



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

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Mark B. McClellan, MD, PhD
Administrator
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File code CMS-1429-P

Dear Dr. McClellan:

The American College of Physicians (ACP), representing 116,000 internists and medical students, is pleased to comment on the Centers for Medicare and Medicaid (CMS) proposed rule “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005,” published in the August 5, 2004 *Federal Register*. The ACP comments address the following issues:

1. Sustainable Growth Rate Formula;
2. Practice Expense – Resource-based Practice Expense Relative Value Units;
3. MMA Section 611 – Initial Preventive Physical Examination;
4. MMA Section 612 – Cardiovascular Screening Blood Tests;
5. MMA Section 413 – Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments; and
6. MMA Section 302 – Clinical Conditions for Coverage of Durable Medical Equipment.

Our specific comments, below, are contained under the headings referenced in the August 5, 2004 *Federal Register* notice.

1 SUSTAINABLE GROWTH RATE FORMULA

Appropriate Accounting for Changes in Law and Regulation

The statute requires CMS to make adjustments in the Sustainable Growth Rate (SGR) formula to reflect increases or decreases in the cost of physician services that are expected to result from changes in law and regulation. It is imperative that CMS account for the full impact of changes in law in regulation in the SGR formula because failure to do so inappropriately penalizes physicians for appropriate, expected increases in utilization.

New, Preventive Medicare Benefits

Congress encourages increased utilization through establishment of new, preventive Medicare benefits. It is imperative that CMS appropriately account for the increased direct spending associated with new benefits in the SGR formula. Further, new, preventive benefits have ancillary costs in addition to the direct expenditure for the newly covered service(s). Newly covered preventive services trigger additional medically necessary services, in the form of increased visits, laboratory tests, diagnostic tests, and procedures. ACP is concerned that CMS has omitted or underestimated the cost of the ancillary medically necessary physician services and, therefore, penalizes physicians and beneficiaries for the resulting increase in volume through reductions to the annual Medicare fee schedule update. CMS must fully account for the direct and ancillary costs associated with new benefits in the SGR formula.

Medicare National Coverage Decisions

CMS encourages increased utilization through National Coverage Decisions (NCDs) that establish Medicare coverage for a new service or expand the conditions for which Medicare covers a service. It is imperative that CMS appropriately account for the increased spending associated with NCDs in the SGR formula. ACP is concerned that CMS has omitted or underestimated costs associated with NCDs. CMS must fully account for the costs associated with NCDs in the SGR formula.

Removing Drugs from the SGR Formula

ACP recommends that CMS exercise its discretionary authority and reverse its policy of including the costs of Medicare-covered physician-administered drugs in determining whether Medicare spending has exceeded the SGR target. Reconsideration of the CMS policy is especially warranted in light of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). CMS officials have argued that including the cost of the drugs and biological products is necessary to counter the incentive the 95% of AWP drug and biological payment methodology provided to physicians. Although ACP rejects this premise, MMA reform of the drug and biological payment methodology diminishes such an incentive even if it had existed.

It is imperative that CMS take action to remove drug and biological costs from the SGR formula as expenditures have risen rapidly and are expected to continue to increase. In its proposed rule on payment reform of Medicare covered drugs, CMS estimated the 2002 allowed charges for the approximately 450 Medicare-covered drugs to be \$8.4 billion, compared to \$3.3 billion in allowed charges in 1998. A study for the Medicare Payment Advisory Commission (MedPAC) that determined there are over 650 drugs in development is an indication that drug expenditures will continue to escalate.

Inclusion of the cost of drugs and biologicals in the expenditure target provides further example of how the SGR formula is out of sync with public policy decisions aimed at improving health. The federal government has supported the development of life-saving and quality-of-life-

enhancing physician administered drugs by increasing funding for the National Institutes of Health (NIH) and streamlining the Food and Drug Administration (FDA) drug approval process. Further, the Department of Health and Human Services (HHS) 2003 action plan and a May 2003 Interagency Agreement between the National Cancer Institute (NCI) and the FDA indicates that the administration strives to accelerate drug development. In its statement announcing the May 2003 agreement, NCI and FDA officials described it as “an important step toward NCI’s goal to eliminate suffering and death due to cancer by 2015” and stated the collaboration “holds great promise for getting better cancer drugs to patients sooner.” ACP believes that the CMS policy to include the cost of drugs and biologicals in the SGR formula threatens to undermine these laudable goals. Continued CMS inclusion of drug costs in the SGR is likely to penalize physicians for administering beneficial drugs to beneficiaries by resulting in/contributing to payment reductions—reductions that jeopardize the financial viability of treating Medicare patients.

Furthermore, physician-administered drugs are clearly not “physician services” as the term is defined in the Medicare statute.

2. PRACTICE EXPENSE

Resource-based Practice Expense Relative Value Units

Discharge Management Clinical Staff Time

ACP objects to the CMS proposal to eliminate the discharge management clinical staff time from all 0-day global procedure codes as the proposal would adversely affect the gastrointestinal endoscopy codes. ACP recommends that CMS retain the discharge management clinical staff time currently assigned to the gastrointestinal endoscopy codes assigned a 0-day global period.

CMS fails to provide any rationale for its proposal to eliminate the 6 minutes of discharge management clinical staff time, which is one-half of the discharge management time assigned to Current Procedural Terminology (CPT) code 99238. Moreover, CMS proposes to maintain the discharge management clinical staff time for 10-day and 90-day global services.

The CPT introductory text to 99238 states:

The code includes...final examination of the patient, discussion of the hospital stay, even if the time spent by the physician on that date is not continuous, instructions for continuing care to all relevant caregivers, and preparation of discharge records, prescriptions and referral forms.

In the case of endoscopy procedures, the physician’s clinical staff provides support to the physician on these discharge management activities by:

- Arranging for required follow-up visits;
- Scheduling needed additional tests;
- Arranging for delivery of pathology results;

- Reminding the patient of dietary restrictions, resumption of medications; and
- Handling follow-up phone calls from the patient and/or the family.

The CMS proposed would disregard these activities when performed in the context of an endoscopy services with a 0 day global period while recognizing similar activities performed in the context of a 10 or even a 90 day global period. This is inappropriate because the clinical staff in the context of a endoscopy services with a 0 day global period is comparable to activities involved in many minor surgical procedures with a 10 day global period, such as removal of a skin lesion (e.g., CPT 17000) and a biopsy of a lymph node (e.g., CPT 38505). In fact, many of the 10 day global procedures do not involve sedating the patient nor do they present the number of comorbid conditions present in many patients undergoing endoscopy.

3. MMA SECTION 611 – INITIAL PREVENTIVE PHYSICAL EXAMINATION

Initial Preventive Physical Examination Definition and Billing Code

ACP recommends that CMS revise its proposal to specify that physicians report the covered initial preventive physical examination using the appropriate CPT Preventive Medicine Service new or established patient code, CPT 99381-99397, and an EKG code, such as CPT 93000, with physicians indicating that it is the covered initial preventive physical examination by using the appropriate "V" diagnosis code, e.g., V70.0. To avoid paying for an initial new patient preventive medicine service to a beneficiary more than six months after the beneficiary enrolled in Medicare Part B, carriers could program their claims processing system to only pay for CPT 99387, 99397, or other new patient Preventive Medicine Service codes, within six months of the beneficiary's Part B enrollment date.

The CPT new patient preventive medicine service code descriptors are purposely vague to allow the physician to tailor the service to the patient's needs, as determined by gender and age. The introductory text to the CPT Preventive Medicine Service codes states that the extent of the focus of the services depends largely on the patient's age and that the comprehensive nature of the service reflects an age and gender appropriate physical examination.

The Government Accountability Office (GAO) supports this view in its September 21, 2004 testimony before the House Committee on Energy and Commerce Subcommittee on Health titled, "Medicare Preventive Services: Most Beneficiaries Receive Some but Not All Recommended Services." In the background portion of the testimony (although not responding directly to the CMS proposed definition of the initial preventive physical examination), GAO states that:

...for some beneficiaries, certain services may not be warranted or may be of limited value. Appropriate preventive care depends on the individual's age and particular health risks, not simply on the results of a standard battery of tests.

Physicians generally use the United States Preventive Services Task Force (USPSTF) age-specific recommended interventions when furnishing a preventive medicine service as guidance.

While the USPSTF recommended interventions are generally consistent with the CMS proposed definition of an initial preventive physical examination, the CMS proposal is too proscriptive and the establishment of a Health Care Financing Administration Common Procedure Coding System (HCPCS) “G” code, G0XX2, only complicates the coding system.

Further, instructing physicians to use the appropriate CPT new patient Preventive Medicine Service code supported by a diagnosis code to indicate screening would be consistent with the agency’s proposed implementation of the MMA-mandated new benefits for cardiovascular screening blood tests and diabetes screening tests, which instructs physicians to bill the new benefits using a CPT code supported by a diagnosis code that indicates screening.

Inclusion of EKG in Definition of Initial Preventive Physical Examination.

It is not clear what happens to the EKG component if the physician cannot furnish an EKG in his or her office. ACP recommends that CMS clarify whether a physician is prohibited from providing the initial preventive physical examination, or must he or she attach some modifier (e.g., -52, "Reduced Services") to the appropriate code. ACP recommends that CMS instruct physicians to bill the EKG using CPT 93000 supported with the appropriate “V” diagnosis code to avoid this problem.

Separate Reporting of Screening-Related Service for which Medicare already Covers

ACP agrees with CMS proposal that Medicare will pay for all Medicare covered screening services separately and will not implement edits to bundle payment for these separately payable services into the payment for the initial preventive service.

Payment for Initial Preventive Physical Examination

Payment for Initial Preventive Physical Examination as a Stand-alone Service

ACP believes that CMS has undervalued the non-EKG portion of its proposed payment for the initial preventive physical examination. Consistent with our previous recommendation that CMS instruct physicians to report the initial preventive physical examination using the existing CPT Preventive Medicine Service new and established patient codes, 99381-99397, ACP recommends that CMS pay the initial preventive physical examination service using the RVUs that are currently assigned to CPT 99381-99397. Although these codes are currently assigned non-covered status in the fee schedule, RVU are assigned and maintained for these services.

ACP recommends that CMS designate CPT 99381-99397 as “active” codes in the fee schedule—thus eligible for separate payment—when the service is provided to a beneficiary within six months of enrollment. CMS should publish the existing RVUs that are maintained for 99381-99397 and make payment for eligible services.

Further, ACP recommends that CMS ask the RUC to review the RVUs assigned to 99381-99387 in the context of the CMS initial preventive physical examination.

Payment for Medically Necessary E/M Service Furnished on the Same Date as an Initial Preventive Physical Examination

ACP recommends that CMS revise its proposal to remove the restriction on the level of service that a physician can bill for a medically necessary E/M service furnished on the same date as an initial preventive physical examination. CPT allows physicians to report a problem-oriented E/M service in conjunction with a preventive medicine service without regard to the level of problem-oriented E/M service. The CMS current Medicare policy pertaining to billing of a medically necessary E/M on the same date as a Medicare non-covered comprehensive preventive examination includes no restriction on the level of service.

The CMS decision to restrict payment for a medically necessary E/M service to a level 2 is especially unwarranted in light of its proposal to link payment for the non-EKG portion to CPT 99203, which requires a detailed history, detailed examination, and medical decision making of low complexity. The CMS proposal effectively limits physicians to treating an acute or chronic (i.e. medically necessary) problem that is self-limited or minor (in the case of established patients) or of low to moderate severity (in the case of new patients) during an initial preventive physical examination even though that the agency believes the preventive examination is of low-to-mid complexity—as demonstrated by its link to CPT 99203. This is unreasonable considering that beneficiaries—even those new to Medicare—have multiple chronic and/or acute conditions.

Medical Record Documentation Expected for Initial Preventive Physical Examination

If CMS decides to finalize its creation of the HCPCS G code, G0XX2, it should specify the documentation that a physician who billed for this service would be expected to maintain.

4. MMA SECTION 612 – CARDIOVASCULAR SCREENING BLOOD TESTS

Proposed Covered Tests and Maximum Frequency

ACP thanks CMS for giving it the opportunity to provide input on implementation of the cardiovascular blood test screening benefit while the agency was developing its proposal to include in this proposed rule. ACP agrees with the CMS proposal to cover a total cholesterol (TC) test; a cholesterol test for high-density lipoproteins (HDL), and tryglycerides test and that the CMS proposed frequency of every five years is appropriate for low-risk elderly patients.

However, ACP reiterates its recommendation that CMS should establish the Medicare coverage frequency as every two years for individuals at elevated risk of cardiovascular disease. ACP recommends that CMS define elevated risk as:

- Men age 20-35 and women 20-45 years with any one of the following:
 - Diabetes;
 - A family history of cardiovascular disease before age 50 years in male relatives or age 60 years in female relatives;

- A family history suggestive of familial hyperlipidemia; or
- Multiple coronary heart disease risk factors (e.g. tobacco use, hypertension).

This is consistent with the 2001 National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines, available at <http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3xsum.pdf>.

Further, ACP recommends that CMS add coverage of a fasting blood glucose as part of the cardiovascular screening blood test benefit in the final rule. ACP recommends that CMS cover fasting blood glucose every two years for beneficiaries over age 45 and for younger beneficiaries who are obese and/or have a family history of diabetes. Fasting blood glucose is inherently a cardiovascular screening test because diabetes carries increased risk of cardiovascular disease.

CMS Proposal to Cover Additional Future Tests

ACP agrees with CMS proposal to amend the Code of Federal Regulations to allow CMS to change the scope of the cardiovascular blood test screening benefit through the NCD process. This is consistent with the ACP February 2004 recommendation to CMS that “CMS investigate whether any planned future edition of USPSTF recommendations would enable the agency to establish Medicare coverage for additional cardiovascular screening tests.”

Coding and Payment

ACP agrees with the CMS proposal that: the existing CPT codes be used to report these tests instead of creating new CMS-maintained HCPCS G codes; physicians use one of three “V” diagnosis codes to indicate the test was done for screening purposes; and the screening services are paid the same amount as if they were furnished for diagnostic purposes.

Potential for Benefit to Include Non-invasive Cardiovascular Screening Tests

ACP recommends that CMS clarify whether the MMA provision authorizing the cardiovascular screening benefit allows CMS to establish Medicare coverage for non-invasive cardiovascular screening tests, such as EKGs and stress tests.

5. MMA SECTION 413 – PHYSICIAN SCARCITY AREAS AND HEALTH PROFESSIONAL SHORTAGE AREAS INCENTIVE PAYMENTS

Improvement to Medicare Health Professional Shortage Areas Incentive Payment Program

ACP recommends that CMS clarify the extent to which automation will not be feasible in the final rule.

Physician Scarcity Areas

ACP recommends that CMS clarify its method for determining the number of primary care and specialty care physicians to calculate the beneficiary to physician ratio that will identify physician scarcity areas. ACP encourages CMS to use the number of practicing physicians when determining the beneficiary to physician ratio.

6. MMA SECTION 302 – CLINICAL CONDITIONS OF COVERAGE FOR DURABLE MEDICAL EQUIPMENT

ACP shares the CMS concern regarding the unnecessary provision of durable medical equipment (DME) items and recognizes that the physician has a primary role in assuring DME is furnished based on the needs of the beneficiary. However, a blanket requirement that all DME prescriptions and renewals require a face-to-face visit is excessive as it has the potential to diminish beneficiary access to medically necessary DME. ACP recommends that CMS refrain from implementing its proposal to require a face-to-face visit for all DME prescriptions and renewals.

The CMS proposal to implement this MMA provision by requiring that a physician furnish a face-to-face service with the beneficiary in order to order an initial prescription and to renew a prescription order is unnecessary and impractical. The additional requirement that the face-to-face examination should be for the purpose of evaluating and treating the patient's medical condition and not for the sole purpose of obtaining the prescribing physician's order for the DME item—that the prescribing physician conduct a sufficient examination of the patient's medical condition to ascertain the appropriate overall treatment plan and to order the DME as only one aspect of that treatment plan—makes it even more unworkable. The following common scenarios illustrate the limitations of the face-to-face visit and focus on full treatment plan, as opposed to sole focus on need to prescribe DME item, requirements:

- A physician would have to make a beneficiary with permanent colostomies make an unnecessary face-to-face office visit (or the physician would have to travel to the beneficiary's home) to fill periodic supply needs;
- A physician would have to make a beneficiary make an unnecessary face-to-face visit to prescribe/renew DME progression items, e.g. prescribing a cane after the beneficiary has used a walker for the appropriate amount of time as dictated by the typical recovery period for the patient of a certain age with a specific condition;
- A physician would have to make a beneficiary make an unnecessary office visit to prescribe nocturnal oxygen or nasal CPAP after an outpatient polysomnogram; and
- A physician performing a consultation at the request of another physician for the sole purpose of assessing the beneficiary's need for a DME item, e.g. a power operated vehicle, would be unable to prescribe (authorize) the item because the proposal requires that the face-to-face visit to pertain to more than the DME aspect of the treatment plan.

In addition, ACP recommends that CMS consider the following options to balance concern regarding unnecessary provision of DME against ensuring that beneficiaries have timely access to medically necessary DME:

- Consider developing additional clinical criteria for prescribing the DME items for which there is a demonstrated need, as documented by a CMS, a GAO, or Department of Health and Human Services Office of Inspector General analysis;
- Determine whether the Durable Medical Equipment Regional Carrier (DMERC) can access carrier claims processing system data to ascertain: whether the prescribing physician has furnished a face-to-face visit to the beneficiary who is to receive the DME item within a reasonable period of time, e.g. six months; whether the beneficiary has been hospitalized recently; the number of diagnoses; and the number of physicians of treating physicians who practice different specialties; and
- Consider identifying conditions and DME items for which the need is permanent and does not change. Establishing such a list would alleviate the burden on physicians to periodically renew prescriptions and allow the government to narrow its focus on the DME items most at risk for unnecessary utilization.

CMS should solicit input from practicing physicians prior to implementing these or any other initiatives.

ACP appreciates the opportunity to comment. Please contact Brett Baker, Senior Associate in the ACP Regulatory and Insurer Affairs Department, by phone at (202) 261-4533 or e-mail at bbaker@acponline.org if you have questions.

Sincerely,

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Chair, Medical Service Committee