Statement

of the

American Medical Association

to the

Committee on Finance
United States Senate

RE: "Improving Quality in Medicare: The Role of Value-Based Purchasing"

Presented by: Nancy H. Nielsen, MD, PhD

July 27, 2005

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Chairman Grassley, Ranking Member Baucus and Members of the Committee, the American Medical Association (AMA) appreciates the opportunity to provide our views today regarding "Improving Quality in Medicare: The Role of Value-Based Purchasing."

The AMA would like to commend you Mr. Chairman and Ranking Member Baucus, and Members of the Committee, for all of your hard work and leadership in recognizing the fundamental problems inherent in the Medicare physician payment update formula and the need to replace the flawed formula. You have also enhanced patient access to care by reducing geographic payment disparities so that rural communities are better able to recruit and retain physicians.

We also extend our gratitude to Chairman Grassley and Ranking Member Baucus for your past and continued efforts in pressing the Centers for Medicare and Medicaid Services (CMS) to use its authority to make administrative changes to the physicians payment sustainable growth rate (SGR) formula that would reduce the cost of replacing the formula with one that reflects the costs of practicing medicine. Without it, we are in grave danger of a Medicare meltdown that would present serious access problems for our nation's senior and disabled patients.

We are also thankful to Senators Jon Kyl and Debbie Stabenow and the over 15 co-sponsors of S. 1081, the *Preserving Patient Access to Physicians Act of 2005*, for their efforts to resolve the Medicare physician payment crisis. In accordance with the recommendation of the Medicare Payment Advisory Commission (MedPAC), this bill would set the Medicare physician payment increase for 2006 at no less than 2.7 percent, instead of the 4.3 percent cut

projected by the current formula. It would also avert cuts in 2007 by providing a positive update based on CMS' measure of practice cost inflation.

We appreciate the opportunity to present our views today on value-base purchasing for physicians' services under Medicare.

AMA COMMITMENT TO THE DEVELOPMENT OF EFFECTIVE QUALITY IMPROVEMENT PROGRAMS

The AMA is committed to quality improvement, and we have undertaken a number of initiatives to achieve this goal. Over the last five years, the AMA has dedicated over $5 million in convening the Physician Consortium for Performance Improvement for the development of performance measurements and related quality activities. It has grown to become the leading physician-sponsored initiative in the country in developing physician-level performance measures. CMS is now using the measures developed by the Consortium in the demonstration projects on pay-for-performance authorized by the MMA. The activities of the Consortium, as well as other AMA initiatives in performance improvement are described in the attached document.

AMA PAY-FOR-PERFORMANCE PRINCIPLES AND GUIDELINES

As quality improvement efforts have evolved, so has the concept of value-based purchasing (or pay-for-performance). The AMA believes that physician pay-for-performance programs designed properly to improve effectiveness and safety of patient care may serve as a positive force in our healthcare system. If done improperly, however, they could be detrimental to the mission of improving care for vulnerable populations. In our ongoing efforts to advance the development and effective implementation of pay-for-performance programs, the AMA's House of Delegates adopted in June comprehensive pay-for-performance (PFP) principles and guidelines.

Overall, these principles address five broad aspects of pay-for-performance programs: (i) quality of care; (ii) the patient/physician relationship; (iii) voluntary participation; (iv) accurate data and fair reporting; and (v) fair and equitable program incentives. More specific guidelines are associated with each principle. These principles and guidelines are attached.

Similar to these AMA principles, which support the use of quality of care measures created by physicians across appropriate specialties, the code set used to capture quality of care measures also needs to be created by physicians working with the specialty societies. To date, the AMA/CPT Editorial Panel has developed over 30 Category II CPT performance measurement codes, and more will be needed and developed. These codes will help diminish the burden on physicians by allowing claims to capture accurate clinical data about the quality of care delivered by physicians. Health plans will also benefit from the development and use of these codes by not having to send record reviewers to obtain the data from the charts.

LEGISLATION TO ESTABLISH VALUE-BASED PURCHASING FOR PHYSICIANS UNDER MEDICARE

Value-Based Purchasing for Physicians and Current SGR Formula Cannot Co-Exist

S. 1356, the *Medicare Value-Based Purchasing Act of 2005*, introduced by Chairman Grassley and Ranking Member Baucus, would establish a value-based payment system for paying for physicians' services. It also contains a "Sense of the Senate" provision that expresses that further action is needed by Congress to address the negative physician payment updates to ensure: (i) long-term stability of the Medicare physician payment system, (ii) appropriate reimbursement for "high quality and efficient delivery" of Medicare services; and (iii) future access and affordability of Medicare services for beneficiaries.

The AMA appreciates the Chairman's and Ranking Member's efforts under S. 1356 to establish a new Medicare payment system for physicians' services, as well as your recognition that Congress must address the flaws of the current SGR physician payment update formula, which have led to ongoing Medicare physician pay cuts that are detrimental to Medicare beneficiary access to care.

We urge the Committee, however, to ensure that any value-based legislation replaces the current SGR physician payment formula with a stable, reliable payment system that preserves patient access and reflects increases in physician practice costs. This would treat physicians similarly to other Medicare providers, such as hospitals, home health agencies and skilled nursing facilities. The flawed SGR formula cannot co-exist with a value-based purchasing program for physicians. The SGR and value-based purchasing are incompatible.

Value-based purchasing may save dollars for the Medicare program as a whole by reducing medical complications and hospitalizations. The majority of measures, however, such as those focused on prevention and chronic disease management, ask physicians to deliver more care. During his May 11, 2004 testimony before the House Ways and Means Health Subcommittee, CMS Administrator, Dr. Mark McClellan, suggested that one of the agency's quality improvement projects, the Chronic Care Improvement Project, "may actually increase the amount of (patient-physician) contact through appropriate office visits with physicians."

The SGR is a spending target that penalizes volume increases exceeding the target. If the SGR is retained, the so-called reward for physicians will be additional pay cuts. This is antithetical to the desired outcome of value-based purchasing and would only compound an ongoing serious problem.

The flaws in the SGR formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. The Medicare Trustees project that physicians and other health professionals face steep pay cuts (about 26%) over the next six years (from 2006 through 2011). If these cuts begin, on January 1, 2006, average physician payment rates will be less in 2006 than they were in 2001, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts

in the amount paid for each service. Physicians simply cannot absorb these draconian payment cuts and, unless Congress acts, physicians may be forced to avoid, discontinue or limit the provision of services to Medicare patients.

The AMA conducted a survey of physicians in February and March 2005 concerning significant Medicare pay cuts from 2006 through 2013 (as forecast in the 2004 Medicare Trustees report.) Results from the survey indicate that if the projected cuts in Medicare physician payment rates begin 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, which is necessary to make value-based purchasing work;

- A majority of physicians (53%) will be less likely to participate in a Medicare Advantage plan;

- About a quarter of physicians plan to close satellite offices (24%) and/or discontinue rural outreach services (29%) if payments are cut in 2006. If the pay cuts continue through 2013, close to half of physicians plan to close satellite offices (42%) and/or discontinue rural outreach (44%); 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.

A physician access crisis is looming for Medicare patients. While the MMA brought beneficiaries important new benefits, these critical improvements must be supported by an adequate payment structure for physicians' services. There are already some signs that access is deteriorating. A MedPAC survey found that 22% of patients already have some problems finding a primary care physician and 27% report delays getting an appointment. **Physicians are the foundation of our nation's health care system. Continual cuts (or even the threat of repeated cuts) put Medicare patient access to physicians' services at risk. They also threaten to destabilize the Medicare program and create a ripple effect across other programs. Indeed, Medicare cuts jeopardize access to medical care for millions of our active duty military family members and military retirees because their TRICARE insurance ties its payment rates to Medicare.**

Factors that Need to be Addressed in Physician Value-Based Purchasing Legislation

We urge the Committee to ensure that any value-based purchasing legislation addresses certain key areas of concern for physicians, many of which are further enumerated in the AMA principles and guidelines.

Requirements for Quality Measurement

We appreciate that several of the requirements for quality measures under S. 1356 would be consistent with AMA principles and guidelines. For example, S. 1356 requires quality measures to be evidence-based, reliable and valid, as well as feasible to collect and report. The bill also requires them to be developed through consultation with provider-based groups and clinical specialty societies. Finally, the bill requires the measures to be relevant to rural areas, as well as the frail elderly over the age of 75 and those with complex chronic conditions. The AMA also urges that quality measures allow for variation when it is necessary to meet the individual patient's unique needs, such as in cases where patients have allergies or adverse reactions.

The AMA is aware that other legislation recently approved by the Senate Committee on Health, Education, Labor and Pensions (HELP) contains provisions that establish a quality measurement system that differs slightly from the provisions in S. 1356. We encourage the Senate Finance and Senate HELP Committees to work together to develop a quality measurement system. The AMA looks forward to the opportunity to work with both Committees in that endeavor.

Funding of Value-Based Purchasing Programs

Value-based purchasing programs must be structured carefully to promote program effectiveness and the safety of patient care, and not penalize physicians. All physicians should be able to participate in the program voluntarily and should receive a positive base payment update, with an additional value-based payment for achieving quality goals. Performance measurement should be scored against both absolute values and relative improvements in those values.

Value-based programs that are funded through an overall percentage reduction of the physician payment update are not consistent with AMA policy. Thus, we cannot support value-based programs that are funded by a withhold pool. This is in contrast to other types of value-based purchasing programs, such as those using a "differential" payment structure, under which a base payment is made for services provided, with an additional value-based payment for meeting reporting and/or quality goals. Further, to maintain broad access to physicians, any Medicare physician payment system must be annually increased to reflect increases in physician overhead costs.

Physicians must also receive payments under a value-based program on a timely basis. There should not be a substantial time lag in determining the amount of payment due to a physician. A physician practice, like any other enterprise must operate on a business plan based on predictable and reliable financial fundamentals. This is nearly impossible if a substantial amount of a practice's revenue stream is unknown and delayed for up to one to two years.

Pilot Testing

In addition, any pay-for-performance program needs to be pilot tested prior to full implementation. Since value-based purchasing is a completely new concept with regard to Medicare payment for physicians' services, pilot testing is critical for determining whether this type of payment system achieves its intended purpose. Pilot tests would also help identify program "glitches" and any needed modifications prior to full implementation of the program.

Measures of Efficiency

Measures of efficiency are another strong area of concern. Efficiency measures have the danger that the lowest-cost treatment will supersede the most appropriate care for an individual patient. We urge that S. 1356 require that efficiency measures meet the same high standards that apply to quality measures. Efficiency measures must be evidence-based, valid measures developed by the medical specialty societies in a transparent process. Efficiency cannot only relate to cost issues, as we have learned from the experience of UnitedHealthcare. Its United Performance insurance product was introduced this year. Although a settlement after intense negotiations has been reached, two large medical groups had informed United they would not participate in the performance program because performance reports for efficiency seemed to take into account primarily the lowest-cost care, and not quality. Most importantly, there must be broad-based consensus regarding what constitutes appropriate levels of care before measuring for efficiency.

Risk-Adjustment

Without an appropriate technique for risk-adjustment, an adequate reflection of a physicians' patient population will be lacking. This would skew the data and have grave consequences for purposes of determining a fair comparison of physician performance, payment and public reporting, as discussed further below.

Public Reporting

The AMA also is very concerned about potential, adverse affects of public reporting, Providing patients with flawed information would undermine the goals of value-based purchasing and violate the oath – first do no harm. Unintentional adverse consequences for patients, including, for example, patient de-selection in the case of those with certain ethnic, racial, socioeconomic or cultural characteristics that make them less compliant must be avoided. Further, patient health literacy issues could distort physician performance measures. Several critical issues must be resolved before public reporting provisions can be implemented. There needs to be a method for ensuring that any publicly reported information is: (i) attributable to those involved in the care; (ii) appropriately risk-adjusted; and (iii) accurate, as well as relevant and helpful to the consumer/patient.

We appreciate that S. 1356, in accordance with the AMA guidelines, would provide physicians the opportunity to review data prior to the data being made public. We urge,

however, that physicians also have the right to appeal with regard to any data that is part of the public review process. Further, physicians should also have the right to have their comments included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by a physician.

Implementation of Value-Based Purchasing Program and Performance Measures

In implementing performance measures, it is important to learn from private sector programs already in existence. We know from some private sector programs that application of measures is more effective if they are implemented on a graduated basis. It is best to begin by implementing only a limited number of measures to assess how well they work, and then build upon the program from that starting point. Thus, we recommend that pay-for-performance legislation include limits on the number of measures with which physicians must comply over certain time periods.

Administrative Costs

The AMA urges that any value-based purchasing program ensure that physicians are not burdened with additional administrative costs, especially for information technology systems that are needed to participate in the program. As discussed above, physicians cannot continue to absorb unfunded government mandates. To that end, we appreciate that S. 1356 would help alleviate some administrative costs for physicians. The bill would provide exceptions under the federal Medicare anti-kickback statute as well as the Stark II physician self-referral law for entities that offer information technology, products, systems and services to physicians for improving health care quality and promoting electronic exchange of health information.

Other Critical Considerations

The AMA wishes to raise overall factors to be considered as we move forward in developing value-based purchasing legislation for physicians: (i) the number of patients needed to achieve a statistically valid sample size; (ii) the desire to keep the data collection burden low, while at the same time maintaining accuracy of the data; (iii) level of scientific evidence needed in establishing appropriate measures; (iv) the ability to trace a performance measure back to one or many physicians involved in a patient's care; (v) the complexities of distributing payments when multiple physicians are involved in a patient's care, and without violating any fraud and abuse laws and regulations; and (vi) protection of patient privacy.

We look forward to working with the Chairman and the Committee to achieve a new payment system that truly benefits our patients.

NEED TO REPLACE THE FATALLY FLAWED SGR PAYMENT SYSTEM

As discussed above, the SGR system is fatally flawed and cannot co-exist with value-based purchasing for physicians. It 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. As discussed below, there are fundamental problems with the SGR, and CMS has the authority to make immediate administrative changes to the formula that would lower the cost for Congress to enact a new one.

Problems under the SGR Payment System

Medicare pays for services provided by physicians and numerous other health care professionals based a target rate of growth (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. (These factors are discussed below under "Administrative Action Needed to Assist Congress in Replacing the SGR.")

Problems with the Payment Formula Due to GDP

GDP Does Not Accurately Measure Health Care Needs

The SGR permits utilization of physicians' services per beneficiary to increase by only as much as GDP. The problem with this "relationship" is that GDP growth does not track the health care needs of Medicare beneficiaries. For example, when a slowed economy results in a decreased GDP, the medical needs of Medicare patients remain constant, or even increase, despite the economic downturn. Yet, physicians and numerous other health professionals, whose Medicare payments are tied to the physician fee schedule and who are doing their best to provide needed services, are penalized with lower payments because of a slowly growing economy, resulting in the decreased GDP. Further, GDP does not take into account the aging of the Medicare population, technological innovations or changes in the practice of medicine.

Historically, health care costs have greatly exceeded GDP. Yet, the SGR is the only payment formula in Medicare tied to that index. In contrast, payments for hospitals, skilled nursing facilities and home health, for example, are all tied to their inflationary pressures.

Technological Innovations Are Not Reflected in the Formula

The Congressional Budget Office has said that Medicare volume increases are due to "increased enrollment, development and diffusion of new medical technology" and "legislative and administrative" program expansions. The SGR system's artificial cap on spending growth ignores such medical advances when it limits target utilization growth to GDP growth.

The United States' population is aging and new technologies are making it possible to perform more complicated procedures on patients who are older and more frail than in the past. Over the last decade, life expectancy has risen by a year for women and two years for men. Life-spans for both sexes rose by about a half year just between 1999 and 2002, and 65-year-olds of both sexes now can expect to become octogenarians. Improvements in the field of anesthesia and surgery make it possible to operate on older and older patients when complex surgery is required. People 80 and older now frequently undergo extensive surgery to prevent heart attacks and strokes.

Both Congress and the Administration have demonstrated their interest in fostering advances in medical technology and making these advances available to Medicare beneficiaries through FDA modernization, increases in the National Institutes of Health budget, and efforts to improve Medicare's coverage policy decision process.

The only way for technological innovations in medical care to really take root and improve care is for physicians to invest in those technologies and incorporate them into their regular clinical practice. The invention of a new medical device cannot, in and of itself, improve health care — physicians must take the time to learn about the equipment, practice using it, train their staff, integrate it into their diagnosis and treatment plans and invest significant capital in it. Although the Medicare hospital payment system allows an adjustment for technological innovations, the physician payment system does not do so. The physician payment system is the only fee structure of Medicare that is held to GDP, and no other Medicare payment system faces as stringent a growth standard.

Government efforts to foster technological innovations could be seriously undermined as physicians now face disincentives to invest in new medical technologies or to provide them to Medicare beneficiaries.

Site-of-Service Shifts Are Not Considered in the Formula

Another concern that is not taken into account in the SGR formula is the effect of the shift in care from hospital inpatient settings to outpatient sites for certain medical procedures. For example, when the 2005 Medicare Trustees report was released, CMS noted that expenditures for inpatient hospital services covered by Part A were lower than previous forecasts, but failed to mention that lower inpatient spending was a contributor to increased Part B spending for physicians' services.

It has been a goal by Congress and the Bush Administration to utilize more physician services through disease management and prevention initiatives in order to avoid expensive hospitalizations and nursing home admissions. Technological innovations have also made it possible to treat many services that once required hospitalization in physicians offices instead. Physicians are keeping seniors with chronic diseases out of hospitals by managing their care in the office. Hospital days per 1000 population between 1995 and 2002 declined by more than 15% among 65 to 74 year olds and by more than 10% for those 75 and older.

Where inpatient care is avoided, deductibles are reduced from about $900 to about $100; if ambulatory care is involved, co-payments are limited to 20% of Medicare's allowed charge in physician offices compared to up to 45% in a hospital outpatient department.

While these trends have led to the treatment of increasingly complex cases in physicians' offices, the increased use and intensity that results is not recognized in the SGR formula.

Beneficiary Characteristics Are Not Reflected in the Formula

A related factor that also is unrecognized in the SGR formula is changes over time in the characteristics of patients enrolling in the fee-for-service program. For example, increases in patients diagnosed with, or having complications due to such diseases as obesity, diabetes and end stage renal disease, require greater utilization of physicians' services. Yet, these types of changes in beneficiary characteristics are not reflected in the SGR.

Spending On Services Necessary to Meet Patient Need

As discussed above, payments to physicians are cut if actual Medicare spending on physicians' services exceeds allowed spending. On March 30, the CMS reported that Medicare spending on physician services grew by 15% in 2004. Other Medicare data, including the 2005 Medicare Trustees Report, suggests spending growth of 12% to 13%. About 7% represents an increase in services per patient. This follows utilization increases of about 5.5% in 2001, 6% in 2002 and 5% in 2003. What happened in 2004 is not some "unprecedented" spending spike. It is the continuation of a trend brought about by expanded life-spans, more chronic disease and better treatments.

Nevertheless, it is not surprising that Medicare spending on physician services continues to increase. First, Medicare's two public trustees have noted that much of the growth in physician services can be traced to technological advances. Revolutionary changes in the practice of medicine have made it possible to keep millions of Medicare's elderly and disabled beneficiaries alive and active well into their 80s. Second, the prevalence of expensive chronic conditions such as kidney failure, heart disease and diabetes has increased dramatically, despite these vast improvements in mortality and quality of life. More than three-fourths of Medicare beneficiaries now have at least one chronic illness, about two-thirds have a least two, and 20% have five or more. Thus, with the positive results of medical advances and the increase in widespread chronic conditions among the elderly, Medicare spending to meet these patients' needs is a good investment for their overall health and quality of life. Congress has recognized the value of this investment by twice intervening to avert sharp Medicare physician pay cuts.

Physician Pay Cuts Can Mean Higher Costs for Beneficiaries

CMS has noted that an increase in Medicare payments for physician and other health professionals would, in turn, increase the Medicare Part B premium for beneficiaries. Physician pay cuts, however, will ultimately cost beneficiaries more because these cuts will force physicians to discontinue providing certain services in the physician's office. Rather, patients will have to receive these services in higher-cost hospital settings.

ADMINISTRATIVE ACTION NEEDED TO ASSIST CONGRESS IN REPLACING THE SGR

As discussed above, CMS has the authority to take immediate administrative action to modify the current SGR physician payment formula. These administrative actions, discussed below, would significantly lower the cost for Congress in replacing the formula with one that reflects increases in physician practice costs.

1. CMS Must Remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996

CMS has the Authority to Remove Drugs from the SGR

The AMA urges CMS to remove spending on physician-administered drugs from calculations of 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, CMS has the authority to revise its previous calculations of actual spending under the SGR by removing the costs of drugs back to the base period using this revised definition. Once CMS has revised calculations of actual spending back to the base period, it will have revised calculations of allowed spending, by definition, because the statute sets the base period allowed spending equal to the base period actual spending. This process would remove drugs entirely from both actual and allowed spending back to the SGR base period. CMS has demonstrated its authority to revise calculations of actual spending by actually revising spending to account for omitted codes and more complete claims data.

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.

CMS Should Remove Drugs from the SGR

In the past, some CMS officials have argued that including drugs in the SGR was necessary to counter-balance incentives for over-utilization in the drug reimbursement system. The AMA does not accept this premise. Certainly physicians are not administering chemotherapy drugs to patients who do not have cancer. Even if such incentives existed, however, they were surely eliminated by the reductions in payment for these drugs under the MMA. Pharmaceutical companies, not physicians, control the cost of drugs. Further, pharmaceutical companies and United States policy, not physicians, control the introduction of new drugs into the market place.

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. However, it is not equitable or realistic to finance the cost of these drugs through cuts in payments to physicians.

2. Ensure that government-induced increases in spending on physicians' services are 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 determined 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.

Spending due to all of the foregoing government initiatives should be reflected in the SGR.

3. Ensure that the SGR fully reflects the impact on physician spending due to national coverage decisions

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 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.

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 flourescein 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, CMS should ensure that the impact on utilization and spending resulting from all national coverage decisions is taken into account for purposes of the SGR spending target.**

The AMA will continue in our long-term commitment to improving the quality of care for our patients. We appreciate the opportunity to provide our views to the Committee on these important matters, and we look forward to working with the Committee and CMS to develop a physician payment system that truly benefits patients by offering the highest quality of care and ensuring access to that care.