS's proposal to require that in order to bill for the technical component of a service, the billing entity would be required to perform the interpretation could negatively impact access to care for patients. This would be true when a physician provides the technical component of a service such as an x-ray in the office and then sends the x-ray or other test to a specialist who interprets the test and separately bills for his/her professional services.

CMS also proposes to modify the definition of "centralized billing" to include a minimum square footage requirement of 350 square feet. CMS would also require the space to contain, on a permanent basis, the necessary equipment to perform substantially all of the DHS that are performed in this space, in order to meet the definition of a ``centralized building."

CMS is also considering whether to require that, for space to qualify as a ``centralized building," the group practice must employ, in that space, a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Finally, CMS seeks comments on whether a group practice should be allowed to maintain a ``centralized building" in a State different from the State(s) in which it has an office that meets the criteria of Sec. 411.355(b) (2) (i), and if so, whether space that is located in a different State must be within a certain number of miles from an office of the group practice that meets the criteria, in order to qualify as a ``centralized building."

CMS's proposed use of size to redefine of the "centralized building" appears to appropriately address the "pod labs" for which CMS has stated concern. We encourage CMS to make regulatory changes which protect the ability of legitimate small group practices to maintain laboratories and other ancillary services in a "centralized building". A requirement that the group practice must employ in the centralized building a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week may negatively affect those small group practices whose utilization of ancillary services does not require a full-time staff person (over 35 hours) or who offer job-share opportunities to staff who do not wish to work full-time. Where a group practice may have locations in more than one state, a reasonable mileage limitation may be difficult to prescribe and may negatively impact those physicians who travel to remote locations across a state line on a regular basis.

I would encourage CMS to not take a broad stroke approach to addressing this perceived area of risk related to contracted physician services. Where legitimate small group practices find means to provide convenient and cost-effective care to patients, it is in no ones best interest to restrict these practices. It would be more appropriate to limit the response to the specific labs identified as potential abusers, issue a fraud alert and investigate whether the labs are in conflict with anti-kickback or other current regulations. This perceived area of risk certainly should not be used to validate sweeping changes which make an already overly complex rule more difficult for physicians to understand and abide by.

Finally, CMS is proposing to change regulations to state that the supplier who reassigns his or her right to bill and receive Medicare payment to an entity has unrestricted access to claims information submitted by that entity for services supposedly furnished by the individual supplier, irrespective of whether the supplier is an employee or independent contractor of the entity. If adopted, the proposal would also mean that if an entity receiving the reassigned benefits were to refuse to provide the billing information to the employee supplier requesting the information, the entity's right to receive reassigned benefits may be revoked.

We agree that a party who can be held responsible for inaccurate claims information must have access to that information. The OIG has indicated that physicians will be held responsible for the accuracy of claims submitted in their names regardless of their knowledge of the claims. Therefore, it is imperative that said physicians have access to claims records. Limitations to access should include only that for which the party bears no liability.

<u>Discussion of Comments – Health Care Information Transparency Initiative</u>

CMS comments that part of the reason health care costs are rising so quickly is that most consumers of health care--the patients--are frequently not aware of the actual cost of their care. Health insurance shields them from the full cost of services, and they have only limited information about the quality and costs of their care. Thus, providers of care are not subject to the competitive pressures that exist in other markets for offering quality services at the best possible price. CMS will post geographically-based Medicare payment information for common elective procedures for ambulatory surgery centers this summer and for common hospital outpatient and physician services this fall.

CMS is developing a project with the goals of providing more comprehensive information on quality and costs, including more complete measures of health outcomes, satisfaction, and volume of services that matter to consumers, and more comprehensive measures of costs for entire episodes of care, not just payments for particular services and admissions. CMS intends for the project to combine public and

private health care data to measure cost and quality of care information at the physician and hospital levels. Quality, cost, pricing, and patient information will be reported to consumers and purchasers of health care in a meaningful and transparent way.

The AAFP supports transparency but has concerns that medical care is not equivalent to many other services for which the pricing and quality may be more easily defined. For instance, providing a patient with Medicare's allowable amounts for office and other outpatient evaluation and management service codes will not explain to the patient the complicated method by which the level of service is chosen. It may also be problematic to quote a price to a patient for a service which may become expanded due to initial findings. We would urge CMS to carefully consider how this information is presented and to include education on the complexity and lack of true quality indicators in the present health care system.

The AAFP is committed to preserving, improving and promoting quality, cost-effective health care. The AAFP supports health care quality improvement endeavors, including the development and application of performance measures that are:

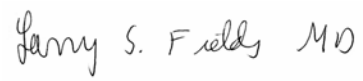
- Aimed at improving patient care, health status, outcomes, and satisfaction
- Consistent with the informed patient's values and preferences
- Consistent with professional knowledge of appropriate and effective care
- Possible given the information and resources available across practice settings

The AAFP has supported the reporting of meaningful information to consumers, physicians and other stakeholders to inform choices and improve outcomes through participation in the Ambulatory care Quality Alliance (AQA). The AQA has developed the AQA Data Sharing and Aggregation Principles for Performance Measurement and Reporting as an effective data sharing and aggregation model. These principles should be upheld by CMS in the development of the project to combine public and private healthcare data to measure cost and quality of care information at the physician and hospital levels. In addition, the AAFP has supported the CMS/AHRQ sponsored six AQA pilot projects that will demonstrate the value of aggregating and reporting data combined from Medicare and commercial insurance sources. The AAFP recognizes the current barriers to the reporting of clinical data and encourages CMS to continue exploration of incentives and assistance to facilitate the adoption of interoperable electronic health record systems in physician practices.

Finally, the observation that providers of care are not subject to the competitive pressures that exist in other markets for offering quality services at the best possible price is correct. Physicians are subject to a unique business model where a third party regulates not only their business model but also the payment for their services, and where the purchaser of the services is distanced from the costs. Physicians are under tremendous pressure from both public and private sectors to lower costs and provide high quality care while receiving the same or less income and facing ever-rising costs of delivering care. While developing a project to provide the public with comprehensive information on quality and costs, I would ask CMS to consider the value of the resources to be spent on this project and whether some of these might be better spent in developing a public health system which assists physicians in the delivery of quality care through practice redesigns such as adoption of electronic health records, group medical visits and patient registries, and which encourages each patient to have a personal medical home through which their care is coordinated.

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

Sincerely,



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