



Statement

of the

American Medical Association

to the

Practicing Physicians Advisory Council

RE: Physician Fee Schedule Proposed Rule
NPI-Outreach And Implementation
Competitive Acquisition For Drugs

Presented by Ardis D. Hoven, MD

August 22, 2005

Division of Legislative Counsel
202 789-7426

AMA RECOMMENDATIONS FOR PPAC

The AMA urges the Practicing Physicians Advisory Council to recommend that CMS —

PHYSICIAN FEE SCHEDULE PROPOSED RULE

- **Use its administrative authority to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996, for purposes of the 2006 physician fee schedule rule;**
- **Ensure that increased spending on physicians' services due to all government initiatives is accurately reflected in the SGR, for purposes of the 2006 physician fee schedule rule;**
- **Ensure that the SGR also reflects the impact on utilization and spending resulting from all national coverage decisions, for purposes of the 2006 physician fee schedule rule;**
- **Delay implementation of the proposal concerning reforms to the methodology for establishing practice expense relative value units until the medical community has a greater opportunity to review the proposal and consult with CMS about our analysis and concerns;**

NPI-OUTREACH AND IMPLEMENTATION

- **Appoint an authoritative leader to serve as the single-point of contact for NPI matters. This person should have the responsibility for coordinating and overseeing the NPI progress and to maintain an ongoing dialogue with each stakeholder in the NPI process - including the vendor community;**
- **Provide rapid responses to open enumeration and National Plan and Provider Enumeration System (NPES) issues and recommendations;**
- **Provide timely outreach and communications on all appropriate NPI issues (including timelines) that arise and coordinate this communication strategy with all impacted health care sectors;**
- **Work with the health care community to develop a coordinated NPI deployment approach and strategy with defined milestones;**

- **Work with the health care community to coordinate the deployment of the NPI with other related HIPAA regulations and Medicare e-prescribing initiatives;**
- **Work with the health care community to develop an appropriate strategy for utilization of the NPI for both electronic data interchange (EDI) and paper forms;**
- **Ensure that the National Provider and Payer Enumeration System (NPES), which will be used for processing NPI applications, has appropriate measures to ensure that the NPI and physician-specific data associated with these numbers is closely and thoroughly safeguarded; and**
- **Apply stringent rules regarding levels of access to NPES data and appropriately monitor access to such data, as it occurs.**

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The American Medical Association (AMA) appreciates the opportunity to submit this statement to the Practicing Physicians Advisory Council (PPAC or the Council) concerning the physician fee schedule proposed rule, competitive acquisition for drugs (CAP), and national provider identifiers (NPI) – outreach and implementation.

PHYSICIAN FEE SCHEDULE PROPOSED RULE

Estimated 4.3% Medicare Physician Pay Cut for 2006

The proposed physician fee schedule rule for 2006 confirms the projections of the Medicare Trustees in their March Report to Congress: **Medicare payments for services furnished by physicians and other health professionals are estimated to be cut by 4.3% in 2006. This steep cut is just the first in a series of cuts that are projected over the next six years, totaling about 26%.**

As the AMA has previously advised PPAC, these cuts are due to the fatally flawed Medicare sustainable growth rate (SGR) physician payment formula, and we are very concerned that physicians will be unable to absorb these cuts and thus forced to limit services to Medicare beneficiaries. In fact, as we indicated at the June PPAC meeting, a recent AMA survey indicates that if projected cuts in Medicare physician payment rates begin as scheduled in 2006:

- More than a third of physicians (38%) plan to decrease the number of new Medicare patients they accept;
- More than half of physicians (54%) plan to defer the purchase of information technology;
- A majority of physicians (53%) will be less likely to participate in a Medicare Advantage plan;
- One-third (34%) of physicians whose practice serves a rural patient population will discontinue rural outreach services, and over half (52%) of physicians whose practice serves a rural patient population will discontinue these important outreach services; and
- One-third of physicians (34%) plan to discontinue nursing home visits if payments are cut in 2006. By the time the cuts end, half (50%) of physicians will have discontinued nursing home visits.

Accordingly, it is clear that the SGR must be replaced with a new formula that accurately reflects increases in the cost of practicing medicine.

Need to Replace the Fatally Flawed SGR Physician Payment Formula

The AMA has previously advised PPAC of the problems with the current Medicare physician payment formula, which is based on a target rate of growth, or the SGR. Under the SGR, if Medicare spending on physicians' services exceeds allowed spending in a particular year, physician payments are cut in the subsequent year. Conversely, if allowed spending is less than actual spending, physician payments increase.

There are two fundamental problems with the SGR formula:

1. Payment updates under the SGR formula are tied to the gross domestic product, which bears little relationship to patients' health care needs or physicians' practice costs; and
2. Physicians are penalized with pay cuts when Medicare spending on physicians' services exceeds the SGR spending target, yet, the SGR is not adjusted to take into account many factors beyond physicians' control, including government policies, that although good for patients, promote Medicare spending on physicians' services.

The AMA appreciates the Centers for Medicare and Medicaid Services (CMS) Administrator McClellan's statement when this rule was released that "the current system of paying physicians is simply not sustainable." We agree, and are continuing to work with CMS and Congress to avert physician pay cuts and ensure

that a stable, reliable Medicare physician payment formula is in place for Medicare patients.

Administrative Actions to Reform the Medicare Physician Payment Formula

In the proposed physician payment rule, CMS requests comments on steps to promote physician payment adequacy without increasing overall Medicare costs. In that context, CMS states it is particularly interested in payment reforms to promote higher quality and avoid unnecessary costs, consistent with paying for better value in Medicare without increasing overall Medicare costs. In addition, CMS encourages comments regarding changes to the SGR methodology, including legal theories that support such steps as removing Part B drug payments (retroactive to 1996) from the calculation of the SGR.

Removing Drugs from Calculations of the SGR

As discussed above, the SGR system is fatally flawed and must be replaced by a new formula that appropriately reflects increases in the costs of practicing medicine. If Congress were to act alone to enact a new formula, the cost of doing so would be significant. Thus, the Administration must join efforts with Congress to achieve this goal. **CMS has the authority to make immediate administrative changes to the formula that would lower the cost for Congress to enact a new one.**

In fact, House Ways and Means Chairman Thomas and Health Subcommittee Chairman Johnson, as well as Senate Finance Chairman Grassley, Ranking Member Baucus (and 87 additional Senators) recently sent written correspondence to CMS Administrator McClellan and OMB Director Bolton, respectively, requesting that increases in Medicare spending due to physician-administered drugs be removed retroactively from calculations of the SGR.

Chairmen Thomas and Johnson also requested that steps be taken to ensure that the SGR accurately reflects spending increases due to such matters as expanded Medicare benefits and national coverage decisions.

CMS has the Authority to Remove Drugs from the SGR, Retroactive to 1996

We appreciate that PPAC has recommended that CMS use its administrative authority to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996, and we urge PPAC to recommend that CMS do so for the 2006 physician fee schedule rule. Recently Administrator McClellan testified that removing drugs will not have any impact on physician payment updates under the SGR for at least several years. Nonetheless, removing drugs *will* significantly reduce the cost of legislation to address the looming Medicare pay cuts and CMS should take this step as soon as possible.

CMS has the authority to remove physician-administered drugs from the SGR, retroactive to 1996. When CMS calculates actual Medicare spending on “physicians’ services,” it

includes the costs of Medicare-covered prescription drugs administered in physicians' offices. CMS has excluded drugs from "physicians' services" for purposes of administering other Medicare physician payment provisions. Thus, removing drugs from the definition of "physicians' services" for purposes of calculating the SGR is a consistent reading of the Medicare statute. Drugs are not paid under the Medicare physician fee schedule, and it is illogical to include them in calculating the SGR.

Further, if CMS adopts a revised definition of "physicians' services" that excludes drugs, it can revise its SGR calculations going back to 1996 using its revised definition. These revisions would not affect payment updates from previous years, but would only affect payment updates in future years. This recalculation would be similar, for example, to the recalculation of graduate medical education costs in a base year for purposes of setting future payment amounts. That recalculation was approved by the Supreme Court.

CMS' authority to remove drugs from the SGR retroactively was corroborated in a legal memorandum drafted by Terry S. Coleman, a former Acting General Counsel of the U.S. Department of Health and Human Services, as well as a former Chief Counsel and Deputy Administrator of the Health Care Financing Administration. The AMA has previously provided this memorandum to CMS.

CMS Should Remove Drugs from the SGR

Drug expenditures are continuing to grow at a very rapid pace. Over the past 5 to 10 years, drug companies have revolutionized the treatment of cancer and many autoimmune diseases through the development of a new family of biopharmaceuticals that mimic compounds found within the body. Such achievements do not come without a price. Drug costs of \$1,000 to \$2,000 per patient per month are common and annual per patient costs were found to average \$71,600 a year in one study.

Further, between the SGR's 1996 base year and 2004, the number of drugs included in the SGR pool rose from 363 to 444. Spending on physician-administered drugs over the same time period rose from \$1.8 billion to \$8.7 billion, an increase of 365% per beneficiary compared to an increase of only 63% per beneficiary for actual physicians' services. As a result, drugs have consumed an ever-increasing share of SGR dollars and have gone from 3.7% of the total in 1996 to 10% in 2004.

This lopsided growth lowers the SGR target for real physicians' services, and, according to the Congressional Budget Office, annual growth in the real target for physicians' services will be almost a half percentage point lower than it would be if drugs and lab tests were not counted in the SGR. As 10-year average GDP growth is only about 2%, even a half percent increase makes a big difference. Thus, including the costs of drugs in the SGR pool significantly increases the odds that Medicare spending on "physicians' services" will exceed the SGR target. Ironically, however, Medicare physician pay cuts (resulting from application of the SGR spending target) apply only to actual physicians' services, and not to physician-administered drugs, which are significant drivers of the payment cuts.

Medicare actuaries predict that drug spending growth will continue to significantly outpace spending on physicians' services for years to come. In 2003, MedPAC reported that there are 650 new drugs in the pipeline and that a large number of these drugs are likely to require administration by physicians. In addition, an October 2003 report in the *American Journal of Managed Care* identified 102 unique biopharmaceuticals in late development and predicted that nearly 60% of these will be administered in ambulatory settings. While about a third of the total are cancer drugs, the majority are for other illnesses and some 22 medical specialties are likely to be involved in their prescribing and administration.

The development of these life-altering drugs has been encouraged by various federal policies including expanded funding for the National Institutes of Health and streamlining of the drug approval process. The AMA shares and applauds these goals. **It is not equitable or realistic, however, to finance the cost of these drugs through cuts in payments to physicians, and thus these costs should be removed from calculations of the SGR.**

Government-Induced Increases in Spending on Physicians' Services should be Accurately Reflected in the SGR Target

As discussed above, the government encourages greater use of physician services through legislative actions, as well as a host of other regulatory decisions. These initiatives clearly are good for patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many have either been ignored or undercounted in the target. Since the SGR is a cumulative system, erroneous estimates compound each year and create further deficits in Medicare spending on physicians' services.

Effective January 1, 2005, CMS implemented the following new or expanded Medicare benefits, some of which have been mandated by the MMA: (i) initial preventive physical examinations; (ii) diabetes screening tests, (iii) cardiovascular screening blood tests, including coverage of tests for cholesterol and other lipid or triglycerides levels, and other screening tests for other indications associated with cardiovascular disease or an elevated risk for that disease, (iv) coverage of routine costs of Category A clinical trials, and (v) additional ESRD codes on the list of telehealth services.

As a result of implementing a new Medicare benefit or expanding access to existing Medicare services, the above-mentioned provisions will increase Medicare spending on physicians' services. Such increased spending will occur due to the fact that new or increased benefits will trigger physician office visits, which, in turn, may trigger an array of other medically necessary services, including laboratory tests, to monitor or treat chronic conditions that might have otherwise gone undetected and untreated, including surgery for acute conditions.

CMS has not provided details of how these estimates were calculated, and certain questions remain. Further, CMS reportedly does consider multiple year impacts and cost of related services, but the agency has not provided any itemized descriptions of how the agency determines estimated costs. Without these details, it is impossible to judge the accuracy of CMS' law and regulation allowances. For example, in reviewing the 2004 utilization and spending data, we found that utilization per beneficiary of code G0101 for pelvic and breast exams to screen for breast or cervical cancer had increased 10% since 2003, yet this benefit was enacted in BBA 1997 nearly eight years ago. Likewise, per beneficiary utilization of code G0105, colorectal cancer screening of a high-risk patient, also enacted in the BBA, was up 13%. These impacts should be taken into account in revising the 2005 and 2006 SGR.

CMS should also seek to identify other spending increases attributable to quality improvement programs and ensure that they, too, are reflected in the SGR law and regulation factor. For example, Medicare's Quality Improvement Organizations (QIO) have encouraged physicians to determine the left ventricular function of all patients with congestive heart failure, measured using a nuclear medicine test or an echocardiogram. Further, CMS revised the codes for end-stage renal disease services in 2004 to encourage four physician visits per month. From 2003 to 2004, consistent with CMS' intent, Medicare spending for the new ESRD codes rose 17% above 2003 spending for the old codes.

We urge PPAC to recommend that increased spending due to all of the foregoing government initiatives is accurately reflected in the SGR for purposes of the 2006 physician fee schedule rule.

Medicare Physician Spending Due to National Coverage Decisions should be Reflected in the SGR

When establishing the SGR spending target for physicians' services, the law requires that impact on spending, due to changes in laws and regulations, be taken into account. The AMA believes that any changes in national Medicare coverage policy that are adopted by CMS pursuant to a formal or informal rulemaking, such as Program Memorandums or national coverage decisions, constitute a regulatory change as contemplated by the SGR law, and must also be taken into account for purposes of the spending target.

When the impact of regulatory changes for purposes of the SGR is not properly taken into account, physicians are forced to finance the cost of new benefits and other program changes through cuts in their payments. Not only is this precluded by the law, it is extremely inequitable and ultimately adversely impacts beneficiary access to important services.

CMS has expanded covered benefits through the adoption of more than 80 national coverage decisions (NCDs), including implantable cardioverter defibrillators, diagnostic tests and chemotherapy for cancer patients, carotid artery stents, cochlear implants, PET scans, and macular degeneration treatment. While every NCD does not significantly

increase Medicare spending, taken together, even those with marginal impact contribute to rising utilization. CMS has stated its view that it would be very difficult to estimate any costs or savings associated with specific coverage decisions and that any adjustments would likely be small in magnitude and have little effect on future updates.

We disagree, and strongly believe that CMS should make these adjustments in its rulemaking for 2006. **CMS already adjusts Medicare Advantage payments to account for NCDs, so it clearly is able to estimate their costs.** With respect to the magnitude of impact, as one example, CMS reported in January that the recent expansion of coverage for implantable defibrillators would make the devices available to some 500,000 people. In addition, CMS has provided us with data showing that 2004 Medicare Part B spending on PET scans (which was initiated through the NCD process) was \$387 million, a 51% increase over 2003, and the agency has acknowledged that PET scans play an important role in diagnosing a number of diseases. Further, in the proposed fee schedule rule for 2006, CMS acknowledges that Medicare coverage of PET scans has increased dramatically since Medicare began covering PET scans in December 2000 when coverage was limited to only a few types of cancers. CMS states that since December 2001, it has significantly expanded Medicare PET scan coverage to include an increased number of cancers and other conditions. This contributed to volume growth in nuclear medicine services of 85% between 1999 and 2003. Further, CMS states in the proposed rule that an increase in claims for imaging services provided in physicians' offices shows a shift in these services from hospital settings to physicians offices, which leads to additional spending on physicians' services. **Yet, although CMS acknowledges the volume growth due to expanding PET scan coverage, as well as a significant shift in site-of-service for imaging procedures, this volume growth is not reflected in the SGR.**

Moreover, the AMA, along with 33 national medical organizations and state medical associations, contracted with the National Opinion Research Center (NORC) to estimate the costs of several NCDs to illustrate that it is possible to make such estimates and provide a sense of their magnitude. NORC's evaluation of the cost of the expanded coverage of photodynamic therapy to treat macular degeneration considered the cost of exams and fluorescein angiography tests to determine the appropriateness of treatment as well as treatment costs. NORC was also able to separate the costs that Medicare would have incurred due to local carrier coverage decisions from the expected costs associated with the NCD for treatment of the occult form of macular degeneration, for which Medicare prohibited coverage prior to the NCD. NORC conservatively estimates that the new coverage is increasing expenditures by more than \$300 million a year and could boost spending by more than twice that amount if used by all the eligible Medicare patients.

While the AMA strongly supports Medicare beneficiary access to these important services, physicians and other practitioners should not have to finance the costs resulting from the attendant increased utilization. **Accordingly, we urge PPAC to recommend, for purposes of the 2006 physician fee schedule rule, that CMS ensure that the SGR**

reflects the impact on utilization and spending resulting from all national coverage decisions.

Reforms to Methodology for Establishing Practice Expense Relative Value Units

CMS announced its plan in the proposed rule to revise the current methodology for establishing practice expense (PE) relative value units (RVUs) for physicians' services. CMS states in the proposed rule that under the new methodology, shifts in some of the PE RVUs could cause financial stress on medical practices, especially on top of the projected Medicare physician pay cuts. CMS, therefore, is proposing a four-year phase-in of the new PE RVUs, beginning in 2006. Under this proposal, dermatology, urology, radiation oncology, gastroenterology, pathology, and physical therapy will see the biggest increases in PE RVUs, while anesthesiology, neurosurgery, cardiac surgery, thoracic surgery, ophthalmology, and rheumatology face the steepest cuts, as do several non-physician practitioners, including audiologists and chiropractors.

In establishing the new PE RVUs, CMS has accepted practice expense survey data gathered and submitted by a number of specialties for use in establishing the RVUs. (CMS accepted survey data from the Association of Freestanding Radiation Oncology Centers, the American Urological Association, the American Academy of Dermatology Association, the Joint Council of Allergy, Asthma, and Immunology, as well a joint survey from the American Gastroenterological Association, the American Society of Gastrointestinal Endoscopy and the American College of Gastroenterology).

CMS is proposing this change in the methodology for establishing PE RVUs without prior consultation with the medical community, and the AMA is concerned that there is not an appropriate amount of time for multi-specialty review and analysis. Because this proposal is a major departure from the existing methodology and will significantly impact a number of medical specialties, it is particularly important that the medical specialty societies have ample time to replicate the new methodology and understand how it is used in determining the new PE RVUs. **Thus, the AMA urges PPAC to recommend that CMS delay implementation of this proposal until the medical community has a greater opportunity to review the proposal and consult with CMS about our analysis and concerns.**

Physician Referrals for Nuclear Medicine Services to Facilities With Which They Have a Financial Relationship

CMS is proposing to expand the "Stark" physician self-referral law by adding diagnostic and therapeutic nuclear medicine services and supplies to the list of procedures for which physicians are prohibited from referring if they have a financial relationship with the entity providing the service. CMS acknowledges in the proposed rule that this is a complete reversal of current policy, which has encouraged physicians to invest in nuclear medicine equipment and ventures, particularly PET scanners, which are very expensive and require substantial financial investment. If this policy is reversed, as proposed, physicians would have to divest their ownership or investment interests. CMS, therefore,

is seeking public comment as to whether, or how, to minimize the impact on affected physicians, *i.e.*, through a delayed effective date or by grandfathering certain arrangements.

The AMA is very concerned about the potential impact of this proposal with regard to disruption of patient care, as well as access to these services, and we will be providing CMS with further comment on this proposal. Further, forcing physicians to divest their investment interests may result in a “fire sale” of this expensive equipment wherein physicians may not be able to recover the initial cost of their investment due to much greater supply than demand. Any resulting losses would only compound the impact of projected Medicare pay cuts, as well as skyrocketing medical liability premiums.

A grandfather clause may help to reduce some of this financial impact, but we urge CMS to ensure that any grandfather clause for physician investment in nuclear medicine arrangements is clearly and properly implemented. When Congress grandfathered certain specialty hospitals during the moratorium on physician ownership of these hospitals, there were lengthy delays that caused confusion surrounding which specialty hospitals (that were “under development”) qualified for the grandfather clause. We urge CMS to ensure that any similar confusion is clarified and eliminated prior to implementation of any grandfather clause for nuclear medicine services.

NPI-OUTREACH AND IMPLEMENTATION

Background of National Provider Identifiers

In July 1993, CMS began development of a health care provider identification system to meet the needs of the Medicare and Medicaid programs and, ultimately, the needs of a national identification system for all health care providers. In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress mandated standards for four national identifiers, including one for providers called the National Provider Identifier (NPI). As a result of HIPAA and the agency’s previous efforts, CMS developed a new identifier for health care providers because existing identifiers did not meet the criteria for national standards. In January 2004, CMS issued a final rule establishing the NPI as the standard for a unique health identifier for health care providers for use in the health care system. Under this rule, physicians could begin requesting an NPI in May of 2005 even though its use will not be required until 2007.

Like other HIPAA Administrative Simplification provisions, the NPI is intended to make life simpler for physicians and providers, payers, and other components of the health system. Theoretically, it will replace the myriad numbers that providers currently use to bill for their services. The NPI should not have the same limitations as other existing identifiers, and it met the criteria that had been recommended by the Workgroup for Electronic Data Interchange (WEDI) and the American National Standards Institute (ANSI). However, as with other HIPAA provisions, the transition to the NPI likely will be extremely burdensome and expensive.

Transition and Implementation Suggestions

The AMA gratefully acknowledges and appreciates the time and support we have received from the CMS staff on NPI issues. We believe that a successful, cost-effective, and timely implementation of the NPI is achievable. We have continuing concerns, however, about implementation of the NPI, which we jointly expressed with other health care organizations to Secretary Leavitt in April 2005. Generally, we believe an increased level of collaboration between the government and the health care community is critical for ensuring a comprehensive implementation and outreach strategy that avoids unnecessary costs, delays, disruptions and confusion about when and how the NPI will be implemented.

To improve the NPI implementation process, we urge PPAC to recommend that CMS adopt the following recommendations:

1. Appoint an authoritative leader to serve as the single-point of contact. This person should have the responsibility for coordinating and overseeing the NPI progress and to maintain an ongoing dialogue with each stakeholder in the NPI process - including the vendor community;
2. Provide rapid responses to open enumeration and National Plan and Provider Enumeration System (NPPES) issues and recommendations;
3. Provide timely outreach and communications on all appropriate NPI issues (including timelines) that arise and coordinate this communication strategy with all impacted health care sectors;
4. Work with the health care community to develop a coordinated NPI deployment approach and strategy with defined milestones;
5. Work with the health care community to coordinate the deployment of the NPI with other related HIPAA regulations and Medicare e-prescribing initiatives; and
6. Work with the health care community to develop an appropriate strategy for utilization of the NPI for both electronic data interchange (EDI) and paper forms.

We believe these recommendations will provide a more cost-effective transition toward NPI implementation and avoid the potential confusion that could result from the current NPI implementation approach.

Other NPI Concerns

In addition to these broad implementation suggestions, we have heard anecdotally from physicians regarding specific concerns with the NPI. Some have had excellent experiences with the online enrollment process, while others have struggled with the Internet-based interface when they applied for an NPI. In conversations with CMS staff, they have noted that they are developing a “tips” page to provide further guidance on how to use the online enrollment form. The AMA believes many physicians will find such assistance useful and has encouraged CMS to post a “tips” page as quickly as possible.

We also have heard concerns regarding the potential security hazards inherent in having so much information associated with an identifying number. Ineffective security measures for the NPI could place personal data at risk, leaving physicians open to identity theft, fraud, or other abuse. **CMS needs to ensure that the National Provider and Payer Enumeration System (NPES), which will be used for processing NPI applications, has appropriate measures to ensure that the NPI and physician-specific data associated with these numbers is closely and thoroughly safeguarded. We urge PPAC to make this recommendation to CMS.** CMS should also educate providers on the importance of keeping their NPIs private.

The AMA is also concerned that businesses desiring to market products and services to physicians may access physician-specific information through the NPES database. **We urge PPAC to recommend that CMS apply stringent rules regarding levels of access to NPES data and appropriately monitor access to such data, as it occurs.** Of course, such privacy and security need to be balanced to meet the needs of providers and payers. For instance, physicians would need enough access to the system to facilitate obtaining an ordering/referring physician's NPI so they can include it on claims for Medicare covered services. The AMA recognizes that CMS intends to issue a separate “data dissemination” rule sometime this fall, which will provide significantly greater detail regarding security and how NPIs will be accessed and personal data will be released. **We look forward to continuing to work with CMS on these important issues, and urge PPAC to recommend that CMS consider these concerns as they continue drafting the data dissemination rule.**

Some physicians have also expressed concern over being required to use an NPI at all. Their reasons vary, but some reflect concern over the security issues discussed above. Others believe the new numbers will add to confusion and bureaucratic hassles rather than reduce them. Although HIPAA only mandates the use of an NPI for providers conducting standard transactions, health plans, including Medicare, may require the use of an NPI for any physician or provider submitting claims. We understand that CMS is planning to require all eligible providers that submit claims to Medicare to obtain and use an NPI. Some have threatened to retire rather than place their personal information at risk. PPAC should be aware that not all physicians want to have an NPI, and should explore options that health plans, including Medicare, might employ for accommodating these physicians to ensure that their patients will continue to have access to care.

Finally, we also are concerned that a significant number of physicians remain uninformed about the NPI, and encourage PPAC to recommend that CMS reach out and educate physicians and providers more aggressively. For example, CMS should release information as soon as possible on its plans for “bulk enumeration” of physicians or other providers (which allows organizations representing physicians or other providers to register their members “in bulk” for the NPI, under certain conditions). Other outreach and education could include:

- Publishing articles in professional trade association and other provider publications;
- Providing information on industry web sites;
- Creating payer education programs and sample materials so that payers have all of the appropriate information and know what to communicate to providers; and
- Encouraging payer and provider seminars with industry partners, like the Workgroup for Electronic Data Interchange.

COMPETITIVE ACQUISITION FOR DRUGS

Under an interim final rule published on July 6, physicians who administer drugs in their offices to Medicare beneficiaries will have the option of participating in a new competitive acquisition program (CAP) beginning January 1, 2006. Physicians who choose this option will be able to obtain most of their commonly administered drugs from vendors selected by Medicare through competitive bidding. The vendors will be responsible for billing Medicare and beneficiaries for the physician-administered drugs.

As the Council may recall, the AMA and other physician groups had asked CMS, in comment letters, to issue an interim final rule with comment period rather than moving immediately to a final rule. We are pleased that CMS honored that request, as well as responding to several other physician recommendations, including:

- Making the program national in scope rather than phasing it in by region or specialty;
- Including most of the drugs that physicians administer to Medicare patients, particularly those that frequently cannot be purchased at the average sales price; and
- Requiring vendors to create plans for assisting beneficiaries who cannot meet the co-payment obligations for their drugs.

However, the AMA still has several concerns about the CAP, and we will continue to urge CMS to make modifications on a few key issues. (The AMA will submit detailed comments on the interim final rule before the September 7, 2005, deadline.) For example, we remain concerned about the extent of information CMS is requiring to be included in physicians' drug orders. Second, we are concerned that some physicians may not be able to file drug administration claims within 14 days. We also are concerned that the administrative burden associated with participating in the CAP still needs to be reduced. **Finally, although we are pleased, as noted above, that CMS is requiring vendors to create a process for helping beneficiaries who cannot meet their co-payment obligations, we have strong concerns that vendors ultimately will be allowed to refuse to dispense additional drugs through the end of the calendar year to patients who have not paid their coinsurance within certain time limits.** The interim final rule allows physicians to opt out of the particular drug category involved if this situation occurs. Yet, allowing vendors to refuse to dispense the drugs would have

negative consequences for patients' health and discourage physicians from participating in CAP at all.

We appreciate the opportunity to provide our views on the foregoing and look forward to continuing to work with PPAC and CMS in resolving these important matters.