

**Response to CMS document issued 10/4/04:
Payment for Oncology Drugs & Administration (file name: Cancer_care.pdf)**

What follows is a response from the Community Oncology Alliance (COA) to the one-page document (Payment for Oncology Drugs & Administration) issued by CMS relating to Medicare cuts to cancer care reimbursement. The seriousness of this issue demands a more thorough review of the cancer care reimbursement issue.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made historic changes to the way that Medicare will reimburse community cancer clinics for the treatment they provide to over 80% of Americans battling cancer. Although the changes are a step in the right direction to balanced Medicare reimbursement — that is, equitable payment for cancer drugs and medical services — **the changes scheduled for 2005 are being rushed without proper data and analysis. As scheduled, the changes will be devastating to cancer care in this country.**

Community cancer clinics have been reaching out to their Members of Congress to educate them on the realities of delivering modern-day cancer care and to explain why the scheduled Medicare reimbursement changes for 2005 will create patient access problems. Clinics are explaining that there are 3 fundamental problems with the changes scheduled for 2005:

- Average Selling Price (ASP) as currently defined is not a realistic acquisition price to cancer clinics — it is the price paid by wholesalers to pharmaceutical manufacturers.
- There is inadequate reimbursement for the costs incurred by cancer clinics when they take possession of a cancer drug; these costs include inventory, storage, pharmacy, waste, etc.
- There is inadequate reimbursement for many of the medically necessary services that are part of modern-day cancer care.

Anyone knowledgeable about the treatment of cancer realizes that it is evolving rapidly; especially over the past few years as new drug therapies have increased the complexity of cancer care. The cost of this increasing complexity is not realistically captured in studies, initiated by the government and others, completed just a few years ago. Government (GAO, OIG) pricing studies on the cost of cancer drugs are obsolete as new drugs introduced since these studies have changed the treatment of cancer.

CMS estimates that the scheduled changes for 2005 will decrease Medicare cancer care reimbursement by over \$500 million or over 8%. This is substantially in excess of the congressional intent of MMA. COA estimates that the scheduled changes for 2005 will cut Medicare reimbursement by close to \$1 billion or 18%. Unfortunately, this 18% will result in a 40-50% decrease in a clinic's operating capital, the amount that funds the provision of medical services. It is challenging if not impossible for any cancer clinic to absorb these cuts and to be able to continue to provide quality cancer care.

It must be made clear that the ASP-based drug reimbursement system is a *conceptual* system that has never been analyzed and/or implemented before by the Centers for Medicare and Medicaid Services (CMS) or any other payer. This system is totally unknown and is being implemented without a safety net.

To date, CMS has been able only to produce a partial list of ASPs for cancer drugs, and those ASPs are based only on 1st quarter ASP data submitted by pharmaceutical manufacturers. It is impossible to characterize this data as “good and consistent” because there has been no comparative analyses of this data. There is no historical comparative data. CMS has not released 2nd quarter ASP data and has now changed the ASP calculation methodology for 3rd quarter. This 3rd quarter data will form the basis for the live ASP-based reimbursement rates that go into effect on 1/1/05. The change in methodology will invalidate trend analysis with 1st and 2nd quarter data. It is simply illogical and dangerous (given that what is at stake is the future of cancer care in this country) to implement a totally new drug reimbursement system without the proper data and analyses to gauge stability and accuracy of the reimbursement system.

One of the key issues is that the ASP system has inherent definitional and structural problems. A few of the key problems with ASP are as follows:

- ASP is a price paid by large drug purchasing intermediaries to pharmaceutical companies. It is not by definition a sales price between community cancer clinics and pharmaceutical companies.
- ASP is an unstable price that will vary quarterly because it is subject to the buying of these large intermediaries. This will cause reimbursement rates to be unstable and vary, resulting in an operational nightmare for cancer clinics. The new 3rd quarter ASP calculation methodology employed by CMS should help reduce variability but CMS will not know the success of this smoothing methodology until later in 2005 when it has multiple quarters of data.
- There will be a 3-6 month lag in reporting/processing ASP, which means that price increases for cancer drugs will not be reflective in reimbursement rates in a timely manner. Cancer clinics will be getting reimbursed less than their cost for cancer drugs over multiple time periods in cases of drug price increases.
- The reimbursement rate of ASP + 6% does not cover all the direct drug costs (e.g., inventory, pharmacy, storage, waste) incurred by cancer clinics.

The argument is made that cancer patients are overpaying for cancer drugs. Patients have overpaid the co-payment for drugs but have significantly underpaid for medical services. If the Medicare reimbursement system were better balanced, as community oncologists have been arguing for years, patients would have still paid the exact same amount because the 20% co-payment is levied by Medicare on all cancer care treatment. The fact is that many patients’ co-payments are not collected by community cancer clinics because patients cannot afford this payment. Over 25% of co-payments are never collected by community cancer clinics, which end up subsidizing these uncollected patient co-payments.

Although significant work is being done on the medical services reimbursement issue, the fact is that the transitional increase of 32% in 2004 is scheduled to decrease in 2005 to 3% and 0% thereafter. This represents a 22% decrease in cancer care services. Key Members of Congress and staff, as well as CMS, are working on this issue by trying to increase services code reimbursement and looking at new codes. However, with less than 3 months before substantial cuts in reimbursement, the cancer community does not know (a) what codes impacting oncology will be increased or added and (b) what is the financial impact of these new codes. Earlier this year, COA formed a task force made up of 18 experienced community practice administrators, and had the expertise of billing and coding consultants as well as a former Medicare Medical Director. Working over 4 months, the task force produced a 22-page document outlining 30 recommendations regarding existing and new codes. The task force testified at an American Medical Association (AMA) hearing on the CPT Workgroup to the RUC. The task force report,

as well as subsequent analyses, has been provided to CMS (including Dr. McClellan), the AMA, and Members of Congress.

With less than 3 months before historic changes are implemented to how Medicare reimburses for cancer care, there is a glaring lack of proper data and analyses. Rushing to implement these changes — especially without data, analyses, and a safety net — jeopardizes the entire cancer care delivery system in this country. Can you imagine if the FDA stopped all safety and efficacy testing for new cancer drugs and simply released them to market to determine if they are safe and/or effective? That is the same experiment we will be conducting on cancer care delivery.

The logic is inescapable that there should at the very least be a transitional payment mechanism in place for 2005, while current and new systems are run in parallel, with a safety net based on 2004 payment. This will allow for more data to be collected and analyzed by CMS; studies mandated by MedPAC, OIG, and others; and more data and information from the cancer community.

Nothing contained in this response should be construed as critical of CMS, which faces a Herculean task in implementing the overall mandate of the MMA. There is simply not enough time, data, and analyses to guarantee that scheduled changes will not inflict significant harm on the cancer care delivery system in the United States.