Statement on the HCFA Medicare Physician Fee Schedule Proposed Rule

September 20, 1999

Attention: HCFA-1065-P RIN 0938-AJ61

Full Title: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2000; Proposed Rule

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM) comments on Health Care Financing Administration (HCFA) Proposed Rule for the Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2000 discuss the following issues:

1. Resource-Based Practice Expense Relative Value Units;
2. Resource-Based Malpractice Relative Value Units;
3. Assisted Suicide;
4. CPT Modifier -25;
5. Pulse Oximetry, Temperature Gradient Studies, and Venous Pressure Determinations;
6. Coverage of Prostate Cancer Screening Tests;
7. Diagnostic Tests;
8. Medicare Payments to Nurse Practitioners and Clinical Nurse Specialists for Performing Physician Services; and
9. Site-of-service differential for the Monthly Capitated Payment for End-Stage Renal Disease services.

1. Resource-Based Practice Expense Relative Value Units

Refinement of Resource-Based Practice Expenses

Section 4505(d)(1)(C) of the Balanced Budget Act of 1997 requires HCFA to develop a refinement process to be used during each of the four years of the transition period. In the November 2, 1998 final rule, HCFA outlined the steps it is undertaking to resolve the outstanding general methodological issues. These steps include: the establishment of a mechanism to receive additional technical advice for dealing with these broad practice expense RVU methodological issues; evaluation of any additional recommendations from the U.S. General Accounting Office, MedPAC, and the Practicing Physicians Advisory Council; and consultation with physicians' and other groups about these issues. Additionally, HCFA has awarded a contract beginning in
May 1999 to obtain assistance in evaluating various aspects of HCFA practice expense methodology. HCFA believes that the awarding of the methodological support contract and the establishment of the AMA RUC subcommittee Practice Expense Advisory Committee (PEAC) represent important steps in HCFA refinement process. Since the HCFA contractor has just begun assisting HCFA with the major methodological issues that HCFA faces in refining the resource-based practice expense RVUs and the PEAC's recommendations on code-level inputs have not been forwarded by the RUC, HCFA is only able to propose a few changes in its practice expense methodology. However, HCFA will consider additional changes for the final rule, based on any recommendations HCFA receives from the RUC or PEAC or other commenters. These changes, if accepted, would be established as interim values and would be effective January 1, 2000. ACP-ASIM will closely follow the activities of the contractor and expects to be able to review and comment upon the contractor's recommendations.

The following discusses more specifically the status of refinement activities and the specific changes HCFA is proposing for the various aspects of HCFA practice expense methodology:

*Top-Down Methodology*

Among the activities HCFA has requested the contractor to undertake are:

- Evaluation of the validity and reliability of SMS data for the specialty groups.
- Identification and evaluation of alternative and supplementary data sources from specialty and multi-specialty societies.
- The development of options for validating the Harvard and RUC physician procedure time data.
- The evaluation of the indirect cost allocation methodology.
- The development of options for the five-year review of practice expense RVUs.

*SMS Data* - ACP-ASIM recognizes that a large number of specialties not represented in the SMS data wish to submit supplementary data that they believe would more accurately reflect the practice expense per hour for their specialty. ACP-ASIM agrees with HCFA that these data should not be used and instead a reliable and standardized criteria for accepting and validating additional specialty-specific data should be developed. ACP-ASIM understands that HCFA's technical contractor will determine: 1) the circumstances, if any, under which HCFA should consider use of survey data other than the SMS data; 2) the appropriate form of these surveys; and 3) how these surveys or future SMS surveys can be appropriately validated for HCFA use. ACP-ASIM looks forward to reviewing and commenting upon the contractor's recommendations.
CPEP Data -- The PEAC is beginning to review the procedure-specific CPEP inputs. HCFA plans to wait until it receives recommendations from the RUC before making significant changes to most code-specific inputs. However, there are a number of egregious errors or anomalies that were pointed out in the public comments HCFA received on the June 1998 proposed rule and the November 1998 final rule that HCFA intends to address in the final rule this fall. These errors were not specified in the proposed rule. ACP-ASIM suggests that HCFA publish this information prior to the final rule this fall to give commenters greater opportunity to review the errors.

Physicians' Clinical Staff in the Facility Setting. ACP-ASIM generally agrees with HCFA's decision to exclude from the raw CPEP data all clinical staff time allotted to the use of clinical staff in the facility setting. We agree that insufficient data have been provided to support a conclusion that it is a typical practice for most specialties to use their own staff in the facility setting. We also concur that Medicare should not pay for the same service twice. In the absence of solid data to show that such costs are typical and that they represent discreet services that are not already paid for by Medicare under Part A of the program, it would be clearly inappropriate to include such cost in the practice expense RVUs for a given procedure. We do not believe that the CPEPs themselves had a sufficient basis for recommending that such costs be included for certain services.

However, we also understand that this proposal has raised a great deal of concern among some physician specialties, including some internal medicine subspecialists. They argue that for some services in their specialty, it is a typical practice for physicians to use their clinical staff in providing certain services in a facility setting. They also argue that such services are separate and distinct from those already being paid by Medicare under Part A of the program.

Given their concerns, we do not believe that HCFA should completely close the door to considering additional data, through the RUC/PEAC refinement process, to support the inclusion of clinical staff costs in the facility setting for certain codes. ACP-ASIM has recommended that the PEAC examine this issue further as part of the refinement process.

We specifically have suggested that if specialties present survey data to the RUC/PEAC on the use of clinical staff in facilities, the RUC/PEAC should consider such data in making its recommendations to HCFA on the refinements of the PE-RVUs. We believe, however, that any such data that are submitted to the RUC/PEAC must:

- Show that it is a typical practice to employ clinical staff for the procedure codes in question and
• Document what types of services the clinical staff are providing. The RUC/PEAC needs to be able to determine if the clinical staff services being provided are physician-substitutive services (which should be addressed through the work RVUs, not the PE-RVUs), general administrative costs (an indirect cost) or specialized clinical assistance that may represent a legitimate practice expense that *should* be paid by Medicare.

ACP-ASIM also believes that it is essential that data on clinical staff in the facility setting be validated by a peer group like the PEAC before it is accepted by HCFA. It is our understanding that the limited data that have been submitted to HCFA to support inclusion of clinical staff in the facility setting have not been subject to validation by the PEAC or any other comparable peer group. Consequently, such data cannot be considered to have the same validity as data that are validated through the RUC/PEAC refinement process.

We also recognize that some are recommending that HCFA delay for one year its decision to edit out clinical staff in facility settings from the CPEP data until the RUC/PEAC examines this issue. ACP-ASIM disagrees. A delay would mean that in the meantime such costs would be included in the practice expense RVUs for calendar year 2000 even though the RUC/PEAC has not had the opportunity to examine the data to support their inclusion. In our view, resource based practice expenses require that adequate data be presented, as validated by a peer group like the RUC/PEAC, to support the inclusion of certain costs in the PE-RVUs before it is assumed that they should be included—not the other way around.

Given that calendar year 2000 transition payments will be based 50% on RBPEs and 50% on historical charges, no specialty will be subjected to extreme reductions next year as a result of requiring them to first present their data to the RUC/PEAC before a decision is made on recommending to HCFA that such costs be included in the PE-RVUs. Since the impact of HCFA's decision to edit out the clinical staff time for facility services is less than two percent, plus or minus, for most specialties when RBPEs are *fully* implemented in 2002, the impact of editing out these costs will be a change in payments of only one percent for most specialties in calendar year 2000.

We are also aware that some specialties have argued that HCFA's proposal may not have eliminated just the cost data on the use of clinical staff in facilities. They suggest that data limitations may have caused HCFA to eliminate all clinical staff time during the intra-service period. Thus a physician's clinical staff providing clinical guidance via phone to a patient's family may also have been eliminated from the CPEP data. We recommend that HCFA address this issue in the final rule, clarify the methodology it used to eliminate the cost data, and make any necessary corrections to
assure that legitimate clinical expenses, such as the example cited above, are not eliminated.

**Physician Time** -- Under the "top down" methodology HCFA is using to calculate the resource-based practice expense for physicians' services, the physician time attributed to each service has now become a significant factor in determining the RVUs assigned to that service. As HCFA discussed above, one of the tasks of HCFA's contractor is to develop options for validating the 1992 Harvard research team study and the AMA/RUC physician time data. HCFA states that the time data resulting from the refinement of the work relative value units (RVUs) have been, on the average, 25 percent greater than the time data obtained by the Harvard research team for the same services. The RUC contends that the HCFA time database is far more complex than what HCFA describes in the proposed rule. HCFA should strongly consider the RUC review of the HCFA time database. ACP-ASIM also is not convinced that HCFA's decision to increase the Harvard research team's time data to ensure consistency between the RUC and Harvard data sources is appropriate. The RUC reviewed old codes due to changes in practice and therefore changing the time associated with providing those services should change. The Harvard times for services not reviewed by the RUC would not necessarily have changed. It can be argued that it is very unlikely that they did change because the RUC did not choose to survey them.

**Site-of-Service Differential** -- HCFA has defined hospitals, skilled nursing facilities (SNFs), and ambulatory surgical centers (ASCs) as facilities for practice expense purposes. For the purposes of the physician practice expense calculation, all other sites-of-service are considered non-facility. The distinction between the non-facility and facility setting takes into account the higher expenses of the practitioner in the non-facility setting, where the practitioner typically bears the cost of the resources--clinical staff, supplies, and equipment--associated with the service. The major purpose of the site-of-service distinction is to ensure that Medicare does not make a duplicate payment for any of the practice expenses incurred in performing a service for a Medicare patient. ACP-ASIM agrees that non-facility RVUs are expected to be higher than the facility RVUs for a given service, because the practitioner bears the costs of the necessary clinical staff, supplies, and equipment. We agree with HCFA's proposal to limit the facility rate so that it cannot be higher than the non-facility rate for any given code and recognize that this change has negligible impact on any specialty.

2. **Resource-Based Malpractice Relative Value Units**

Section 4505(f) of the Balanced Budget Act of 1997 (BBA) requires HCFA to implement resource-based malpractice relative value units (RVUs) for services furnished beginning in calendar year 2000. ACP-ASIM recognizes and supports HCFA's decision to create the resource-based malpractice RVUs on actual malpractice
premium data and current Medicare payment data on allowed services and charges, RVUs, and specialty payment percentages. However, ACP-ASIM urges HCFA to update the malpractice insurance data set used to develop the resource-based malpractice RVUs as the cross-section of data is already four years to six years old. In the proposed rule, HCFA indicates that it plans to collect more recent data (1996-1998) to use in future refinement of malpractice RVUs, but does not expect that these more recent data will result in any significant changes since malpractice premiums have been stable in recent years. Regardless, HCFA should update its malpractice RVUs with more recent data as soon as possible.

In calculating resource-based malpractice RVUs for each procedure, HCFA used work RVUs to account for differences in risk-of-service. In the rule, HCFA recognizes that adjusting for risk-of-service using work RVUs may not exactly reflect risk-of-service differences because certain procedures with relatively high work RVUs may have low malpractice claim frequencies while certain procedures with relatively low work RVUs may have high malpractice claim frequencies. Until a more appropriate factor is used, HCFA should retain the current malpractice RVUs for all services with zero work RVUs and be open to suggestions for constructing malpractice RVUs using a different factor.

3. Assisted Suicide

ACP-ASIM understands that HCFA is conforming its regulations to the Medicare law amendment, Public Law 105-12 (The Assisted Suicide Funding Restriction Act of 1997) which prohibits the use of Federal funds to furnish or pay for any health care service or health benefit coverage for the purpose of causing, or assisting to cause, the death of any individual, by adding a new paragraph (q) to § 411.15. ACP-ASIM agrees that the prohibition should not apply to withholding or withdrawing medical treatment, nutrition, or hydration. In addition, the prohibition should not apply to furnishing a service to alleviate pain, even if doing so may increase the risk of death, as long as the purpose is not to cause or assist in causing death.

4. CPT Modifier -25

ACP-ASIM opposes HCFA's proposal that for procedures where the global surgery rules do not apply (for example, the global code is "XXX"), a provider may only bill for a separately identifiable E/M service by using the CPT modifier -25. HCFA states that requiring the use of modifier -25 will assist carriers in claims adjudication. Actually, it will assist carriers by inappropriately denying legitimate claims. This proposal will create a major administrative hassle for internists' practices and those of other physicians who provide E/M services and separately identifiable services on the same day. The proposed change will force physicians to make wholesale use of the -
25 modifier. The purpose of the Correct Coding Initiative (CCI) was to identify coding pairs that should not be billed together. Medicare has addressed this issue as recently as Phase IV of the CCI. There is no need to address the issue again a year later. If HCFA is concerned about inappropriate billing of services, then it should use focused medical review to identify individuals whose patterns of coding stand out from their geographic area and specialty peers. There are many problems with creating a blanket policy to cover all services provided in conjunction with E/M services. For example, requiring modifier -25 for vaccines is redundant as all vaccines are separate services. In summary, focused medical review is the best solution to variations of coding practices, along with clear CPT language and physician education. HCFA's proposal to require the use of modifier -25 could lead to fragmented patient care and will impose major hassles on physician practices.

5. Pulse Oximetry, Temperature Gradient Studies, and Venous Pressure Determinations

ACP-ASIM does not agree with HCFA's contention that CPT codes 94760, 94761, 94762, 93740, and 93770 (pulse oximetry and venous pressure determinations), are simple diagnostic procedures that are always provided with an E/M service or a more complex procedure. While the technical work involved in these procedures is small, the physician work involved in interpreting them can be complex and therefore these services should remain separately identified and reimbursed under the Medicare physician fee schedule. ACP-ASIM opposes HCFA's proposal to discontinue separate payment for CPT codes 94760, 94761, 94762, and 93770 and to list them in the physician fee schedule with a status code of "B" for "payment always bundled into payment for other services."

6. Coverage of Prostate Cancer Screening Tests

ACP-ASIM is pleased that the Balanced Budget Act of 1997 provides for Medicare coverage of one screening digital rectal examinations (DRE) and one screening prostate-specific antigen blood test annually for men over the age of 50 beginning January 1, 2000. In addition, we note that the law provides for coverage for years beginning after 2002 of other procedures as HCFA find appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors as HCFA consider appropriate. ACP-ASIM supports the creation of new HCPCS codes, G0102, prostate cancer screening DRE, to be used for the screening DRE, and HCPCS code G0103, prostate screening; prostate specific antigen (PSA). ACP-ASIM is concerned that HCFA plans to bundle the DRE into the payment for an E/M service when a covered E/M service is provided on the same day as a DRE. The DRE is a
specifically identifiable service that should be separately payable if all the aforementioned coverage requirements are met.

7. Diagnostic Tests

ACP-ASIM agrees that it is appropriate to revise the 1997 regulation that requires that diagnostic tests covered and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician in order to be considered reasonable and necessary and, therefore, covered under Medicare. ACP-ASIM supports HCFA's proposal to revise the supervision regulations to add an exception that would specify that no physician supervision is required for diagnostic tests performed by nurse practitioners (NPs) and clinical nurse specialists (CNSs) when they are authorized by the State to perform these tests as the Balanced Budget Act of 1997 removed the restrictions on these areas.

ACP-ASIM supports HCFA's proposal to modify the supervision regulation to state that diagnostic tests furnished by physician assistants (PAs) as legally authorized under State law require only a general level of physician supervision. PAs are licensed to practice with physician supervision. Also, for purposes of Medicare, they must be either employees or contractors of physicians, and their services may be billed only by the physicians.

We also agree that the physician supervision rules should not apply to pathology and laboratory codes in the 80000 series of the CPT payable under the physician fee schedule as this family of codes falls under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. ACP-ASIM supports these proposals because they recognize the appropriate role of state law, scope of physician assistant services, and jurisdiction of CLIA regulation.

8. Medicare Payments to Nurse Practitioners and Clinical Nurse Specialists for Performing Physician Services

ACP-ASIM opposes the HCFA proposal to further weaken its regulations regarding the qualifications NPs to bill separately under Medicare. Reducing the training requirements for independently practicing NPs and allowing them to provide care without any supervision or collaboration with physicians, could reduce the quality of care provided under the Medicare program—potentially endangering patients' health as a result. It is our understanding that HCFA has already been petitioned to start paying NPs for potentially dangerous services such as critical care and radiation therapy management. HCFA needs to draw the line and only allow adequately trained and experienced NPs to perform independently of physician supervision. Furthermore, encouraging payment for ancillary practitioners will not reduce Medicare costs.
Instead it will likely increase costs as supplemental services provided by NPs are billed.

HCFA must define in the regulations the terms "scope of practice" and "collaboration" for NPs. Rather than allowing NPs to perform services "legally authorized" by the Balanced Budget Act, HCFA is proposing to allow anything "not legally prohibited." HCFA should specify that, for Medicare to pay for a service (or level of service with regard to E/M codes), the specific service authorized for NPs must be stated explicitly in state laws or regulations or in the guidelines or other mechanisms defining the collaboration between the NP and a physician or physicians. This proposed requirement is consistent with how Medicare pays for physician services.

Explicitly defining NP scope of practice will also aid Medicare carrier's medical review. Under current rules, it is extremely difficult or impossible for carriers to determine whether a NP is qualified to perform a particular service.

9. Site-of-service differential for the Monthly Capitated Payment for End-Stage Renal Disease services

ACP-ASIM recognizes and supports the Renal Physician Association's (RPA) concern about the first time application of the site-of-service (SOS) differential to the Monthly Capitated Payment (MCP) for End-Stage Renal Disease (ESRD) services. It is inappropriate to apply the SOS differential to the MCP. HCFA should revert to its previous policy that utilized a single SOS for MCP services, which better reflects nephrology practice. The series of E/M services that make up the MCP is highly variable and unpredictable, on both a patient and time basis. Nephrologists must be prepared to provide E/M services of every level of intensity to every patient every day, often with little prior indication.

The "office" and "facility" settings allowed for by the revised interpretation of site-of-service for the MCP does not recognize the fact that a nephrologist may be required to provide MCP services in the dialysis facility, his or her office, a hospital outpatient department, the observational or transitional care settings of a hospital, or the emergency room. Historically, billing for MCP services reflects this diversity of service sites. Accordingly, the use of the site-of-service differential for the MCP is an artificial construct that does not account for the multiplicity of service locations in which the nephrologist may be required to provide MCP services. In order to appropriately recognize practice expenses, HCFA should re-institute previous policy in this area, under which a single site-of-service was utilized for the ESRD MCP series of procedure codes, and to establish a reimbursement level that represents the median between the two levels currently proposed.
Summary of ACP-ASIM's Recommendations

To summarize, ACP-ASIM recommends that HCFA incorporate the following comments in its final rule.

Resource-Based Practice Expense Relative Value Units

1. Interested parties should be able to review and comment on the recommendations made by the contractor HCFA selected to assist the agency in evaluating methodological issues;
2. Specialty-specific data submitted to supplement SMS data should not be used and reliable, standardized criteria for accepting and validating additional specialty-specific data should be developed;
3. HCFA should publish the procedure-specific CPEP input changes that it intends to make in the final rule before it is published this Fall as these changes—identified as errors in comments on the 1999 Medicare fee schedule proposed and final rules—were not identified in this proposed rule;
4. HCFA should exclude from the raw CPEP data all clinical staff time allotted to the use of clinical staff in the facility setting. However, HCFA should consider future recommendations that may be forthcoming from the RUC/PEAC during the refinement process that:
   o Show that it is a typical practice to employ clinical staff for the procedure codes in question and
   o Document what types of services the clinical staff are providing. Any recommendations for inclusion of clinical staff in the facility setting must differentiate between physician-substitutive services (which should be addressed through the work RVUs, not the PE-RVUs), general administrative costs (an indirect cost) or specialized clinical assistance that may represent a legitimate practice expense that should be paid by Medicare.
5. HCFA should not delay for one year its decision to edit out clinical staff time in the facility setting. A delay would be contrary to the idea of a resource-based system as it would require HCFA to continue paying for costs that may not be typical and that have not been validated through the refinement process.
6. HCFA should clarify the methodology it used to eliminate cost data on the use of clinical staff in facilities in the final rule, and it should make corrections if any legitimate clinical expenses were inappropriately eliminated.
7. HCFA should consider letting the RUC review its physician time database.
8. HCFA should implement the proposal to limit the facility rate so that it cannot be higher than the non-facility rate for any given code.

Resource-Based Malpractice Relative Value Units
1. HCFA should implement the proposal to create resource-based malpractice RVUs on actual premium data. HCFA should update its malpractice insurance data set as soon as possible.

2. HCFA should remain open to suggestions for determining differences in risk-of-service. In the meantime, it should retain the current malpractice RVUs for all services with zero work RVUs.

**Assisted Suicide**

We agree with the manner in which HCFA proposes to conform its regulations to Public Law 105-12, The Assisted Suicide Funding Restriction Act of 1997.

**CPT Modifier -25**

We oppose the proposal to require that all E/M services be appended with modifier -25 when performed on the same day as a procedure for which global surgery rules do not apply.

**Pulse Oximetry, Temperature Gradient Studies, and Venous Pressure Determinations**

We oppose the proposal to discontinue separate payment for CPT codes 94760, 94761, 94762, and 93770 by listing them in the physician fee schedule with a status code of "B" for "payment always bundled into payment for other services."

**Coverage of Prostate Cancer Screening Tests**

We support the creation of new HCPCS codes for a screening DRE and PSA, however, we oppose the plan to bundle the payment for a screening DRE into the payment for a Medicare-covered E/M service when they are performed on the same day.

**Diagnostic Tests**

1. We support the proposal to revise the supervision regulations to:
   o Add an exception that would specify that no physician supervision is required for diagnostic tests performed by NPs and CNSs when they are authorized by the State to perform these tests; and
   o Modify the supervision regulation to state that diagnostic tests furnished by PAs as legally authorized under State law require only a general level of physician supervision; and
2. We agree that the physician supervision rules should not apply to pathology and laboratory codes in the 80000 series of the CPT payable under the physician fee.

*Medicare Payments to Nurse Practitioners and Clinical Nurse Specialists for Performing Physician Services*

HCFA should not implement its proposal to expand Medicare payments to nurse practitioners. Instead, the proposal should be modified to ensure that only adequately trained and experienced NPs perform services without physician supervision. HCFA should only pay for a service if state law, regulation, or another mechanism defining collaboration between a NP and a physician(s) specifically authorizes a NP to furnish the service.

*Site-of-service differential for the Monthly Capitated Payment for End-Stage Renal Disease Services*

HCFA should use a single site-of-service differential to the ESRD MCP as it better reflects nephrology practice.