



**STATEMENT OF JOSEPH S. BAILES, M.D.
ON BEHALF OF
THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY**

Good afternoon, I am Dr. Joseph Bailes, Interim Executive Vice President and CEO of the American Society of Clinical Oncology, or ASCO, and a medical oncologist from Houston, Texas. I am pleased to be here on behalf of ASCO to address issues related to Medicare payment for Part B drugs and related services.

ASCO is the medical society for physicians and other health care providers involved in cancer treatment and research. With more than 24,000 members worldwide -- and a third of those members in private practice in the United States -- ASCO is the leading voice of oncology professionals on matters of quality cancer care and access.

The issues under consideration today are familiar to ASCO. We have been engaged in the debate over reform of reimbursement for cancer therapy for at least 15 years, since around the time that ASCO first established a Washington office. We have long been concerned about imbalances in payment methodology, with too much emphasis on drug payment and too little on payment for services.

With the passage of the Medicare Modernization Act of 2003, or MMA, Congress attempted to resolve those imbalances. However, with a change of this magnitude it is not surprising that there are some problems. This hearing provides an opportunity to air some of the continuing concerns under MMA so that we can work together to assure both quality cancer care for our patients and responsible reimbursement policy for the federal Medicare program. We are here to share with you our thoughts about how to achieve both.

Payment for Drugs

We appreciate that the “average wholesale price,” or AWP, system was an unbalanced method of compensating oncologists for cancer care under Medicare. As currently structured, however, the system of “average sales price,” or ASP, does not ensure that all physicians can purchase chemotherapy drugs without suffering financial loss that threatens the access of patients to some therapies.

In September 2005, the HHS Office of Inspector General (“OIG”) issued a report finding that reimbursement for drugs under the ASP system was “generally adequate.” The report found that, for 35 of the 39 drug codes analyzed, the average amount paid for drugs was less than the Medicare reimbursement amount. For 4 of the 39 drugs, the average amount paid for drugs exceeded the reimbursement amount.

The OIG's conclusion that reimbursement was "generally adequate" and its analysis based on average drug costs to physicians do not appropriately consider the many situations faced by particular physicians in which the Medicare payment amount does not cover the cost of the drugs. Although the OIG's conclusions did not highlight this problem, the report shows that for 17 of the 39 drugs reviewed, at least 20 percent of physicians incurred an out-of-pocket loss. Only 3 of the 39 drugs could be obtained by all physicians at the Medicare payment amount or less. The OIG's conclusion fails to acknowledge that out-of-pocket losses are incurred by physicians in many circumstances, a situation that threatens access to care for some cancer patients. In some of those circumstances, practices are referring patients to hospital outpatient departments. We have received reports from ASCO members that, in some instances hospitals are not accepting those patients. This is a particular challenge to patients without secondary insurance.

To avoid the potential access problems created by this shortfall in Medicare payment, ASCO supports legislation that would ensure that the Medicare reimbursement amount is sufficient to cover what physicians have to pay to obtain drugs. Legislation introduced by Representative Ralph Hall, H.R. 5179, would create a floor for Medicare payment to ensure that it is not lower than the "widely available market price." The Medicare statute is currently asymmetrical in that it allows the Centers for Medicare & Medicaid Services ("CMS") to lower the payment rate when it exceeds the widely available market price but does not permit raising the payment rate when it is less than the widely available market price. This inconsistency should be rectified immediately.

The statute defines the widely available market price as "the price that a prudent physician or supplier would pay." We believe that a physician who shops among the distributors of oncology drugs for the lowest price is a prudent buyer. If that physician cannot obtain a drug for the Medicare payment amount through that process, Medicare needs to revise the payment amount.

H.R. 5179 would also exclude prompt pay discounts to wholesalers and distributors from the calculation of ASP. This change is analogous to the change in the definition of "average manufacturer price" that was enacted by section 6001(a)(2) of the Deficit Reduction Act of 2005 ("DRA"). Under the DRA, average manufacturer price will be used beginning in 2007 to set the upper payment limit for reimbursement to pharmacies for drugs reimbursed by Medicaid.

The DRA, however, excluded prompt pay discounts extended to wholesalers from the calculation of average manufacturer price of this purpose, presumably because pharmacies do not receive those discounts. The same principle should apply under Medicare Part B. Including prompt pay discounts received by wholesalers and distributors distorts the calculation and contributes to situations in which individual physicians are unable to obtain some chemotherapy drugs at or below the Medicare payment rate.

We strongly support H.R. 5179 as a means of bringing Medicare payment into better alignment with market prices and thus avoiding access challenges for patients.

Payment for Related Services

The MMA made some adjustments to payment for services but they were not sufficient to cover the cost of providing the full range of services required for comprehensive cancer care. Further legislative changes beyond those in MMA are required to recognize services not currently reimbursed by Medicare. In addition, CMS must revise the manner in which it is calculating the practice expenses associated with particular services.

Payment for Coordination of Cancer Care

One very important payment reform is embodied in legislation introduced by Representatives Lois Capps and Tom Davis. Inspired by a series of recommendations from the Institute of Medicine (“IOM”), H.R. 5465 would establish a new Medicare service for comprehensive cancer care planning and coordination at the time of diagnosis, at the end of active treatment, or when there is a change in the cancer survivor’s condition or care.

The care planning service was recommended by the original IOM cancer care quality report in 1999, and the most recent report on adult survivorship issues in 2005 underscored the importance of coordination of care as the survivor moves from active treatment to a period of monitoring side-effects of treatment and possible second cancers. By paying oncologists for comprehensive care planning, the quality of cancer care will be enhanced, patient satisfaction will be boosted, and cancer care resources will be more efficiently utilized.

Practice Expense Relative Value Methodology

ASCO continues to be concerned about the CMS methodology for determining practice expense relative values consistently with MMA. A CMS contractor, the Lewin Group, and the Government Accountability Office have both issued reports concluding that the CMS methodology of allocating practice expense relative values for “indirect” costs is biased against services that do not involve physician work. We believe that drug administration services, which are considered to involve little or no physician work, are adversely affected by the current methodology. CMS, however, has not revised its method of calculating practice expense relative values to remedy this bias.

Our concern about the calculation of practice expense relative values has been heightened by the proposal published by CMS on June 29, 2006. The MMA required CMS to use the supplemental survey of oncologists’ expenses sponsored by ASCO to determine practice expense relative values. However, under CMS’s proposal, surveys would no longer be used to determine the practice expense relative values attributed to the “direct” costs of clinical staff, supplies, and significant equipment. In addition, CMS is proposing to change the method of determining the practice expense relative values attributable to the “indirect” costs of administrative staff and overhead. We do not believe that CMS has discretion to discount or disregard this survey data in determining practice expense relative values for drug administration services performed by oncologists.

ASCO has just begun its analysis of CMS's proposed changes, but we are concerned about proposed decreases in payments for many drug administration services. For example, the practice expense relative value units assigned to the key service of a chemotherapy infusion (first hour) would decline by 13 percent. It is important that the CMS methodology result in appropriate payment amounts for drug administration services that are adequate to support the services and consistent with the intent of Congress in MMA. We urge this Committee to review carefully the CMS proposal and offer guidance to the agency regarding alternative approaches that will sustain necessary cancer care services.

Demonstration Projects and Quality Cancer Care

The oncology demonstration projects administered by CMS in 2005 and 2006 have provided additional resources to permit oncology practices to provide high quality cancer care. In addition, these projects have yielded useful data for assessing the quality of cancer care and contributing to quality improvement efforts. The current demonstration project assesses compliance with cancer guidelines, an initiative that holds promise not only for enhancing cancer care quality this year but also in guiding the development of future "pay-for-performance" in cancer care.

ASCO is collaborating with CMS, other government agencies, patient advocates, and third-party payers in the Cancer Quality Alliance, a voluntary alliance that addresses issues of quality care in oncology. In this setting, it has been suggested by experts that the demonstration project will have value only if it provides sufficient longitudinal data to enable meaningful analysis and direction for future quality improvement efforts. We would urge the Committee's support for a multi-year extension of the demonstration project to enable collection of enough data to support well-informed quality enhancement initiatives.

Competitive Acquisition Program

The MMA also enacted a Competitive Acquisition Program ("CAP") under which physicians can obtain drugs from a Medicare contractor for specific patients, and the contractor is responsible for billing the Medicare program and the patient. One purpose of the CAP was to meet the needs of individual physician practices that, for whatever reason, find themselves unable to purchase drugs through traditional channels at acceptable prices. We believe there may be a legitimate role for the CAP, but as currently configured, there are still significant issues that need to be addressed with the program.

A primary concern is the fact that the rules permit CAP vendors to terminate access to drugs for patients who fail to pay their coinsurance within 45 days. This provision is an unexpected and unwelcome burden for cancer patients. Oncologists in practice frequently face the necessity to deal with unpaid coinsurance, sometimes absorbing the loss, sometimes extending payment terms, and sometimes referring patients to charitable organizations. All these options are open to CAP vendors, and they should not be absolved from those options any more than oncologists. Arguably, one of the reasons oncologists may avoid CAP is the potential harm to their patients from this provision, which should be revisited without delay.

Another potentially inhibiting factor for oncologists is the failure of CAP to reimburse practices for the administrative costs associated with the program. Our members tell us that there would be a significant new administrative burden in dealing with the CAP contractor. Since there would be no additional reimbursement to cover these costs, that factor may be discouraging for practices as they decide whether to enroll in the program.

Other issues of concern include the rule that a physician may not transport CAP drugs from one practice location to another. This rule can interfere with the operation of practices with multiple offices. Also, the CAP rules establish a vague negotiation process for the physician and the CAP vendor to work out the disposition of unused drug. It would probably encourage enrollment in the CAP if this process were clearer.

Patient Coinsurance

Patient coinsurance is an issue not just in CAP but also in Part B generally. Cancer drugs can be very expensive, and the 20 percent coinsurance can amount to many thousands of dollars for a course of treatment. Patients who lack secondary or supplemental insurance are often hard pressed to pay the coinsurance involved.

In a report issued by the Medicare Payment Advisory Commission (“MedPAC”) in January 2006, however, MedPAC noted that patients who are unable to cover their coinsurance are increasingly being referred to hospitals. Medicare pays 70 percent of the bad debt incurred by hospitals. MedPAC also stated that it plans to study long-term solutions to this problem.

ASCO agrees with MedPAC that this problem needs to be addressed. Although the 20 percent coinsurance requirement is appropriate for many types of services covered by Medicare, it is frequently an unreasonable burden on cancer patients who are treated with state-of-the-art medicines. Congress should resolve this issue by eliminating, or at least significantly reducing, the patient burden of coinsurance for Part B drugs.

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As the issues raised in this hearing amply reflect, Medicare reimbursement for cancer care is as complex and challenging as ever. ASCO has provided its members a wide range of tools and services to help them adjust to this rapidly changing environment. Among these are the Quality Practice Oncology Initiative, practice management workshops, practice guidelines, and a hotline for Medicare policy questions. We are happy to share information about these and other similar efforts at a later time.

There remain many potential pitfalls before we achieve a reimbursement system that ensures comprehensive quality cancer care. We appreciate the Committee’s interest in scheduling this hearing and are committed to working with you to continue improvements in reimbursement and quality of care for the benefit of our patients.