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August 29, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule,
and other Part B Payment Policies for 2008 (CMS-1985-P)

Dear Mr. Kuhn:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes to payment policies under the Medicare physician fee schedule and other Part B policies, which were published in the Federal Register on July 12, 2007. ASCO is the national organization representing physicians who specialize in the treatment of cancer, and we are very interested in issues raised by the proposal.

PROPOSED REDUCTION IN THE CONVERSION FACTOR

Unless Congress acts, the sustainable growth rate (SGR) methodology will result in an estimated 9.9% reduction in the fee schedule conversion factor in 2008. Further cuts of almost 40% are projected in the absence of a permanent fix to the Medicare payment formula for physicians. This reduction is entirely unwarranted in light of the increased practice costs faced by physicians and the small increases in recent years that have failed to keep up with inflation. CMS should take administrative steps that would lessen the reduction, such as removing drugs retroactively from the definition of physician services subject to the SGR methodology. We also urge CMS to work with Congress to avert scheduled cuts in 2008 and, in the longer term, repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs.

PHYSICIAN QUALITY REPORTING INITIATIVE

ASCO generally supports the proposed continuation of the PQRI program into 2008. ASCO has actively participated in the AMA Physician Consortium for Performance Improvement process to develop new cancer-related quality measures that could be adopted in 2008 and with the goal of replacing 2007 PQRI measures 71, 72, 73, and 74.

Moving forward, we encourage CMS to continually reassess and evaluate methodologies to assess the quality of care provided to people with cancer. We

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have been concerned during this initial year of PQRI that measure specifications and the implementation methodology may have an adverse affect on participation as well as the quality of data collected through the program. One of the challenges for oncology has been reconciling reporting requirements with the realities of clinical practice. For example, it is common for patients to visit the physician office for chemotherapy without having a physician evaluation and management encounter on the same day. However, several current cancer-related measures cannot be reported unless chemotherapy is administered on the same day as an evaluation and management visit.

We also encourage CMS to explore alternative strategies for quality reporting under the value based purchasing program. For example, as part of the 2006 Oncology Demonstration Project, CMS collected data from oncologists on cancer disease status. As we have stated before, if reporting on disease status were continued in lieu of other PQRI reporting requirements, the Medicare program would have a rich repository of claims data that could be analyzed for specific cancer quality measures. ASCO remains interested in working with CMS to discuss the details of alternate methodologies.

CMS has noted separately in the proposed rule that the recent law requiring reporting on anemia quality indicators will be implemented on January 1, 2008. The statute requires that “Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include...information on the hemoglobin or hematocrit levels for the individual.” CMS states in the proposed rule its intent to use the anemia indicators to “facilitate assessment of the quality of care for this condition” and “help determine the prevalence of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy.” Given CMS’ intent to use this requirement to evaluate quality, we would strongly urge that for those physicians who elect to participate in PQRI, reporting on anemia be considered equivalent to reporting on any other PQRI measure, and therefore tied to PQRI data reporting and bonus. While we understand that reporting on anemia is mandatory and participation in PQRI is voluntary, we believe that extending this opportunity is an important signal that CMS views anemia quality indicator reporting to be on par with the other measures. The implementation requirements for both types of measures could remain unchanged; that is, the anemia reporting occurring on every claim including a bill for the treatment of anemia and the PQRI measures reported for a minimum of 80% of applicable cases. ASCO would help educate our members accordingly.

COMPENDIA FOR DETERMINING MEDICALLY ACCEPTED OFF-LABEL USES

Section 1861(t)(2) of the Social Security Act (in conjunction with sections 1832 and 1861(s)(2)) requires Medicare to cover “medically accepted” uses of drugs and biologicals used in cancer chemotherapy regimens if the uses are supported by citations that are included, or approved for inclusion, in specified compendia. The compendia specified in the statute are AMERICAN HOSPITAL FORMULARY SERVICE – DRUG INFORMATION, AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS (which is no longer published), and UNITED STATES PHARMACOPOEIA –

DRUG INFORMATION. The statute provides that CMS “may revise the list of compendia . . . as is appropriate for identifying medically accepted indications for drugs.”

The Proposed Changes

CMS has proposed to establish a process for adding or deleting compendia from the list of authoritative compendia. Under the proposal, CMS would annually issue a notice inviting requests to revise the list. The notice would establish a 30-day window for accepting requests, which would start 45 days (or later) after publication of the annual notice. Requests would be required to include a copy of the compendium at issue and would need to include detailed, specific documentation showing that the compendium does or does not meet CMS’s standards for compendia. CMS would publish a list of the complete requests received, and the public would have 30 days to comment on them. CMS would reach a final decision within 120 days after the close of the comment period. CMS proposes to execute the various steps in the process through notices posted on its website, although other “reasonable means” could also be used. In addition to the annual notice, CMS would reserve the right to act on its own initiative at any time.

The standards that CMS is proposing to apply in evaluating the compendia appear to fall into three categories. First, CMS is defining a compendium as having the following characteristics:

- It is a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, such as a compendium of anticancer treatment.
- It includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.
- It is indexed by drug or biological (and not by disease).

Second, CMS would “consider a compendium’s attainment” of the “desirable characteristics” recommended by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) at its March 2006 meeting. As listed in the July 12 notice, the Committee identified the following desirable characteristics:

- Extensive breadth of listings.
- Quick throughput from application for inclusion to listing.
- Detailed description of the evidence reviewed for every individual listing.
- Use of pre-specified published criteria for weighing evidence.
- Use of prescribed published process for making recommendations.
- Publicly transparent process for evaluating therapies.
- Explicit “Not recommended” listing when validated evidence is appropriate.

- Explicit listing and recommendations regarding therapies, including sequential use or in combination in relation to other therapies.
- Explicit “Equivocal” listing when validated evidence is equivocal.
- Process for public identification and notification of potential conflicts of interest of the compendia’s parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

Third, CMS is proposing additional criteria:

- Unspecified “reasonable factors” such as, for example, factors “that are likely to impact the compendium’s suitability for this use, such as a change in ownership or affiliation [,] the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. We may also consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians or both in choosing among treatment options.”
- The compendium’s grading of evidence and the process by which the compendium grades the evidence.

Comments on the Proposed Process

We agree with CMS’s conclusion that there should be a formal process to consider revisions to the list of authoritative compendia. We do not, however, support the proposed process as outlined in the July 12 Federal Register.

Initially, we question the need for an annual process. The universe of compendia is small – only six compendia were identified for consideration by the MedCAC in 2006, and new compendia are rarely introduced. An annual process to consider and reconsider these same six compendia, and possibly one or two additional compendia in future years, seems highly disproportionate to the scope of the potential work involved.

In addition, the informal process proposed by CMS would be inconsistent with statutory requirements. Section 1871 of the Social Security Act provides that any “rule, requirement, or statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits” must be promulgated as a regulation after a 60-day period for public comment. The identity of the compendia deemed authoritative under section 1861(t)(2) directly affects the drug uses covered under the Medicare Part B benefit, and therefore any changes in the list of authoritative compendia may be adopted only through the issuance of regulations after notice and opportunity for public comment. The proposed process of using notices posted on the CMS website and a 30-day public comment period does not conform to the requirements of section 1871.

ASCO suggests that CMS announce a procedure in which it is continually open to receiving requests to add or delete compendia from the list authorized by section 1861(t)(2). If a request is



supported by adequate information, CMS could propose a regulation for public comment in the same manner as for other changes in the regulations.

Comments on the Proposed Criteria

We have serious concerns about the criteria that CMS is proposing to use in deciding which compendia should be deemed authoritative. Our initial concern is that the proposal gives no indication as to how CMS will apply the criteria. The proposed factors do not appear to be definitive standards that must be met but instead are apparently only a list of characteristics that CMS will apply, or not apply, in particular cases in some unspecified manner. Any criteria used to evaluate compendia should be recast as specific standards that must be met or should otherwise provide clear rules defining what qualifies as an authoritative compendium.

Moreover, we question the substance of the proposed criteria. The July 12 notice states that “MedCAC concluded that none of the compendia fully display the desirable characteristics.” By proposing to adopt the MedCAC criteria, which the statutorily authorized compendia apparently do not meet, CMS seems to be preparing a case for revoking the authoritative status of the currently designated compendia. ASCO strongly opposes dismantling the coverage requirements set in statute, including invalidation of the originally named compendia. Instead, we believe that it would be more consistent with the statute to identify the characteristics of the compendia that Congress deemed satisfactory, and apply those criteria to other compendia that are not currently recognized.

In addition, the proposed criteria are not closely tied to the statutory standard for revisions to the list. Section 1861(t)(2) permits CMS to revise the list “as is appropriate for identifying medically accepted indications for drugs.” Under this statutory language, the test for a satisfactory compendium should be whether the compendium identifies the medically accepted uses of drugs with sufficient accuracy. By contrast, many of the proposed criteria, such as those requiring descriptions of the evidence, use of a published and transparent process, dealing with conflicts of evidence, and grading the evidence, do not directly bear on the statutory standard. ASCO recommends that CMS adopt the standard that a compendium should identify medically accepted uses of drugs with sufficient accuracy as the key determinant for authoritative status.

The proposed criteria should also be consistent with the statutory standard for using the compendia to determine Medicare coverage. Section 1861(t)(2) requires Medicare coverage when the “use is supported by one or more citations” in the compendia. For a compendium to be useful for purposes of section 1861(t)(2), its format should make clear whether its citation does or does not support the particular use of the drug. In that connection, we note that the proposed criteria would consider whether the compendium grades the evidence used in making its recommendation. Although grades of evidence may be valuable from a medical standpoint, they are a confusing factor in determining whether the compendium citation “supports” a particular drug use. To implement section 1862(t)(2), we believe that it would be desirable for a compendium to make clear whether it regards each drug use as medically accepted or not, thus avoiding the need for interpretation of its conclusions.



ASCO Recommendation

Section 1861(t)(2) makes the compendia authoritative only with respect to drugs used in cancer chemotherapy regimens. Although Medicare contractors are free to rely on the compendia in determining coverage for other types of drugs, we believe that CMS's focus on evaluating compendia should be on their statutory function, which relates to cancer treatment.

As discussed above, the key determinant under the statute should be whether a compendium identifies the medically accepted uses of drugs used in cancer therapy with sufficient accuracy. We suggest that, as a practical matter, the most efficient way to assess this characteristic is to seek the opinions of oncologists. A group of qualified oncologists could be added to the MedCAC for the purpose of evaluating a compendium and could recommend to CMS whether the compendium is sufficiently accurate in identifying medically accepted uses of drugs used in cancer chemotherapy regimens. We encourage CMS to consult with ASCO in forming an expert panel for this purpose.

United States Pharmacopoeia – Drug Information

We understand that the publisher of UNITED STATES PHARMACOPOEIA – DRUG INFORMATION is no longer updating the compendium under that name and that the successor publication is called DRUGPOINTS. We urge CMS to advise its contractors that DRUGPOINTS is an authoritative compendium under section 1861(t)(2) and to provide the contractors with any instructions necessary for the contractors to begin using the successor publication immediately.

INTRAVENOUS IMMUNE GLOBULIN

There is currently a payment amount based on 1.97 relative value units for pre-administration related services for intravenous infusion of IVIG. CMS is proposing to continue this payment amount through 2008.

ASCO supports this proposal. There continue to be significant problems in obtaining IVIG for less than the Medicare payment amount, and this additional payment amount helps to mitigate the adverse financial impact that many physicians experience in obtaining IVIG for their patients.

WAMP AND AMP THRESHOLD

The statute authorizes CMS to establish a payment amount for a drug based on its widely available market price (WAMP) or average manufacturer price (AMP) if the ASP exceeds the WAMP or AMP by a specified threshold percentage. For 2005, the statute set the threshold at 5%, and CMS has administratively continued the threshold at the same percentage in subsequent years. CMS is proposing to maintain the threshold at 5% in 2008 as well.

ASCO supports continuing the threshold at 5%. The ASP-based payment system does not ensure that physicians are able to purchase drugs for less than the Medicare payment amount,



and in many cases they are not able to do so. The surveys of WAMP and the calculations of AMP should not be used to reduce the Medicare payment amounts.

COMPETITIVE ACQUISITION PROGRAM

There are serious problems with the competitive acquisition program (CAP) that make it unattractive to most physicians. While we recognize CMS' attempt in this proposal to improve aspects of the CAP, we believe that the CAP has fundamental defects that the proposals do not resolve.

CMS is proposing to broaden the definition of "exigent circumstances" in which a physician can cancel the CAP election agreement before the end of the calendar year. Because of the problems posed by the CAP, which physicians may not recognize when they enroll in the program, ASCO supports these changes.

The notice asks for comment on the current rule requiring drugs to be shipped to the site at which they are administered. As ASCO has previously commented, this restriction is an obstacle to CAP enrollment by oncologists who use satellite offices that are not continually staffed. Physicians who administer drugs are well-qualified to maintain their integrity when transporting them to an alternative site of administration, and there should be no restrictions on their doing so. We do not understand the basis for CMS's concerns that the CAP vendor needs to maintain control over the drugs and that this control is somehow jeopardized if a physician transports drugs from one practice site to another. Once the CAP vendor ships drugs, it is relying on the receiving physician to properly handle and account for them, and we do not see how the CAP vendor's interests are threatened if the physician is permitted to transport the drugs to another practice site.

CMS also asks for comments on the current requirement that the physician enter the CAP's prescription order number on the claim form that the physician submits to Medicare for the related drug administration services. CMS recognizes that this administrative requirement is burdensome and asks for comment on alternative mechanisms. We suggest that the Medicare contractors simply match claims from the CAP vendor to claims from physicians. Generally, it should be possible to match the claims successfully, and if there are substantial discrepancies, the contractor could make inquiries or conduct an audit. This change would eliminate a significant current administrative burden on physicians who participate in the CAP.

REPORTING OF ANEMIA QUALITY INDICATORS

The proposal implements the recent statutory amendment requiring that claims for drugs administered for the treatment of anemia in connection with the treatment of cancer must be accompanied by information on the patient's hemoglobin or hematocrit level. The proposed regulation provides that the claim must indicate the patient's "most recent" hemoglobin or hematocrit level.



ASCO supports the proposal to require the “most recent” hemoglobin or hematocrit level to be reported. This formulation makes clear that patients are not required to undergo a medically unnecessary blood test solely for the purpose of the Medicare claims process.

* * * * *

Thank you for the opportunity to comment on the proposal.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD
Chair, Government Relations Council