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September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1429-P – Proposed Revisions to Payment Policies Under the
Medicare Physician Fee Schedule for 2005

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes in the Medicare physician fee schedule for 2005 published in the Federal Register on August 5, 2004. ASCO is the national organization representing physicians who specialize in the treatment of cancer. In summary, our comments are as follows:

- The proposed changes in payments for drugs and drug administration services would reduce the funds available to support chemotherapy by 47-58% in 2005 compared to 2004. This massive reduction in payments will inevitably lead to adverse effects on patient access and care.
- To avoid these consequences, CMS should use its authority under the Medicare Modernization Act (MMA) to create temporary add-on codes for 2005 that would maintain support for chemotherapy at its present level while further study of this issue is carried out. In addition, CMS should adopt the coding changes recommended by the CPT Editorial Panel related to drug administration.
- Based on the preliminary information released by CMS, it appears that many physicians will not be able to purchase certain drugs at a price that is at or below the Medicare payment amount. This situation is likely to result in patient access problems, since physicians cannot reasonably be expected to incur routine out-of-pocket losses. ASCO recommends that CMS use its inherent reasonableness authority to increase drug payments up to 15% where necessary to make the Medicare payment level sufficient to cover the price of drugs charged by the specialty distributors that service the physician office market.

- CMS should modify its proposal to require that durable medical equipment (DME) suppliers be independent of the prescribing physician. This proposal would apparently terminate the current practice of physicians furnishing certain DME, such as ambulatory infusion pumps and the related drugs, to their patients. This change would be highly disruptive to patient care and is unnecessary to address any DME abuse issue.
- ASCO supports the proposed new code for concurrent bone marrow aspiration and biopsy. We believe, however, that the proposed relative value is too low.

MASSIVE PROPOSED REDUCTIONS IN PAYMENTS FOR ONCOLOGY SERVICES

The proposed rule describes the impact of the proposed reductions in payments as an 8% reduction in payments for drugs as well as an 8% reduction in the combined revenue from both drugs and physician fee schedule payments. This presentation is misleading. Characterizing the payment change as an 8% reduction in drug payments suggests that 92% of the revenue remains available to physicians, but in reality almost all of that revenue is used to pay for the drugs.

A more realistic measure of the impact of the proposed reductions on oncologists and their patients is to estimate the change in the Medicare revenue available to support chemotherapy services. That amount consists of the payments for drug administration services plus the difference (margin) between the payments for drugs and the cost of the drugs to physicians.

Based on the impact analysis in the proposed rule, coupled with data from the Medicare claims file, it is possible to calculate that change. **ASCO estimates that the proposal will reduce the funds available to support chemotherapy by about 48%** from 2004 to 2005 assuming that CMS is correct that drug payments will be reduced by only 8%. An ASCO survey of its members indicates, however, that drug payments will be reduced by about 14.4%. That degree of reduction means that **the funds available to support chemotherapy services will be reduced by about 57%**. The methodology for these estimates is described in an attached memorandum from Muse & Associates.¹

It is inevitable that this very large reduction in the Medicare funds to support chemotherapy services will have adverse consequences on patient care.

¹ The Muse & Associates memorandum was prepared based on the initial results of the survey. The initial survey results showed that Medicare payments for drugs would decline 15% and that, on average, physicians would pay ASP+1.5%. The final survey results showed a 14.4% reduction in drug payments and that physicians would pay ASP+1.9%. The final survey results are the basis for the conclusions in these comments, and the resulting estimates differ only slightly from the estimates in the Muse memorandum.

NEW CODES AND PAYMENT AMOUNTS FOR DRUG ADMINISTRATION SERVICES

The Medicare Modernization Act requires CMS to evaluate the existing drug administration codes. Any increased expenditures for new or revised codes adopted in 2005 and 2006 as a result of this review are not subject to the normal requirement that changes in payments due to coding revisions must be budget neutral. Thus, any increased payments for new or revised codes related to drug administration would not be funded by reductions for other services.

As recommended by ASCO and other specialty societies, the CPT Editorial Panel has adopted some revisions in the drug administration code. The appropriate relative values for these codes are being evaluated by the AMA's Relative Value Update Committee. ASCO urges CMS to adopt these revised codes.

Beyond these recommendations, however, ASCO urges CMS to adopt a series of temporary G-codes for drug administration services to offset the very large reductions that will otherwise go into effect in 2005. The payment amount associated with each of these codes would be a percentage add-on amount sufficient to offset the reductions in drug margins and payments for drug administration services. Thus, for each of the drug administration codes, there would be add-on G-code that could be billed concurrently.

These codes could be temporary for 2005, and possibly continuing into 2006, while the effects of the 47-58% reduction is further evaluated. ASCO strongly urges CMS to adopt this approach to prevent the huge reduction in support for chemotherapy, and its resulting adverse effect on patient care, that will otherwise occur.

DRUG PAYMENTS INADEQUATE TO COVER THE PRICES PAID BY PHYSICIANS

Physicians pay varying amounts for drugs. ASCO surveyed its members about the prices paid for the drugs for which CMS published projected 2005 payment amounts in Table 28 of the Federal Register notice. Although this was not a scientific survey, and payment rates and prices may change by 2005, the survey nevertheless revealed a potentially significant problem. **For every drug, the price paid by some physician practices was greater than the projected Medicare payment amount.** Overall, a fifth of the drug purchases were at prices greater than the estimated payment amounts. (The results of the survey are attached.) If the Medicare payment does not at least cover the price paid by a physician for a the drug, there are likely to be patient access difficulties.

Under section 1842(b)(8) of the Social Security Act, CMS has the authority to adjust Medicare payment rates by up to 15 percent if, by being grossly excessive or deficient, they are not inherently reasonable. If the Medicare payment rate is less than the amount that physicians must

pay to obtain the drug, we believe that the payment rate is inherently unreasonable. Accordingly, we recommend that CMS take the following steps under this authority:

- (1) In the final rule, CMS should, at a minimum, authorize payment higher than 106% of ASP for any drug for which the widely available market price is greater than the payment amount. For this purpose, the widely available price should be considered the price available to any physician practice from specialty drug distributors that market to physician practices.
- (2) CMS should establish a process by which organizations and individuals can submit information to CMS showing that the widely available price is less than the Medicare payment rate. CMS should promptly implement the higher payment amount upon presentation of satisfactory evidence.
- (3) Higher payment amounts implemented in this manner should be retroactive to the beginning of the calendar quarter.
- (4) Instead of comparing the widely available market price to the Medicare payment amount, it would be desirable to allow for a margin, e.g., 4 percent, to cover some of the drug-related costs. Under such an approach, CMS would exercise its inherent reasonableness authority if the Medicare payment was not at least 4 percent above the widely available market price.

ALLOCATION OF PRACTICE EXPENSES

CMS asks for comments concerning alternative methods of allocating practice expenses to the drug administration codes. ASCO has commented in the past that the current method of allocating “indirect” costs, which uses both physician work and direct costs as the bases for allocation, discriminates against services, like drug administration services, that do not have significant physician work associated with them. (Prior to the MMA, they had no associated physician work.)

Many of the indirect costs incurred by oncologists who furnish chemotherapy in their offices are related to that chemotherapy service. The costs of space, utilities, equipment, other overhead, and administrative staff are heavily influenced by the presence of the chemotherapy service. We are concerned, however, that the CMS methodology for allocating indirect costs results in much of this cost being deemed a cost of providing visit and consultation services, since those are the services that have the physician work on which the CMS allocation methodology relies.

CMS’s contractor, The Lewin Group, and the Government Accountability Office, have both concluded that the allocation methodology should be revised because of this bias against services that lack a physician work component. Lewin recommended development of a proxy to use in

the methodology for services that lack a physician work component. Since Lewin apparently does not have the capability to test various proxies or other alternative approaches in the CMS methodology, it recommended that CMS do so.

ASCO recommends that CMS commission a more complete study of this issue by a contractor with access to the physician fee schedule methodology to allow a thorough analysis of the problem. In addition, ASCO recommends that CMS ask the Medicare Payment Advisory Commission to analyze and make recommendations on this issue.

CALCULATION OF PRACTICE EXPENSE RELATIVE VALUE UNITS

When the practice expense relative value units for the chemotherapy administration codes were reviewed in the American Medical Association's PEAC process, some minutes of staff time were removed from them on the ground that they duplicated staff time in the Level 1 visit code that was concurrently billed in many cases. Under the Medicare Modernization Act, physician work was added to the drug administration codes, and billing a concurrent Level 1 visit is no longer permitted. Although physician work was added to the drug administration codes, the staff time associated with a Level 1 visit was not. As a result, the duplication identified in the PEAC process no longer exists, and the staff minutes removed from the chemotherapy administration codes should be restored.

DURABLE MEDICAL EQUIPMENT FURNISHED BY PHYSICIANS

The MMA authorizes CMS to establish clinical conditions for payment of durable medical equipment (DME). CMS is proposing that the prescribing physician must be independent from the DME supplier and not a contractor or employee of the supplier.

This proposal would appear to prohibit physicians from supplying DME to their patients. ASCO strongly opposes this proposal. Oncologists have long furnished ambulatory infusion pumps and the related drugs to their patients. Indeed, the Stark Law contains an exception designed specifically to permit physicians to furnish infusion pumps to their patients. Physicians should continue to be permitted to furnish DME to their patients.

CODE FOR CONCURRENT BONE MARROW BIOPSY AND ASPIRATION

CMS is proposing to establish a new G-code (Medicare-only code) to cover a bone marrow biopsy and aspiration procedure performed on the same day, in the same encounter, through the same incision. At present, the Correct Coding Initiative allows payment only for a bone marrow biopsy in such a circumstance. Under the proposal, a new add-on code would be created to report the aspiration when performed in addition to the biopsy. The proposed relative value is 0.41 RVUs in the office setting and 0.28 RVUs in the hospital setting. If the two procedures are

performed at different sites, both procedures could be reported with the -59 modifier and be subject to the general payment rules for multiple procedures.

The proposed relative values include a work relative value of 0.16 RVU, which is based on the assumption that the service requires five minutes of physician time. In addition, the proposal assumes five minutes of registered nurse time and two minutes of lab technician time.

ASCO supports the adoption of this new code, but we believe that the proposed relative value does not adequately reflect the additional resources required. We believe that 15 minutes of physician time (and, similarly, 15 minutes of registered nurse time) would be a more accurate reflection of the incremental time involved. Thus, the work relative value should be 0.48 RVU.

RE-PRICING OF CPEP INPUTS – EQUIPMENT

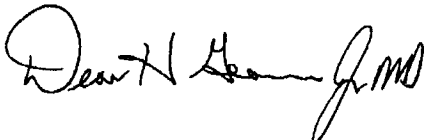
CMS is proposing to re-price various items of equipment that are included in the CPEP inputs. One of the types of equipment included in the inputs for chemotherapy administration codes is E91003 (ventilator hood & blower). In reviewing the proposed price change for this equipment, we have concluded that E91003 does not describe the equipment used for preparation of chemotherapy drugs.

We believe that oncologists typically use a Class II or III biological safety cabinet. This is the recommendation in the Occupational Safety and Health Administration Technical Manual, Section VI, Chapter 2, “Controlling Occupational Exposure to Hazardous Drugs” (section V.B.2), http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.

The cost of such a biological safety cabinet is much greater than that of a ventilator hood and blower described in E91003 (proposed price \$1612.50). The cost is more in line with that of the equipment designated in Appendix D of the Federal Register notice as “hood, biohazard” (proposed price \$6884.25). ASCO therefore recommends using “hood, biohazard” as a CPEP input to the chemotherapy administration codes, instead of E91003.

Thank you for the opportunity to submit these comments.

Sincerely,



Dean H. Gesme, Jr., MD
Chair, Clinical Practice Committee

ASCO SURVEY OF PRACTICES

Drug (Projected Medicare 2005 Payment)	Average Price Paid	% of Practices Unable to Cover Cost of Drug	Average % \$ Shortfall	% of Practices Where Payments Exceed Cost of Drug	Average % \$ Overage
Pamidronate (\$67.27)	\$74.70	58.7 %	-18.6 %	41.4 %	7.4 %
Gemcitabine (\$107.46)	\$105.36	43.6 %	-2.7 %	56.4 %	5.6 %
Epoetin (\$10.37)	\$10.24	38.6 %	-6.2 %	61.4 %	5.8 %
Irinotecan (\$123.86)	\$123.03	26.1 %	-3.2 %	73.9 %	3.1 %
Docataxel (\$287.59)	\$276.62	25.0 %	-5.4 %	75.0 %	6.6 %
Darbepoetin (\$18.10)	\$17.37	23.3 %	-3.2 %	76.7 %	6.3 %
Vinorelbine (\$64.67)	\$63.91	23.3 %	-52.6 %	76.7 %	16.9 %
Carboplatin (\$131.77)	\$123.63	15.0 %	-8.1 %	85.0 %	8.6 %
Trastuzumab (\$50.84)	\$49.28	14.7 %	-2.3 %	85.3 %	4.1 %
Rho(D) immune globulin (\$13.04)	\$12.65	14.3 %	-26.6 %	85.7 %	10.0 %
Topotecan (\$731.46)	\$697.20	11.3 %	-10.8 %	88.7 %	6.8 %
Pegfilgrastim (\$2,260.77)	\$2,145.42	9.5 %	-2.2 %	90.5 %	6.0 %
Zoledronic acid (\$202.50)	\$195.71	6.6 %	-17.9 %	93.4 %	7.7 %
Filgrastim (\$267.04)	\$247.21	6.3 %	-4.7 %	93.8 %	8.4 %
Paclitaxel (\$25.84)	\$21.38	5.8 %	-19.9 %	94.2 %	19.8 %
Rituximab (\$438.38)	\$418.47	1.5 %	-5.0 %	98.6 %	4.7 %

Memorandum

To: Deborah Kamin
 Senior Director of Cancer Policy and Clinical Affairs
 American Society of Clinical Oncology

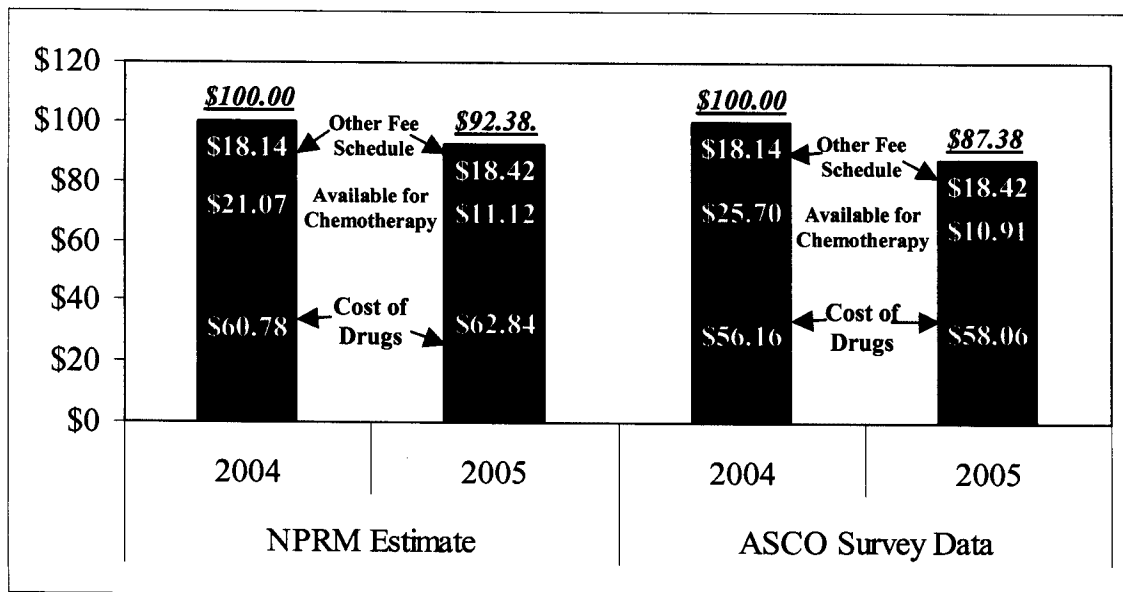
From: Don Muse, Ph.D.
 Steven Heath

Date: September 22, 2004

Re: The Real Size of the Reduction in Monies Available for Medicare Beneficiaries with Cancer

The Centers for Medicare and Medicaid Services (CMS) has published a Notice of Proposed Rule Making (NPRM) that states that the reduction in monies to Oncologists for services to Medicare beneficiaries will be as much as 8 percent between 2004 to 2005. We disagree based

Total Medicare Payments, Cost of Drugs and Monies Available for Chemotherapy Services: 2004 and 2005, NPRM and Alternative Estimates



on our analysis of the data presented in the NPRM and , alternatively, on the reduction in payments for drugs shown in an ASCO survey. Based on our analysis summarized in the chart, we estimate that actual cut will be between 47 percent and 58 percent.

All of our analysis assumes that Oncologists will not receive the add-ons for possible new or revised codes discussed as possibilities in the NPRM.

Analysis Assuming the NPRM is Correct

Medicare Sources of Oncologist Revenues

Assume that the NPRM is correct and that, in 2004, Oncologists' revenues from Medicare were 71 percent from reimbursement for drugs and 29 percent was from the Part B Fee Schedule. Hence, in 2004, if an Oncologist receives \$100 in Medicare payments, they receive approximately \$71.34 from drug reimbursement and \$28.66 from the fee schedule. Using this example, the NPRM would indicate that reimbursement would be \$92.38 in 2005.

Narrowing Oncologist Part B Fee Schedule Revenues to Those for Drug Administration Services

All of the \$28.66 that Oncologists would receive from the Part B Fee Schedule is not associated with drug administration services. Using data from the Medicare claims file, we estimate that in 2004 the \$28.66 in Part B fee schedule services split into \$10.52 from drug administration services and \$18.14 from other services such as office visits.¹ According to the NPRM, the Oncologist in our example will receive \$8.33² from the fee schedule for drug administration services in 2005. The Oncologist would receive \$14.37 for other services such as office visits.³ The other Part B for services in 2005 are simply the \$18.14 inflated by 1.5 percent or \$18.42.

Drug Costs in 2004 and 2005

According to the data and estimates in the NPRM, \$60.78⁴ of the \$71.34 is paid by the Oncologist to the drug supplier in 2004. This leaves \$10.55 of the Medicare drug payment available for patient care.⁵ In 2005, the Oncologist will receive \$65.63 for drugs (ASP + 6%) from Medicare and will pay the drug supplier \$62.84 (ASP+1.5%, as estimated in the ASCO survey).⁶ This leaves \$2.79 of the Medicare drug payment available for patient care.⁷

Total Monies Available for Chemotherapy Services

The funds available to Oncologists to support chemotherapy services is the sum of drug administration payments and payments for drugs above the cost of the drugs. Total Medicare

¹ Drug administration services represent 36.7 percent of the total allowed amounts for services furnished by oncologists(\$28.66 x 0.367).

² A reduction of about 21 percent from 2004 (\$10.52 x ((1-(0.2197)) x 1.015)).

³ (\$22.70 - \$10.52) x (1 - (0.2197)) x 1.015)).

⁴ ((((\$71.34*(1-0.08))/(1.06*1.0339)))*(1.015)).

⁵ (\$71.34 minus \$60.78).

⁶ ((\$59.89 x 1.0339) x 1.015).

⁷ (\$65.63 minus \$62.84).

revenues available to the Oncologist in our example is \$21.07⁸ in 2004. In 2005, the Oncologists will have \$11.12⁹ for chemotherapy services. In sum, the reduction in monies available to Oncology practices in 2005 for chemotherapy services will be 47 percent¹⁰ using the NPRM assumptions.

Use of Alternative Assumptions

We have made an alternative calculation based on the findings in the ASCO survey that the actual reduction in drug payments to Oncologists between 2004 and 2005 will be 15 percent and not the 8 percent contained in the NPRM. Insertion of that data leads to significantly larger reductions for chemotherapy services. Using the survey findings, the reduction in monies available to the Oncologist in 2005 for chemotherapy services will be 58 percent.

Please call me at 202-496-0200 if you have any questions.

⁸ (\$10.55+ \$10.52)

⁹ (\$2.79+8.33)

¹⁰ ((\$21.07/\$11.12)-1)