August 24, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Mr. Kuhn:

I am writing on behalf of the American Academy of Family Physicians, which represents nearly 94,000 physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed rule regarding proposed revisions to payment policies under the Medicare physician fee schedule and other Part B payment policies for 2008 as well as the proposed elimination of the e-prescribing exemption for computer-generated facsimile transmissions. CMS published the proposed rule in the *Federal Register* on July 12, 2007. Our comments follow the order of the issues as presented in the proposed rule.

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

The Academy continues to support the CMS transition to the "bottom up" method of assigning direct practice expense, which is scheduled for the second year of a four year phased implementation in 2008. This methodology is more clear and understandable than the "top down" methodology used in the past, and CMS should endeavor to make all elements of the payment for a medical service as transparent as possible.

In its discussion of the current methodology for calculating PE RVUs, CMS notes that it assumes all equipment is used 50% of the time. CMS acknowledges that this across-the-board assumption does not capture the actual usage rates for all equipment. However, CMS believes it lacks the empirical evidence to justify an alternative proposal. CMS invited comments relating to alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category-specific usage rate assumptions.

We have previously commented that equipment costs are not a primary driver in the costs of most services provided by family physicians. This is reflected in the distribution of labor, supplies and equipment based on clinical practice expert panel inputs, which shows equipment as 10% of the direct practice expense for family medicine.

That said, we would agree with CMS that a uniform equipment utilization rate of 50% is unrealistic and arbitrary and leads to overpricing of certain equipment and underpricing of other equipment. For instance, a Medicare Payment Advisory Commission (MedPAC) performed a study of the issue and found that magnetic resonance imagery machines have a utilization rate that is higher than 90% and computed tomography machines have a utilization rate that is higher than 70 % in the representative surveyed markets. We note that in response to comments on the initial implementation of the resource-based practice expense methodology in 1998, CMS

modified the Abt Associates equipment utilization assumption of 70% to a 50% assumed utilization for all procedure specific equipment. This equipment utilization rate has not been re-examined since 1998.

We appreciate CMS's willingness to work with the physician community to examine whether variable utilization rates would more accurately price medical equipment at the procedure level. We believe that CMS should initiate a review of equipment utilization rates, and we recommend that this review be objective, by including all equipment (or potentially all equipment above a certain dollar threshold) in the proposal. Any savings achieved through this review should be redistributed within the Medicare physician payment system to avoid further depletion of an already inadequate funding pool.

Further, we urge CMS to address this issue quickly, because it has a significant impact on the value of equipment-intensive services as well as a significant impact on the payment for all other services. A change in the equipment utilization assumption would be an important step to ensure that payments for service that require high expense equipment are not overpaid. MedPAC and others have expressed concern that overvaluing and, thus, overpaying, services distorts the market and provides the incentive to increase utilization.

Geographic Practice Cost Indices (GPCIs)

General Comments

As required by law, CMS proposes to update the GPCIs that geographically adjust Medicare payment allowances from one Medicare payment locality to another. We recognize that GPCIs are a statutory part of the Medicare Fee Schedule and that CMS's proposal simply fulfills its statutory obligations regarding the GPCIs. However, the Academy 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 payment 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. To the extent that physicians choose to practice in areas with different expenses, those are business and personal decisions that should not be incentivized by Medicare payments. 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).

In calling for the development of a geographic index, Congress clearly recognized the important implications that the index might have on the distribution of physician services. The Urban Institute and the Center for Health Economics Research (UI/CHER) developed the initial index pursuant to a Congressional mandate in the Omnibus Budget Reconciliation Act (OBRA) of 1986. Specifically, Congress requested that the Secretary:

> (i) develop and **assess** an appropriate index to be used for making adjustments to reflect justifiable differences in the costs of practice based upon geographic location **without exacerbating the geographic maldistribution of physicians**, and
> (ii) assess the advisability and feasibility of developing an appropriate adjustment to assist in attracting and retaining physicians in medically underserved areas. (Emphasis added)

Yet, we are not aware that CMS has ever assessed the UI/CHER indices for their accuracy in reflecting alleged geographic differences in physician practice costs. This despite the fact that the OBRA of 1990 required the Secretary to conduct a validation study of the GPCIs by July 1, 1992.

Notwithstanding our geographic payment policy, the *Federal Register* notice makes clear that CMS intends to continue to adjust the Medicare physician fee schedule using GPCIs developed by the UI/CHER. The UI/CHER indices utilize input price proxies under the assumption of uniform component cost shares across all geographic areas. With the exceptions of malpractice insurance costs, for which CMS maintains a national data set, and equipment, supplies and other costs, for which CMS assumes there are uniform national prices, the UI/CHER indices utilize proxy data assessing geographic variation in costs.

The UI/CHER indices suggest that there is substantial geographic variation in physician practice costs that corresponds with community size. Specifically, the indices show urban communities as having higher costs and rural areas as having lower costs.

The large variation in practice costs suggested by the UI/CHER indices means that their use in adjusting the Medicare physician fee schedule has a substantial impact on physician fees. That impact is to perpetuate a substantial portion of the geographic differential in Medicare prevailing fees which existed before CMS implemented the Medicare physician fee schedule. Given the impact of a geographic differential on the maldistribution of physician services, it is of essential policy importance to verify the accuracy of the UI/CHER indices.

There are several grounds on which to challenge the ability of the UI/CHER indices to accurately and appropriately reflect true and legitimate differences in physician practice costs (i.e., those differences that are not attributable to practice style for which adjustment would be inappropriate).

First, the UI/CHER indices are modeled after the Medicare Economic Index (MEI). As a Laspeyres index, the MEI is an appropriate measure of change over time in the practice costs faced by physicians. It is based on the comparatively safe assumption that the relative changes in the prices of the input proxies accurately reflect relative changes in the prices of the corresponding physician practice cost components. However, the UI/CHER indices propose to measure geographic differences in practice costs at a single point in time. The use of a Laspeyres index to measure practice cost differences across geography requires an additional and more tenuous assumption about the ability of the absolute proxy values to accurately reflect component price differences at a single point in time.

Second, the UI/CHER indices apply uniform weights to practice cost components despite evidence of systematic geographic variation in component shares. Intuitively, it appears that this variation in practice inputs is attributable to differences in case mix, specialty mix, the availability of other health care resources, input prices, and practice style. Of policy importance is the extent to which this variation can be justified by factors over which physicians have no control, such as case mix and the availability of other health care resources. This is a question that should be subjected to further investigation.

Third, the UI/CHER indices use questionable proxies. For instance, aside from physicians' own time, the largest component of physician practice expenses is non-physician, (i.e., employee) wages. Staff wages are based upon United States census data and account for about 40 percent of the practice expense GPCI. To calculate an employee price adjuster, CMS uses the median hourly

earnings of four occupational classes found in physician offices: Clerical Workers, Registered nurses, Licensed practical nurses, and medical technicians.

The wages of the remainder of the employee pool are not calculated, but are inferred to be relative to the four categories measured. The problem with the use of the four proxies is that physician practice management requirements, compliance requirements, skill sets, and professional work activities have evolved since the four proxies were selected by the Center for Health Economics Research in the early 1980's. While salary data on these four occupational codes are conveniently available nationwide, much has changed in medicine since the four occupational codes were selected. As a proxy measure, the data do not include or account for the variations in costs related to the most highly compensated employed staff: physician assistants, practice administrators, office managers, coding specialists, etc. who are recruited and retained not from a local pools of workers, but from the national market of eligible individuals. The cost of high wage employees is not captured by CMS's proxies. Rather, the measures chosen as proxies understate the cost of providing services and miss the costs associated with attracting high cost professionals into areas where they are not abundant.

Likewise, as a proxy for medical office rental costs, CMS uses fair market rental data produced by the Department of Housing and Urban Development for residential, two-bedroom, Section 8 apartments. On its face, residential rents do not appear to be a plausible proxy for the cost of office space. CMS believes most physicians locate their offices in residential areas, despite the absence of any data substantiating such a conviction. On the contrary, most physicians select medical office sites in close proximity to a medical complex or on major thoroughfares or at crossroads to promote accessibility to commercial patients. The cost of the land is a function of the traffic on the thoroughfare. Residential real estate is usually situated on acreage in close proximity to amenities or employment. Thus, the value of residential real estate is not an accurate predictor of commercial rental values.

Furthermore, the UI/CHER index does not reflect variable patterns in the use of office space, in terms of solo versus group practice, ownership versus leased space, and legitimate variation in the square footage. In regard to the residential rent proxy, we note that the Congressional mandate in the OBRA of 1986 called upon the Secretary to:

> collect data with respect to the costs of practice (including, but not limited to, data on nonphysician personnel costs, malpractice insurance costs, and **commercial rents**) for the purpose of refining the index...prior to December 31, 1989, and periodically updating the index thereafter.

We do not believe that the Housing and Urban Development index of residential unit rents employed in the UI/CHER index qualifies as a measure of commercial rents, and once again, the proxies skew the measurement of costs.

Also, CMS has not supported its assumption of uniform national prices for supplies, equipment, and other expenses. The lack of competitive markets for these items in rural communities may result in higher costs. Contrary to the assumption that rural practices order medical equipment and supplies by mail at prices competitive with urban markets, physicians usually purchase supplies and equipment from known suppliers on which they depend for prompt and personalized service. Because supplying rural physicians involves higher shipping costs and because rural markets are less

competitive, prices are higher. For these same reasons, rural physicians also face higher equipment maintenance and service costs.

Several other factors excluded from the UI/CHER indices may also translate into higher costs for rural physicians. These factors include longer work and on-call hours, higher equipment maintenance costs, less efficient use of medical equipment due to the need to maintain "standby capacity," higher costs related to obtaining continuing medical education, costs of obtaining locum tenens coverage, and higher volumes of uncompensated care for some physicians.

Finally, the physician work proxy is an inappropriate application of a hedonic wage model, which has been shown to apply poorly to professional workers because it violates the assumption of a competitive labor market. Furthermore, the use of Census data on the hourly earnings of professional workers uncritically assumes that the geographic distribution of these occupational categories is an appropriate model for the distribution of physicians.

We note that eliminating inappropriate geographic differentials was a major focus of the original Medicare physician payment reform implemented in 1992 because geographic differentials proved to be a strong disincentive in regard to physicians choosing a rural practice location. However, Medicare has yet to adopt regulatory policy that has had a measurable effect in reducing or eliminating these strong geographic disincentives. CMS has not systematically and verifiably demonstrated significant differences in the cost of practice, which might be used to justify continuing geographic differentials in the Medicare fee schedule. We believe that eliminating geographic differentials from the Medicare physician fee schedule is likely to have a significant and positive impact on the availability of medical care to rural beneficiaries. If a GPCI is to be utilized, we feel it incumbent on CMS to validate any geographic index that it proposes to use in modifying physician fees.

In conclusion, we appreciate CMS's proposals to update the GPCIs. However, the present GPCIs are an inaccurate measure of the geographic variation in practice costs, and updating them as proposed does not address our underlying concerns. In fact, consistent with our position that there should be no differential in physician fees based on practice location, we would recommend that CMS either work with Congress to eliminate the GPCIs or otherwise create permanent GPCIs with a uniform index of "1.0" to ensure uniform payment geographically.

Revision of Payment Localities

Within the context of its proposed GPCI update, CMS solicits comments on three possible locality reconfigurations in California. CMS also seeks comments about other potential approaches to locality revisions and about using a transition to phase-in changes in a new locality structure blending new and revised payments. Whatever decisions CMS makes with respect to California, it may apply more broadly in the future.

We consulted with our California chapter regarding the possible locality reconfigurations in that state. Based on that consultation, we do not have a preference among the specific options listed in the proposed rule. Our concern and that of our members in California and elsewhere is that all of the options would reduce payment to some physicians to increase payments to others. Unfortunately, setting up yet another system that creates a series of winners and losers perpetuates the payment problems in Medicare without addressing the underlying inequities and burden created by the flawed sustainable growth rate (SGR) formula. Adjusting the way locality

payments are calculated, without addressing the fundamental problems in the payment system, is not a workable solution to a much more significant problem. Our California chapter has heard from members in counties such as Santa Cruz that many physicians are no longer accepting Medicare patients because payments do not reflect the physician's cost of providing services. While the payment locality reconfigurations contemplated by CMS would boost payments to physicians in Santa Cruz County, they would do so at the expense of physicians in other counties such as Solano and Napa, who also face Medicare payments that are not keeping pace with their cost of providing services. We can not support any proposal that exacerbates this problem.

Coding – Additional Codes from Five-Year Review

General Comments

In the proposed rule, CMS states its intent to accept all of the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) recommendations, with the exception of code 93325 (Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)), related to the remaining codes in the recent Five-Year Review. Among these are nursing facility codes commonly done by family physicians.

We appreciate and support CMS's acceptance of the RUC's recommendations regarding the nursing facility codes. The substantial work and significant effort required of physicians that provide care in the nursing facility settings was evident in the survey data presented to the RUC. We believe the accepted RVUs will bring these codes more into line with the RVUs approved for other evaluation and management (E/M) services during the recent Five-Year Review.

Budget Neutrality/Five-Year Review Work Adjuster

In this *Proposed Rule*, CMS announces that the Five-Year Review Work Adjuster will increase from -10.1% to -11.8%. We strongly urge CMS to eliminate this work adjuster.

The Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in RVUs for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. To limit the increases in Medicare expenditures as mandated by the statute, CMS has applied various adjustments to the Medicare Physician Payment Schedule, including re-scaling the RVUs, creating a separate "work adjuster," or applying a budget neutrality adjustment to the Medicare conversion factor. In 2007, CMS created a new "work adjuster" to ensure budget neutrality following the implementation of the improved work RVUs from the 2005 Five-Year Review of the resource-based relative value scale (RBRVS).

During 1993 - 1995, CMS achieved budget neutrality by uniformly reducing all work relative values across all services. These adjustments to the work relative values caused confusion among the many non-Medicare payers, as well as physician practices, that adopt the RBRVS payment system. The constant re-scaling also impeded the process of establishing work RVUs for new and revised services. The physician community argued that any budget neutrality adjustments deemed necessary should be made to the conversion factor, rather than the work relative values.

In 1997, following the first Five-Year Review of the RBRVS, CMS modified the approach to apply budget neutrality and implemented a separate work adjuster. This approach was short-lived as CMS converted this adjustment to the conversion factor in 1999. CMS later articulated that the creation of the work adjuster was not effective.

> "We 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 RVUs to determine a payment amount that matched the amount actually paid by Medicare." (*Federal Register*, Vol. 68, No. 216, Pg. 63246).

From 1998 to 2006, CMS has implemented all work neutrality adjustments by adjusting the Medicare conversion factor. We request that CMS consider the history and these additional arguments to reconsider the agency's current position on this issue:

1.) Adjusting the conversion factor does not affect the relativity of services reflected in the recommended RVUs. Adjusting the RVUs has the potential to inappropriately affect relativity. For example, if Service A has 0.50 work RVUs and 1.00 total RVUs, while Service B has 1.00 work RVUs and 1.50 total RVUs, then the relative value of Service B to Service A is 1.50 (i.e., 1.50/1.00). Effectively reducing the work RVUs of both services by 12%, as proposed, would mean Service A would have 0.44 work RVUs and 0.94 total RVUs, while Service B would have 0.88 work RVUs and 1.38 total RVUs. After this adjustment, the relative value of Service B to Service A would be 1.47 (i.e., 1.38/0.94). Thus, the adjustment to the work RVUs can inappropriately affect the relativity among services, whereas an adjustment to the conversion factor would not. This impact on relativity seems most acute on those services for which the RUC and CMS agreed that work has not changed. Adjusting the work RVUs for these services effectively reduces their relative value, contrary to RUC and CMS intent in maintaining the current value. This gets to the very heart of the Medicare physician fee schedule as a resource-based relative value scale.

2.) If the work RVUs continue to be adjusted as proposed, it will dampen the improvements to the E/M services valuation. CMS has publicly lauded the RUC for its recommended increases to E/M, and we would surmise that the agency would want to achieve the full benefit of these improvements. Likewise, if the RVUs continue to be adjusted as proposed, it will obfuscate the hard work done by the RUC. The RUC goes through a very detailed and difficult process to arrive at its recommended changes in work RVUs, most of which CMS accepts. Adjusting the conversion factor leaves the recommended changes in work RVUs unscathed.

3.) An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVUs. That is, an adjustment in the Medicare conversion factor will not necessarily affect the payment rates of other payers who use the Medicare RVUs and their own conversion factors. However, any adjustment in the RVUs will impact the payment rates of such payers. The payment rates of payers who peg their rates to a percentage of Medicare will be affected regardless. We believe that CMS must consider such "ripple effects" as it decides how to adjust for work neutrality.

4.) We believe an adjustment to the conversion factor is preferable because it recognizes that 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.

5.) Applying the work neutrality adjustment to the conversion factor would coincide with CMS' current mission of making the Medicare payment transparent.

For all of these reasons, we argue that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is a step backward, and we strongly urge CMS to instead apply any necessary adjustments to the conversion factor.

Drug Compendia

In the proposed rule, CMS notes that it has received multiple requests to amend the listings of compendia that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. CMS also notes that there is no established regulatory process by which it can currently accept and act definitively on such requests and no transparency about the criteria upon which it could base a decision. CMS invites public input on this topic.

We believe that when a prescription drug or biological product represents safe and effective therapy, then Medicare (or any other third-party payer) should consider the intervention as reasonable and necessary medical care, irrespective of FDA approved labeling, and should provide coverage and payment for such a product. Furthermore, we have supported the passage of laws, such as Section 1861(t)(2)(B) of the Social Security Act, that when an "off-label" indication is supported by one or more citations which are included in one or more compendia, or by supportive clinical evidence in peer-reviewed medical literature, then the indication should be considered "medically accepted."

Unfortunately, of the three named compendia in Section 1861(t)(2)(B), the *American Medical Association Drug Evaluations (AMA-DE)* is no longer in publication and the *United States Pharmacopeia – Drug Information (USP-DI)* will cease publication under that name in the near future. Thus, only the *American Hospital Formulary Service – Drug Information (AHFS-DI)* will remain as a named compendium for coverage of off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

No single compendium is sufficiently comprehensive or timely to list all relevant off-label indications, and it is counter to patients' best interests to rely on a single compendium. Thus, the current situation is unsatisfactory and needs to be rectified by both the addition of new compendia by the Secretary and greater reliance on peer-reviewed medical literature to determine the medical acceptability of an off-label use of a drug or biological in an anticancer chemotherapeutic regimen.

As regards the criteria for an acceptable compendium, we note that the AMA criteria include the following:

- Preferably published by a not-for-profit association or standards-setting organization with no influence from either the pharmaceutical industry or third-party payers;

- Comprehensive in scope and timely with respect to updating and publication;
- Evidence-based recommendations, or in the absence of unequivocal scientific evidence, recommendations based on a consensus of panels of experts who are unbiased; and
- Inclusion and reliance on physician specialists to participate on expert panels.

Given these criteria, which we support, we urge CMS to recommend to the Secretary the addition of *The NCCN Drugs and Biologics Compendium*, published by the National Comprehensive Cancer Network (NCCN), to the list of recognized compendia to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen. *The NCCN Drugs and Biologics Compendium* provides recommendations about appropriate uses of drugs and biologicals from multidisciplinary NCCN Guideline panels of 15-20 experts representing different specialties (e.g., medical, surgical, radiation oncology), subspecialties and clinical professions. Compendium recommendations are based upon scientific evidence and expert judgment, and they are derived directly from NCCN Guidelines that are nationally recognized by the oncology community. The NCCN is a not-for-profit association representing the 19 comprehensive cancer centers in the United States, and it makes both its Compendium and NCCN Guidelines freely available to the cancer community. The American Society of Clinical Oncology, the American Cancer Society, and many other cancer-related organizations also have offered support of *The NCCN Drugs and Biologics Compendium* to be a recognized compendium by the Secretary.

We have no other specific compendia to recommend to CMS at this time. However, we encourage CMS to explore other options and, hopefully, identify at least one additional compendium to *AHFS-DI* and *The NCCN Drugs and Biologics Compendium* as suitable for recognition by the Secretary to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen. Furthermore, we encourage CMS to emphasize the importance of referring to the peer-reviewed medical literature when none of the recognized compendia lists the particular off-label use. We believe that it is essential to consider the interests of cancer patients first and foremost regarding coverage and payment decisions on potentially lifesaving drugs or biologicals for off-label uses in cancer.

As CMS considers the authoritative drug compendia that may be used in determining medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program, we believe it should also consider concerns with deficiencies in this area under the new Medicare Part D outpatient prescription drug program. The Medicare Modernization Act of 2003 (MMA) refers to Section 1927(k)(6) of the Social Security Act for the definition of the term, "medically accepted indication." Section 1927(k)(6) states that "the term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)."

This poses three significant problems. First, similar to Section 1861(t)(2)(B), of the three recognized compendia in Section 1927(g)(1)(B)(i), the *USP-DI* will cease publication under that name in the near future. Only *AHFS-DI* and *Drugdex*, an expensive drug database published by a for-profit company, remain as named compendia for coverage of off-label uses for all Part D drugs (not just cancer drugs). Second, the MMA fails to recognize supportive clinical evidence in the peer-reviewed medical literature, i.e., Section (g)(1)(B)(ii), for determining accepted uses of

drugs. Third, unlike Section 1861(t)(2)(B), there is no provision in the MMA for the Secretary to revise the list of compendia for identifying medically accepted indications of drugs.

The Academy encourages CMS to work to correct these serious deficiencies. Many Part D beneficiaries with a wide range of diseases could potentially be denied coverage and payment for drugs appropriately prescribed for off-label indications because the two currently named compendia fail to include them (e.g., the compendia were dated or not sufficiently comprehensive).

Physician Self-Referral Provisions

CMS proposes to make a series of changes to the physician self-referral rules, commonly known as the Stark rules. These include:

- An anti-markup provision of the technical and professional components of diagnostic tests, which essentially requires a physician who purchased the professional or technical component of a diagnostic test to charge Medicare no more than he or she paid the entity from whom the test was purchased
- Clarifying that in the case of a dispute about whether or not a service is subject to the Stark rules, the burden of proof lies with the entity submitting the claim to prove that the service was not subject to the Stark rules
- Revising the exception for obstetrical malpractice insurance subsidies to list specifically nine conditions or requirements that must be met to qualify for the exception
- Prohibiting unit-of-service (i.e., "per-click) based payments from space and equipment leases under the Stark rules
- Excluding interest in a retirement plan from the definition of ownership and investment interests subject to the Stark rules
- Clarifying that percentage compensation arrangements may be used only for paying for personally performed physician services and must be based on the revenues directly resulting from the physician services rather than based on some other factor
- Defining a designated health services entity that owns or controls another entity as having the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls
- Revising the rules regarding services provided "under arrangement" such that if a physician enters into a joint venture to provide services to a hospital, then the joint venture is the provider of services and the physician is effectively prohibited from referring Medicare patients to those joint ventures

The Academy has followed the self-referral issue for many years and has concerns about some of the changes proposed in this rule. In general, these changes will make it even more difficult for physicians to participate in legitimate business ventures without the fear of inadvertent violations.

Indeed, the proposed changes and "clarifications" to the self-referral rules are sweeping in their scope, and in some cases, they appear to ban arrangements that CMS explicitly permitted a few years ago. We are concerned that the proposed new rules will make it much harder for physicians to stay in small and independent practices, since the new rules make it harder and harder for small

physician groups to join together to provide ancillary services that none of them can provide independently.

More specifically, although CMS did not offer a proposed change, it did request comments on potential changes to the in-office ancillary services exception. The Academy would strongly oppose any proposal that would further limit the services that can be provided by a physician practice under the in-office ancillary services exception. This exception has enabled physicians throughout the country to provide services in their offices where patients are most likely to seek them and benefit from their timely provision. It additionally provides for integration of data systems so that lab values and radiology data is available immediately. This exception allows physicians the greatest amount of flexibility in managing the care of their patients and gives them the opportunity to add services that may be lacking in the community.

We would also oppose any significant changes to the centralized building definition. The use of a centralized building for services allows both large group practices and coalitions of smaller practices to better provide necessary services for their patients. The in-office ancillary services exception has allowed physician practices to provide what is needed to their patients and the impact of changes to this exception could hurt the practice of medicine. It would be a serious mistake to make the practice of medicine less innovative and reduce the investment in the community of health care services that physicians are making.

We are encouraged to see the proposal to loosen the restriction on the exception for obstetrical malpractice insurance subsidies. We urge CMS to expand this exception to include physicians in all specialties. The rising burden of malpractice insurance is a reality for all physicians and this should be recognized. Patients in medically underserved areas will greatly benefit from an expansion of this exception to include all specialties.

We are also encouraged to see an opportunity for physicians who inadvertently enter into arrangements that are missing a required procedural step to show compliance through an alternate method. However, we would recommend that CMS go even further in using its regulatory discretion to determine if a violation was inadvertent. These regulations are complex, and CMS should be focusing on those who intentionally or willfully disregard or ignore the self-referral requirements, not those who missed a signature or a single document while attempting to comply.

The many other proposals to reduce exceptions to the self-referral restrictions represent a change in direction for CMS that causes concern for the Academy. As we continue to study these proposed changes, we encourage CMS not to implement them until the full potential impact on both physicians and their Medicare patients can be determined. We note, in this regard, that CMS states in the impact analysis section of the proposed rule that it cannot even gauge with any certainty the extent of the savings to the Medicare program. Given such uncertainty even within CMS, we believe CMS should not proceed until the proposals and their implications can be more fully studied.

Lastly, we understand that there are legitimate concerns about inappropriate utilization of certain services. However, completely restricting the ability of physicians to invest in their own industry is far from the answer to this issue. Innovative physicians have filled the gaps in the current medical delivery model by taking responsibility for the creation and maintenance of ancillary services that are of utmost importance to their patients.

Medicare Economic Index (MEI)

In the proposed rule, CMS proposes to replace the Bureau of Labor Statistics' white collar occupation and employment cost index (ECI) series with a composite benefit index for the 2008 MEI update. Because the white collar benefit ECI series is being discontinued, CMS needs a replacement, and they are using the expertise of Global Insight, Inc., the same group they have used to maintain and forecast the MEI and the white collar benefit ECI series and all their market baskets, to come up with a replacement. We agree with CMS that Global Insight is one of the best at economic forecasts, and we trust this new composite index will be a good replacement.

That said, we are concerned that the forecasts for the MEI (prior to and after this replacement) have been and continue to be downward (i.e., from over 3% down to below 2%) for the foreseeable future. This replacement will not change those forecasts, because the proposed ECI series have also been forecasted to drop in the future. This downward trend and forecast appear related to the source(s) of information being used to assess practice costs, and under current law, it is bad news for the update to the conversion factor, because, under current law, the conversion factor update equals the MEI plus or minus the performance adjustment factor (where the performance adjustment factor is the result of how actual Medicare expenditures compare to the Sustainable Growth Rate). A declining MEI coupled with a flawed SGR system will only make it that much harder to achieve positive updates in the Medicare conversion factor. Accordingly, we encourage CMS to examine the downward trend in the MEI more carefully to ensure that it is an accurate reflection of the price changes for various inputs needed to produce physicians' services and not a product of inaccurate sources of data being used to assess practice costs.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

CMS proposes to eliminate the exemption for computer-generated faxes from the e-prescribing standards. Currently, entities that transmit prescriptions or prescription-related information by means of computer-generated faxes are exempt from the requirement to use the adopted National Council for Prescription Drug Programs' (NCPDP) SCRIPT standard.

The Academy is very supportive of standards based e-prescribing and of the NCPDP SCRIPT standard for that purpose. An issue is that there are forces outside the control of a physician that limits their ability to do true e-prescribing. For this reason, many of the physicians faxing prescriptions now will move back to paper instead of moving forward to true e-prescribing. We believe that one of the core tenets of the Medicare Modernization Act is to improve the quality, safety, and efficiency of care delivery. By removing this exemption for computer-generated facsimile transmission, quality, safety, and efficiency will suffer as physicians are forced to revert back to paper-based prescriptions. To truly move e-prescribing forward, incentive for all stakeholders should be initiated, not restricting the electronic transmission of prescriptions from physicians.

Tax Relief and Health Care Act (TRHCA) of 2006 – Section 101(b): Physician Quality Reporting Initiative (PQRI)

For the 2008 PQRI, CMS proposes to limit for inclusion measures that are endorsed or adopted by either the National Quality Forum (NQF) or the AQA. CMS lists the measures that it proposes to include in the 2008, including 2007 PQRI measures and measures under development by the AMA's Physicians Consortium for Performance Improvement. The proposed measures include

structural measures related to adoption/use of e-prescribing and adoption/use of health information technology (i.e., electronic health records (EHRs)). Lastly, CMS outlines at least five different data submission options it is considering that would permit eligible professionals to provide data on quality measures through an appropriate medical registry.

We are supportive of limiting for inclusion only those measures that are endorsed or adopted by either the NQF or AQA. The Academy has relationships with both organizations and is comfortable that measures endorsed or adopted by either one represent acceptable measures for PQRI purposes. We have reviewed the proposed PQRI measures for 2008 as listed in the proposed rule and have no objections to any of them at this time.

With respect to addressing a mechanism for submission of data on quality measures via a medical registry or electronic health record, the Academy is supportive of allowing the submission of quality measurement directly from EHRs and electronic registries when such data is reportable. We question the need to have a different set of requirements and procedures for registries and for EHRs. The proposal for use of the DOQ-IT specification should also be used for registries, as they contain the same data and reporting should be consistent across stand-alone registries and EHRs.

Additionally, the AAFP has a long established policy on data stewardship which addresses the reporting and aggregation of patient de-identified clinical data. We recommend that any option considered would be in line with that policy. The policy is cited below and may also be found online at www.centerforhit.org/x429.xml :

> The amount of health data generated in digital format, stored in computer databases internal and external to the physician practices, and transmitted to and from family physicians' practices will grow exponentially. The following data stewardship guidelines should be followed in the collection, storage, transmission, analysis, and reporting of these data. Execution of these processes must be in a manner that is ethical and protects the interests, including that of privacy, of both the patients and their physicians from whom the data arise.
>
> The guidelines specifically address the conditions under which de-identified clinical and administrative data derived from physicians' electronic systems is collected and used by third parties (e.g., Medicare and other payers, commercial health plans, retail pharmacies, hospitals, clinical laboratories, and any intermediary parties such as clearinghouses or application service provider software vendors who store physician data in remote sites).
>
> NOTE: Nothing herein or below shall be construed as contravening the standards for health information contained in HIPAA that relate to privacy or security of personal health information. Generally, the recommendations below pertain to de-identified and aggregated data only.
>
> 1. Submission of data from physician practices to third parties must be voluntary.
> 2. Physician practices reserve the right to submit data to entities of their own choosing, either in addition to or as part of the chain of data submission

(e.g., to payers, health plans, or community data repositories), for purposes such as quality improvement and pay-for-performance programs.

3. Third parties who collect, store, manage, or analyze data derived from physicians' EHRs and other office-based systems, must provide physician practices with a clear written policy detailing the intended uses of such data prior to submission of such data. In addition, any change in the use of such data, or the terms of the agreement, must be relayed to those physician practices prior to the use of such data. This notification must be written, provided in a timely manner, and allow physician practices the right to decline those uses.
4. Third parties should share with physician practices any analysis of the practice's data or aggregation of such data that has the potential to improve efficiency, quality, or safety in that practice.
5. To maximize the quality of care and patient safety, data submitted to third parties, under the scenarios outlined in items 2-4 above, must be non-discoverable in a court of law.
6. Processes that measure and assure accuracy of the data need to be in place during collection, submission, storage, analysis, and reporting.
7. Adoption of standards defining data capture, representation, and messaging are needed for collection and transmission of these data. These standards would include controlled vocabularies and data structure (i.e., an XML document).
8. Third parties should be responsible for verifying the completeness of submitted data and checking the validity of each data element of all collected data.
9. Storage of these data must adhere to industry standards for data of similar criticality and confidentiality.
10. A process must be in place for physician practices to validate any reports. There must be adequate time for those practices to perform this validation.
11. Third parties must be responsible for the completeness of the data reported back to physician practices.
12. Payers who have collected data for quality or performance measurement purposes must allow near real-time access to these data to the physician practices generating these data. The purpose of the data is to improve quality and safety, and there is no logical reason to delay decision-making by physician practices that impact quality and safety by restricting access to the data.
13. Data required for submission must be clearly defined in both purpose and format. Only data critical to fulfilling the stated objectives should be required.
14. Standards regarding benchmarking, display, and use of particular technologies (e.g., web-based and application programming interfaces) must be adopted. Using industry standards allows for easy access to the reporting data either via the web or integrated into other applications. To afford near real-time access to the data, reporting to participating physician practices should be at least web-based.
15. To maximize the value of quality and performance data, these data must be stratified by risk and/or severity."

TRHCA – Section 101(d): Physician Assistance and Quality Initiative (PAQI) Fund

The TRHCA provided $1.35 billion to fund the PAQI fund for services furnished in 2008. CMS proposes to use this money to fund bonus payments to be made during 2009 for physician reporting of measures during 2008. In essence, CMS proposes to use the entire PAQI to fund PQRI bonuses through 2008. CMS notes that the alternative is to use the PAQI fund to offset some of the negative 9.9% update projected for the 2008 conversion factor.

We oppose CMS's proposed use of the entire PAQI to fund PQRI bonuses. We believe the PAQI would more appropriately be spent offsetting some of the projected negative update to the 2008 conversion factor. We note that this is the approach taken in the Children's Health and Medicare Protection (CHAMP) Act currently being considered by Congress. Since Congress also created the PAQI, we believe this reflects a measure of Congressional intent in this regard. We support the CHAMP Act and, by extension, the intent to use the PAQI to offset the negative Medicare conversion factor update in 2008.

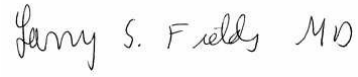
Other Issues – Anticoagulation Management

The Academy strongly disagrees with the CMS decision to continue to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of E/M codes. We are especially frustrated by CMS's position since the initial impetus for the creation of these codes was the statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. During the creation of the code, the Current Procedural Terminology (CPT) editorial panel and the RUC were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of E/M codes. CMS did not offer any explanation for its decision to bundle these codes into E/M services when it published the final rule for the physician fee schedule for 2007. There is still no explanation offered in the 2008 proposed rule.

These CPT codes are recognition of the important work of managing serious disease and the CMS decision to not pay separately for this service could have a devastating impact. The Academy strongly encourages CMS to reverse its position that these services are bundled and instead change their status to a separately payable, covered service. Anticoagulation management services are an important responsibility, and CMS should recognize the extensive work involved by paying separately for this service.

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,



Larry S. Fields, M.D., FAAFP
Board Chair