CMS-1372-IFC-1

Submitter : Mr. Dennis Jackman **Date & Time:** 02/09/2004 12:02:00

Organization : Aventis Behring

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Our complete comments are attached refering to the following issues: Table 1A on pages 18 and 19 incorrectly classifies IVIG as a generic drug. IVIG is a biologic and each brand within the HCPCS code has been approved for a Biologics License Application by the FDA. There is payment discrepancy between J 1563 and J 1564. Both are HCPCS codes for IVIG with the only difference being the unit of measure yet there is a $10 per gram difference in their reimbursement. We would urge CMS to use the J 1564 code for equalizing the reimbursement values. Despite the statutory language within MPDIMA, the conference report language is explicit in stating that IVIG reimbursement should be 95% of AWP for 2004 (page 153 of the report). Aventis Behring calls upon CMS to work with congressional staff to address the varying reimbursement figures from the statute and conference report. Lastly, Aventis Behring believes that the reimbursement for Alpha-1 Proteinase Inhibitor is inconsistant with the statute. The payment rate put forward by CMS is 85% of AWP for the lowest priced product in the HCPCS code, yet the statute is explicit in stating that blood products (other than clotting factor) will be reimbursed at 95% of AWP. As stated above, our complete set of comments are attached. Thank you for your consideration.

Submitter : Ms. Stephanie Bates **Date & Time:** 02/10/2004 12:02:00

Organization : n/a

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs, My husband died from cancer. We had wonderful care the whole time he was sick. If it had not been for the care we received, I believe he would have died within a week instead of the five months that he did live. We had wonderful insurance. I only had to pay the $1,000 deductible. His medical bill was $276,000. in 1988 and I can?t imagine what it would cost today. We were so thankful to have the insurance, as we were one of those couples who lived from paycheck to paycheck to survive. My concern now lies with the Medicare patient who is not able to receive appropriate care due to the changes since the Prescription Drug Bill has now passed. Some patients are not able to receive their treatment at the office where a nurse who knows them gives them the best-individualized care a patient can receive. These patients are having to be sent to the hospital for their treatments and are given by a hospital nurse who is overworked and unable to provide the same care as in the clinic.. This is all due to the fact that Medicare has cut reimbursement so drastically that some chemo drugs cost more to purchase than Medicare reimburses for the drug. That does not even account for the care provided by the skilled oncology nurse that administers the chemo agents, the supplies, the comfortable facility the patient uses while receiving chemo and having access to the vast knowledge the nurses and doctors have as it comes to the fight of their lives and surviving this horrible disease. The real scary part of this issue is that the private insurance companies base their fee schedules off of the Medicare model and will follow right behind by not allowing their patients the same treatments in the office anymore. So this isn?t just a Medicare issue. It affects ALL cancer patients. If it doesn?t change, by 2005, doctors offices will be closing their doors, leaving the cancer patient out in the cold. We have to change this because this is so fundamentally wrong. People with cancer are fighting the biggest battle of their lives. They don?t need to worry about reimbursement as well. We have to change CMS-1372-FC. Thank you for your consideration and your support.

CMS-1372-IFC-3

Submitter : Ms. Amanda Holbrook **Date & Time:** 02/13/2004 12:02:00

Organization : Oklahoma Oncology, Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

re: CMS-1372-IFC The care of cancer patients is already being affected by the passing of the Medicare Prescription Drug Bill. As of January 1, 2004, oncologists receive AWP - 15% for cancer drugs. This cut in reimbursement is affecting the quality of care that cancer patients currently receive and will only worsen come 2005, when oncologists may start receiving ASP + 6%. This amount of reimbursement is not enough to cover the cost of the drug and related administration costs. This is a very serious change that must be reversed. Oncologists must receive reimbursement for the cost of the drug as well as the cost of administering the drug - at the very least ASP + 12%. Cancer care patients are being turned away. Let's stop this in 2004. And let's prevent community oncology practices from closing their doors in 2005. Medicare sets the standard, and private insurance companies follow its lead. This bill is not only affecting Medicare patients and their families; eventually, all cancer care patients and their families will be devastated by this bill if something is not done quickly. Please hear the cry of patients who are struggling with this terrible disease. Is it not enough that they are battling cancer? Must they also fight for proper treatment? Sincerely, Amanda Holbrook Administrative Assistant Oklahoma Oncology, Inc.

CMS-1372-IFC-4

Submitter : Mrs. Donna Highers **Date & Time:** 02/16/2004 12:02:00

Organization : N/A

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs: CMS-1372-FC I being a cancer patient, would like to comment on the cancer cuts we will be facing, I'm very concerned there will not be any Drs. or treatments in the years to come if the medicare bill is not changed. Please help all of us who suffer from cancer.

CMS-1372-IFC-6

Submitter : **Mrs. Barbara Crabb** **Date & Time:** **02/23/2004 12:02:00**

Organization : **N/A**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1372-IFC I find it so hard to understand why our Congress would so drastically reduce the much needed cancer care in our Medicare Program. I just recieved chemotherapy for breast cancer. I can't imagine what I would have done without the professional, caring and even loving treatment I recieved through my oncologist. It is only through practices like this that we can continue to have the quality cancer care that we need and deserve. I understand that some changes can be made to this billI. Please do all you can to insure that these much needed changes are made. Thanks you, Barbara Crabb

CMS-1372-IFC-7

Submitter : **Ms. Penny DeMarco** **Date & Time:** **02/26/2004 12:02:00**

Organization : **South Atlanta Hematology Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The 2004 Medicare fee schedule is reimbursing our office less than cost on the following drugs, 5FU, Camptosar, Ellence, Gemzar, Interleukine, Leupron, Pentostatin (by hundreds of dollars), Trisenox, Zoladex, Zometa, Faslodex and Navelbine. We are having to refer a large number of our patients to the hospital for treatment. The hospital now has a waiting list. This is a major inconvenience to our patients. After extensive analyses, with further reductions of services in 2005, we foresee our chemotherapy infusion center closing. Access to care in our area will be limited. We are currently preparing to close sattelite offices. The hospital has already informed us they cannot handle the overflow of patients. If changes are not made the situation will become very servious for all cancer patients. Oncologist will no longer be able to afford to provide life saving and life prolonging outpatient chemotherapy. Thank you.

CMS-1372-IFC-8

Submitter : Dr. Jacob Bitran **Date & Time:** 02/27/2004 12:02:00

Organization : Oncology Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

In order to maintain access to ambulatory oncology cancer for medicare receiptients, it is imperative to keep the level of reimbursement as proposed by CMS in 2004 ongoing on a year to year basis. Any decrease in reimbursement would lead to practices such as our own, turning away medicare receipients as the acrual costs of providing care would exceed the level of reimbursement.

CMS-1372-IFC-9

Submitter : **Mrs. Candace Hayes** **Date & Time:** **02/27/2004 12:02:00**

Organization : **Suburban Hematology Oncology Associates, PC**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to comment on CMS-1372-FC, Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for 2004. We are a community based Oncology practice in a suburb of Atlanta. The 2004 drug reimbursement cuts have caused us to re-evaluate each Medicare patient and if his/her treatment costs us more than our overhead, we have to send these patients to the hospital for their treatment. The hospital charges patients $3.00 to park and they usually have to spend 8 hours there for a treatment that would take them 4 to 6 hours here in the community outpatient setting. We also require them to come to our office for blood tests prior to writing orders and sending them to the hospital. So, this quickly becomes an all day affair for some very sick seniors. There are some drugs that Medicare is paying us less than the cost to acquire the drug. These drugs are Gemzar, Sandostatin LAR, Taxotere, Zometa, Rituxan, Doxil, Irinotecan, and Carboplatin. As a result, we are having to make arrangements for our Medicare patients to receive this drug at the local outpatient center at the hospital. However, this hospital is very limited in its ability to accomodate our needs. The other local hospital does not give chemotherapy in its outpatient treatment center and those patients have to be admitted. That is of much greater cost to Medicare and a much larger co-insurance to the patient. The reduction in payment for 2005 is even worse. The administration codes which are paying at an acceptable level now, will be reduced in 2005. We certainly will not be able to give chemotherapy to medicare patients in 2005. ASP, as currently defined, will lead to the end of the community based cancer care for seniors. The ASP system in MMA is calculated includes providers paid under Part A. We, as a community based oncology practice, can not compete with the purchasing power of a large hospital system. Please understand that there are many costs associated with keeping drugs on hand. There are storage costs, inventory, procurement and waste to name a few. ASP plus 6% simply will not cover those costs for us. I don't know where these patients will go....my guess is that they will not seek treatment or will not finish a treatment once it is started. Many of our private payers have started to try and implement these cuts as well. I fear that we will only be seeing these patients in the office for office visits and then shipping them out to the hospital for treatment. Most certainly, their care will be delayed due to staffing and the fact that there will be no room for them for weeks. Imagine being told that you have cancer but your treatment will have to be delayed for 4 to 6 weeks because there is no room for you at the hospital. One last thing...giving chemotherapy requires highly trained nurses. Most of the oncology certified nurses work in community based clinics such as ours. The hospital staff lack this certification and extensive training. In case of a drug reaction I know that I would rather be in the same office as my doctor, not in the hospital waiting for an emergency room doctor, who knows nothing about me (or cancer), to make his way to the outpatient treatment center. Quality to care and access to care are in real danger. Think about this as if you or a loved one were a cancer patient. You would most certainly want the highest quality and easiest access to the medical care you needed. Thank you for taking the time to read this and please obtain as much data as possible before making such a drastic decision.

CMS-1372-IFC-10

Submitter : **Ms. Laurie Hofer** **Date & Time:** **03/02/2004 12:03:00**

Organization : **Peachtree Hematology & Oncology Consultants**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

I am a Canadian registered nurse who has been working in clinical research in this country for the past 5 years. Coming from a system of socialized medicine has opened my eyes to the importance of "quality" care, meaning timeliness of treatment, consciencious planning and follow up. This can only be accomplished by dedicated staff members who can take the time to anticipate needs and accept some of the burden of those dealing with a life threatening illness. Our patients are suffering physically, emotionally and spiritually. You cannot possibly compensate for services based on cost of drugs alone. As practices struggle to keep costs down, the patients are the ones who will feel the impact of decreased staff and services. An added burden in a time of confusion and personal loss. This is an exciting time in cancer research, and there are good reasons to be hopeful for the future. Please consider your decisions carefully and think about how lucky we are in this country to have
access to the best of technology and knowlegeable professionals. I urge you to think forward with hope and optimism.

CMS-1372-IFC-11

Submitter : **Dr. Daniel Scullin** **Date & Time:** **03/02/2004 12:03:00**

Organization : **Consultants in Blood Disorders and Cancer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Attached is a Word document outlining our practice's input on CMS-1372-FC. Thank you for reviewing this very important issue for community oncology.

Submitter : Dr. Mark Moskowitz **Date & Time:** 03/02/2004 12:03:00

Organization : Florida Cancer Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Sir: I am a medical oncologist who devotes 100% of his time to caring for patients, 75% of whom are medicare beneficiaries. The Medicare Improvement Act will harm their access to oncology care because reimbursement will be cut in 2005 to the point that it will be impossible to serve these folks as they should be served. Many rural oncology clinics, which serve many parts of the United States unserved by hospital-based oncology units, will be forced to close. Medical oncologists like myself will be forced to limit the number of medicare patients we care for, since our practice expenses will far outweigh our profitability. Hospital-based oncology units will probably remain open but will not have the capacity to care for our patients since 80% of cancer chemotherapy is now given in physician's offices. Patients prefer being treated in physician offices because they are small, friendly places located close to their homes. I am not sure why cancer care needs such draconian cutting; we ill all be old and many of us will get cancer. We are creating a bleak world for these people, who have enough on their plates without the cancer treatment infrastructure being jeopardized in the name of a payment system (ASP+ 6) that no one ... no one understands. Yours truly, Mark J. Moskowitz, MD

CMS-1372-IFC-13

Submitter : **Dr. Steven Weiss** **Date & Time:** **03/02/2004 12:03:00**

Organization : **Northwest Oncology**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

March 2, 2004 Re File Code CMS-1372-FC Dear Sirs I am deeply disturbed about the payment reform for drugs and biologicals proposed for 2005. I work in an Oncology practice in Broward County, South Florida. I deal primarily with an elderly population, many of whom have advanced malignancies. The mission of my practice is to provide the highest quality of care to an aging and needy population, fearful of pain, debility, death and the unknown. Patient care involves extensive counseling of the patients by my supportive staff including teaching patients about the management of their malignancies, complications and side effects of treatments, dealing with the psychosocial issues relating to their malignancy, family related issues, diet issues, coping skills, end of life issues, and many other concerns relating to their cancer. These are non-covered services under the medicare program. The actual amount of time spent in preparing and administering the chemotherapy is often small compared to the time spent addressing these other issues. Already, with the budget tightening that we are feeling this year, I have been forced to limit these critical services. The effect this has had on our patients is palpable in their level of anxiety when dealing with these life altering issues under their extreme circumstances. The margins made in the chemotherapy division of our office have funded the necessary positions to provide this crucial care leading to improved quality and quantity of life. If the proposed cuts for 2005 come to fruition, I will be forced to dismantle this support network in order to maintain the viability of our office. It is a shame that the ones who will suffer the most by the medicare reform are the very patients that it was initially intended to help. The actual dollars and cents issues have been well defined by COA and ASCO and I will not reiterate them here. Please consider the impact of this act on the most needy of the medicare population. Respectfully, Steven Weiss, MD

CMS-1372-IFC-14

Submitter : Mrs. Mary Kruczynski **Date & Time:** 03/02/2004 12:03:00

Organization : Community Oncology Alliance

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I feel only two comments appropriate at this juncture: First, the transitional fees for administration put in place in 2004 are a tremendous help when coupled with the decreased drug reimbursement fees for the same calendar year and obviously, this reimbursement increase was recognized by Congress and CMS as necessary to preserve community cancer care. Why then, in 2005, when drug reimbursement will be further reduced, does Congress find it logical to eradicate that increase. Do you know something that we don't? Even the cost of living will increase, yet you deem it appropriate to further reduce our reimbursement. We will furnish you with information to support the logical decision made for 2004 to be continued well beyond. Please look for our commentary. Second, almost one hundred percent of the drugs administered in the private community oncologist office are losers, when we assume payment of 80% of 85% of the Medicare allowable; something we receive more often than not, due to the many Medicare recipients who do not have medigap insurance, either because they did not deem it necessary or could not afford to purchase same. How can we be excpected to remain whole when we are losing each and every time? We aim to furnish you with specific examples of this type of thing happening each and every day in our private practice. Even Aetna has jumped on the bandwagon, enforcing a $45. copay on top of the usual $25. copay for E&M services for patient's requiring an injectable medication. Many are choosing to forgo their drugs for lack of the additional money. They choose, food, clothing and shelter in lieu of drug. This is shameful.

CMS-1372-IFC-15

Submitter : Mr. robert stackpole **Date & Time:** 03/04/2004 12:03:00

Organization : UrologicalGroupOfUnionCounty

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

The Medicare cuts in reimbursement for office-given parental anti-cancer medications are much too great. My office will make the patints purchase their medication at great expense and bring it to the office. You will have unhappy doctors and patients. Please fix it. RHStackpole,MD urologist

CMS-1372-IFC-16

Submitter : Mr. Steve Nally **Date & Time:** 03/04/2004 12:03:00

Organization : Atlanta Cancer Care

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This is written on behalf of a community hematology/oncology practice. We provide care in the form of 82,000 visits annually to Medicare beneficiaries and other patients. There are significant issues with the proposed Rule we ask you to consider. There are 18 major drugs which at Medicare allowable are not reimbursed at our cost: In addition, there are 34 drugs, which if the 20% patient coinsurance is not collected are below our cost. This insufficient reimbursement has negative effects on Medicare program cost management as well as beneficiary access to and quality of care. Over the past five years, this practice has donated approximately $2 million per year in charitable write offs. Much of this has gone to Medicare beneficiaries without secondary insurance who could not afford to pay their portion of the fees. With the under payments for drugs in 2004, we can no longer afford to do this. Instead, we send beneficiaries to the hospital for chemotherapy. This causes an unnecessary interruption in the continuity of care, is less convenient to the patient and in short, deprives them of community access to care. Additionally, hospitals typically do not provide the same immediate access to support services such as physician supervision, social work, hospice coordination, financial counseling, clinical trials and nutrition services that are present in the community oncology setting. We believe it is imperative that you understand and appreciate the benchmarking power of CMS over the healthcare market as a whole. This year, perhaps emboldened by the passage of the MMA, many health insurers are acting preemptively to reduce fee schedule levels to below or at Medicare allowable. United, Cigna, Blue Cross Blue Shield and other insurers have acted in some fashion along these lines. We estimate a net decrease of $1.5 to $2 million in revenues this year due to the ?downstream? effects of the MMA. While this does not have a direct impact on Medicare beneficiaries, it does indirectly and greatly affect them in that the reduction in reimbursement will cause a reduction in resources (funded by the practice, but not reimbursed) across the practice. Although not specifically covered in the contents of the Rule, because this is part of the larger program mandated by the MMA, we believe it is appropriate to discuss the effects of this legislation in the years 2005-2006. Our concerns are threefold about this model of change. First, The ASP as detailed by the MMA automatically leaves about half of community oncology practices unable to purchase drugs because reimbursement will be less than cost by definition. Over time as larger purchasers paying less for drugs reduce the ASP, this will inevitably lead to community oncology practices going out of business and systematically reduce access to quality care. Because there is no defined ?floor? to the cost reduction, the community oncology practices which provide over 80% of all cancer care will soon be devastated. Even the untried and questionable concept of regional vendors will not be in place until 2006 at the earliest. Lastly, it seems as if the concept of changing the reimbursement model and, after the fact, determining the adverse impact is a bit like building a road without knowing your destination. It is not especially rational or effective. It seems more appropriate to analyze the situation and make changes based upon knowledge and information rather than best guesses. The reimbursement anticipated in the 2005 timeframe is expected to cause a $4.5 million loss to this practice if we continue to accept Medicare beneficiaries (which we will not). In summary, we recommend that the rational and least destructive approach is to continue reimbursements in 2005-2006 at the 2004 level; actually analyze data and plan in a rational manner for a positive and constructive change that does not significantly compromise patient access to quality cancer care.

CMS-1372-IFC-17

Submitter : **Mr. Ted okon** **Date & Time:** **03/04/2004 12:03:00**

Organization : **Community Oncology Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment submitted for a further explanation of comments submitted by the Community Oncology Alliance (COA). Based upon our analysis, the payment system for 2004 is adequate as a transitional phase. Although the 2004 system retains the AWP-based system, there is generally adequate payment for most cancer drugs. However, there are several very commonly used cancer drugs where the reimbursement for these drugs is now less than typical acquisition costs incurred by community oncology clinics. CMS should adjust these drugs.On the services side, our estimate concurs with the CMS estimate that services-related reimbursement (e.g., chemotherapy administration) has been increased for 2004 in excess of $500 million. Although this amount is lower than the $718 million under-reimbursement for services by Medicare estimated by COA, we believe that this increase moves in the right direction of equitable payment for all of the essential services required by seniors covered by Medicare. The Medicare payment system has not kept pace with modern-day cancer care and does not adequately pay for all of the essential services required by cancer patients. For example, the planning and management of complicated cancer treatment ? typically involving combinations of toxic medications ? by community oncologists is simply not captured in existing E"&"M or administration codes. We would be remiss if we did not comment on changes dictated for 2005 and beyond by MMA. We estimate that for 2005, Medicare reimbursement for cancer care will be decreased by $890 million. This calculation is substantially different than the CBO score for all of Part B, which was a decrease of $200 million. Relating to drug reimbursement changes for 2005, we are extremely concerned about implementing a system (ASP) that is totally new and untested. There are several key aspects of the ASP system, as currently crafted in MMA, that are flawed and need to be changed:? ASP will be the basis for reimbursement to community oncology clinics (that are reimbursed under Part B) but the calculation of ASP (as currently contained in MMA) will include purchasers that are not reimbursed under Part B (such as hospitals that are reimbursed under Part A). We understand and appreciate the concept of Medicare paying for drugs based on competitive market value, but that value should be based on those providers covered under Part B only. ? ASP as defined in MMA will be a price paid by large purchasing intermediaries (e.g., wholesalers), not community oncology clinics that purchase drugs from these purchasing intermediaries. As such, ASP is a price ?one step removed? from community oncology clinics that will be reimbursed based on ASP.? If ASP (the average or ?mean? price) is equal to the median price, by definition at least 50% of the intermediary purchasers will be purchasing at a price above ASP. The percent of community oncologists purchasing above ASP increases when the purchases of large non-Part B providers (hospitals, wholesalers) are included in the ASP formula.? COA has calculated that at least a 112% multiplier is required above drug acquisition cost to cover the direct drug costs (storage, inventory, pharmacy, procurement, capital, waste, and reimbursement) not adequately reimbursed by Medicare Using current, actual drug acquisition costs, COA and individual community oncology clinics have estimated ASP. These analyses arrive at the conclusion that there will be a substantial decrease in Medicare reimbursement in 2005. In addition to the problems with ASP, the transitional increase to services reimbursement will be decreased from 32% in 2004 to 3% in 2005. It is especially disconcerting and perplexing as to why services reimbursement would be increased in 2004 and then decreased one year later when inflation increases.

CMS-1372-IFC-18

Submitter : **Mrs. Sandra Rosenberg** **Date & Time:** **03/04/2004 12:03:00**

Organization : **Michael S. Buchholtz, MD, PC**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Re: file code CMS-1372-FC This office is staffed by three board certified medical oncologists/hematologists, two nurse practitioners, three oncology certified registered nurses, three lab/phlebotomists, four billers/collectors and myself, the Administrator. I am extremely upset by what I see as the future of community based oncology practices.This year, the reimbursement for drugs has dropped significantly. Imferon, J1750 and Octreotide, J2352 are two drugs that are reimbursed less than our cost. Administration of drugs has increased so that my forcast for my practice for 2004 is about equal to 2003. But, 2005 is going to be disasterous for our patients. This is a unique practice that spends an inordinate amount of time on the telephone with patients, family members, physicians, home care and hospice. These calls are not reimbursed but we are committed to our patients. Reimbursement for 2005 by Medicare is simply not justified by our cost of running this practice. I predict the necessity to let go staff in every category that are sorely needed to treat our population of patients. We shall have to send patients to the hospital for chemotherapy and other treatments. It is extremely tough being in the oncology field looking into the eyes of cancer patients who rely on this practice for their very existence and to realize what will happen because of patient care disruptions that will occur in the future. No office can viably provide patient care that is reimbursed for less than our cost.

CMS-1372-IFC-19

Submitter : Mrs. VANESSA HEMSTROUGHT

Date & Time: 03/04/2004 12:03:00

Organization : CHARLESTON CANCER CENTER

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

AS A HEALTH CARE PROVIDER IN THE ONCOLOGY FIELD I SEE PATIENTS WHO HAVE VERY LITTLE TO LIVE ON. WE PAY INTO MEDICARE ALL OUR ADULT LIFE. IT'S SHAMEFUL THAT LITTLE BY LITTLE THE BENEFITS WE ARE INTITLED TO ARE BEING STRIPPED AWAY. IF WE WOULD CONCENTRATE ON OUR OWN COUNTRY AND THE NEED HERE, WE WOULD BE BETTER OFF. SINCE NONE OF YOU WILL EVER KNOW THE HARDSHIP THE REST OF US FACE, MAKING THESE CUTS TO MEDICARE MUST BE EASY. HOW SAD THAT THE PEOPLE AND COUNTRY THAT YOU SWORE TO UPHOLD IS THE VERY ONE THAT YOU BETRAY....

CMS-1372-IFC-20

Submitter : Mr. Donnell Angelle **Date & Time:** 03/04/2004 12:03:00

Organization : Southwest Oncology Associates Ltd.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

In regards to CMS-1372-FC, we are an oncology practice which caters to several medicare recepients and unfortunately due the the changes in reimbursement for oncology practices, we are feeling the impact of these changes. About 46 of our drugs are being reimbursed at below our cost. Increase in services is helpful, but reductions in the percentage of these services will only cripple our reimbursement further next year and will be devastating in the years to follow. Changes will have to be made in regards to the way we treat patients and we are trying not to have to divert them to other facilities, but if these changes are not reversed or amended we may have no alternative. I ask that you please consider changing to ASP + 12% and leave the increase in practice expense. We already have to eat-up the cost of supplies as it is. We also will have to evaluate the expenditures in regards to staff that take care of these patients and other support staff. If these cuts continue, we may have to reduce the amount of staff needed to care for these patients. The "big picture" here is the patients are the ones who will suffer the most and are already feeling this impact. Please consider reevaluating this change for the better of patient care.

CMS-1372-IFC-21

Submitter : Dr. steve roshon

Date & Time: 03/04/2004 12:03:00

Organization : ohio and west virginia hematology and oncology society

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear sirs, We have many concerns about this legislation. On the e and m side oncologist manage difficult patients. There are few ways to distiguish this work. We need a code to recognize the complex nature of chemo. The addition of e and m to the infusion codes does not address complexity, inadequate payment for overhead, etc. A modifier for e and m service should not be required. The improved infusion code payment is about where it should be in 2004 but should remain in 2005. Also there should be allowed multiple 96410 when more than one drug is infused. Each drug requires assessment, supplies, etc. The amount for 96412 and 90781 are too low. Finallly oncologist provide a great service to patients by making access to pharmaceuticals efficient and cost effective. Waste is kept to a minimum and the oncologist takes the risk of nonpayment. It is absolutely necessary to pay enough to cover the cost of the drug and the associated drug related overhead to keep this business line intact. Even one drug at inadequate amount is unfair to the risk taking physician. We have many such drugs in 2004 and more in 2005. This must be fixed to preserve quality and access. We suggest and add on to purchase price or a dipensing fee for staying in this difficult business. Thanks, Steve Roshon, MD

Submitter : Mr. dolores meals **Date & Time:** 03/04/2004 12:03:00

Organization : N/A

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

re: FILE CODE: CMS-1372-FC Sirs; Please hear my plea regarding the degree and manner in which CMS reduced cancer drug payments. there are still cancer drugs that cost more to purchase than medicare reimburses: these drugs are (1) sandostatin lar, medicare pays $71.11 per mg. and I buy it for $77.66 per mg. (2) faslodex, medicare pays $78.36 per 25 mg and I buy it for $79.25 per mg. (3) nitrogen mustard, medicare pays $10.74 per mg and I buy it for $11.18 per mg. (4) alkeran iv, medicare pays $375.88 per 50 mg and I buy it for $376.26 per 50 mg. There are also 33 cancer drugs which I must collect 100% of the co-payment in order to have my cost covered by payment. Some of these 33 drugs have a large 20% copay and if the patient does not have a second insurance company then they must pay out of their pocket. In some cases the patient does not have the out-of-pocket 20% copay and therefore cannot receive the drugs. The drug companies cannot give assistance in these cases because the patient has medicare insurance and therefore does not qualify for assistance. Of the 33 drugs where the copay must be obtained, an example is the very popular bowl cancer drug called Camptosar. a common copay for one treatment can be $208.11 every week. there is no way that a community physician can afford to buy high and sell low on drugs with the medicare community and still stay in business. I am personally afraid that CMS is botching up cancer care in the USA and that in 4 years when I am medicare eligible, there will be NO CANCER CARE FOR SENIOR CITIZENS. Yes, I know the mexican trade-off is giving the saved monies for the Rx portion of all this. Well, I bet dollars to doughnuts that when I'm 65 I will still pay for my Rx's. There needs to be attention given to the fact that in 2005 medicare will be reducing reimbursement for services by 29%. For medicare to justify this measure is unthinkable. This purely is a measure to eliminate out-patient chemotherapy clinics and move everything back to the hospital. In the hospital the cost of administering chemotherapy is higher, efficiency of administration is reduced by half and time consumption is enormous for patients. Patients either receive prompt, efficient, safe cancer care in a controlled and well planned physician clinic or ??????? I'll find out when I turn 65. Remember, if we all live long enough, we'll get cancer of something.

CMS-1372-IFC-23

Submitter : Dr. RONALD CANTOR **Date & Time:** 03/04/2004 12:03:00

Organization : RI Cantor, MD. WA Biermann, M.D. Associates

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing oncologist in the Philadelphia region. Our group of five board certified oncologists provides care for a demographically heterogeneous group of patients ranging from urban, suburban, and rural areas as we have two offices in Philadelphia and two offices in Montgomery County. I have always been an advocate for my patients and a believer in Medicare. The changes in Medicare's cancer funding in 2004, I believe,represent a balanced trade-off for most drugs and services. Although our revenues and hence, incomes, have diminished as a consequence of these changes we still find ourselves solvent and able to provide quality care without compromising our patients. We are currently being compensated at a less than aquisition (85% of AWP) price for the following agents: Doxil, Carboplatin, Iron dextran, Gemzar, Camposar, Lupron, Navelbine and Faslodex. If not for the 2004 incriment in reimbursement for services, we would likely be unable to provide these drugs. The projected changes for 2005 however, will dramatically change this. Clearly, ASP + 6% will not be close to sufficient to pay for drugs. A reduction in reimbursment for services coupled with this insufficient drug pricing will be disasterous and likely force us to either treat Medicare patients in the hospital or refer them elsewhere. We cannot afford to provide care at a loss and remain viable. Please consider all of this with great care as our citizenry is at risk. Sincerely, Ronald I. Cantor, M.D.

CMS-1372-IFC-24

Submitter : **Dr. Stephen Allen** **Date & Time:** **03/04/2004 12:03:00**

Organization : **St. Louis Cancer Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir: I am a medical oncolgoist in private practice in Missouri. I am in a community based 4 physician group. I am now writing to comment on the specifics of the 2004 reimbursement changes and the future changes in 2004 and 2005. I am most concerned about patients' access and quality of care. The following drugs are currently being reimbursed by Medicare below our ability to acquire these drugs, namely we would incur a loss by providing these drugs in our office. These drugs include Epirubicin, Zometa, Faslodex, Zoladex, Lupron, 5FU, Sandostati and Camptosar. It is noteworthy that Gemzar, a commonly used therapeutic agent, had been in this category and the drug company lowered the price and we now are able to receive a two cent margin. We receive no reimbursement for administering IV antinausea medication in the office except the cost of the drug. We also do not receive reimbursement for normal saline used in administering chemotherapy or any IV bags under 250 cc. When we receive less from Medicare than what we can purchase the drug, we are forced to have patients treated at a hospital or another facility. Patients are angry about this and I have encouraged them to write you- this needs to be changed. Moreover, mistakes are much more likely to occur when patients are outside our offices. Chemotherapy mistakes can be fatal. Although the changes for 2004 are substantial and detrimental to patients, the current plans for 2005 and beyond pose many more problems. As you know, for 2005 a new system is being introduced which has not been tested before, namely, the ASP system. Oncologists, as I understand, will be able to increase drug prices by 6% but no one really knows what ASP means and its unclear whether or not myself and people like myself will be able to acquire the drug at ASP or even close to ASP. Also the ASP methodology includes receiving drug information from wholesalers and non Medicare Part B providers to determine ASP. Obviously, i cannot be expected to deliver chemotherapy at a loss in the office. This obviously untenable and I will be forced to have patients treated at other facilities. Patients will be unhappy and more mistakes will be made. It is amazing to me how little this markup is and what it is expected to cover. This 6% markup, assuming we can get the drug for an ASP price, is far from adequate as it does not allow for wastage, storage problems, handlilng and the overall overhead involved with obtaining, storing and safely administering chemotherapy. Also many of the increases in reimbursement for chemotherapy administration will be slowly taken away in 2005, further in 2006, etc. I know there are major budgetary issues that our Country must face. All of us must make sacrifices but I am very concerned for patient care. I think there will be invariably more mistakes with drugs that are very toxic and potentially could cause great harm to patients. If reimbursement is inadequate, there may be shortages of chemotherapy drugs. Ironically, this potential disaster may occur just as we are making such incredilbe strides in cancer treatment.

CMS-1372-IFC-25

Submitter : **Dr. David Hetzel** **Date & Time:** **03/04/2004 12:03:00**

Organization : **Hope:A Women's Cancer Ctr**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am sending this comment regarding CMS-1372-FC and how the most recent changes to Medicare reimbursement are impacting my private practice. I fully support Medicare reform, in fact health care in general, but need to convey the fact that several chemotherapy drugs that I administer to patients are being reimbursed at less than typical acquisition costs. I am a gynecologic oncologist that treats women's cancer. There are several drugs on a national arena that show inadequate reimbursement rates such as Carboplatin, Hycamtin, Gemzar, Doxil, and Novantrone. When combined with supplies that are not reimbursed including fluids and syringes (they don't come for free), it further demonstrates that if this is not amended we will be forced to send our patients elsewhere for treatment or be unable to provide the quality of care they deserve. We have reevaluated our patients and have already had to outsource some of the treatments if the only payor is Medicare. We have also taken in consideration that there was a increase to infusion codes but 2005 will show a 29% decrease in our services reimbursement. Ultimately, our hands will be tied. The unfortunate reality is that some of our patient's actually travel 2 hours one way to get here because we are the only practice in 16 counties. If the hospital cannot or will not take this overflow what will happen? Thank you for your attention. David J.Hetzel, MD

CMS-1372-IFC-26

Submitter : Mr. ABE MOSHEL **Date & Time:** 03/04/2004 12:03:00

Organization : HEMATOLOGY ONCOLOGY ASSOCIATES

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

The proposed reimbursement cuts scheduled to take place in 2005 will make the provision of oncology medical care in the community setting, a service of the past. Trying to manage budget deficits on 4,900 medical oncologists in the entire USA is unconscionable. Yes the checks we receive from Medicare are large in dollar volume but there is little room for adjustments. Our practice of 3 MDs employs 6 fulltime and 2 perdiem RNs. The personnel cost for an Oncology certified RN is $100,000 including benefits. They are worth every penny. Closing down of community practices will force patients back into hospitals at much greater cost to Medicare. One of our patients was admitted to a hospital and none of the nurses was familiar with port access. They stuck his arms innumerable times for vein access and he looked like an elephant upon discharge. When our patients have a fever or anemia we can treat them at a fraction of the cost of a hospitalization. Chemotherapy and administration costs are much lower in the community setting. Obscene profits are not being earned by the oncology community but by the insurance industry. Modern Healthcare reported on January 26, 2004, that United Healthcare Insurance earned $1,830,000,000 (1.83 billion dollars) PROFIT in 2003. This is obscene, especially when they are underpaying Medicare reimbursement by 50% to community oncology practices. A living reimbursement must be given to physicians. ASP plus 6% (incorrectly including 3% earned by wholesalers), joined with a 24% decrease in administration fees will not generate sufficient cash flow for this practice to remain viable.

CMS-1372-IFC-27

Submitter : Mr. craig scott

Date & Time: 03/04/2004 12:03:00

Organization : Santa Barbara Hem Onc Med Group

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

the new reimbursement rates have changed how we take care of the patients, we are putting patients in the hosptial for many treatments that would have been done in the clinic, for less money to medicare and we think a safer procedure to the patient, for that is all we do in our chemo area. The patients don't like going to the hospital because we know their history, there chance of reaction etc and they know and trust us. We explain to them that we are not able to take an out of pocket expense for their treatment. We are uncertain however whether they pay more in the hospital through their insurance or just medicare. But it seems to be the wrong way to try to treat patients to me. With Medi-Medi patininets nearly all patients who want treatment will have to go to the hospital, only some straight medicare patients will go into the hospital to be treated. NExt year we contemploate that the straight Medicare patients will mostly go into the hospital, depending on what you ultimately decide....

CMS-1372-IFC-28

Submitter : Mr. Bud Rogers **Date & Time:** 03/04/2004 12:03:00

Organization : Broome Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

With the changes to cancer drug payments in 2004, our oncology practice will have a 15.8 % decrease in collections in 2004, even when we take into account the increases in drug administration payments. This will have a negative effect on our practice. In 2005, we will not be able to survive with drugs being paid at ASP + 6%. National estimates are that revenue will decline by 29% in 2005. We think it will actually be much greater than that based on the drop in revenue we are already experiencing in 2004. We suggest you transition these changes in drug reimbursement at a slower rate and collect real data on how this is effecting oncology practices. We do not believe that you want to destroy oncology practices across the country. The current proposals for 2005 and beyond will force us, and other oncologists to stop treating patients - then where will they go? to hospitals which are not ready to treat them and where it is more expensive to treat them. Access to comprehensive cancer care could become a real problem
In the first quarter 2004, we have 9 chemo drugs that are reimbursed below our cost. We understand that this will not be corrected until April 2004. That is a hardship on us and other oncology practices. We have a pharmacist, phar. tech, social worker and chemo certified RNs that we will have to look at to see if we will be able to keep them employed. But it will be the patients who will have to pay the price by not having these professional staff involved in their care.
Our biggest concern is what will happen in 2005 and beyond. If you keep that ASP, it needs to be correctly defined based on what we have to actually pay for the drugs. ASP plus six percent is not adequate. It would be much more reasonable to have ASP plus 12 %. We suggest you look to ASCO for direction on what is adequate reimbursement for drugs, their administration and support for all the other needs that cancer patient have. Again, payment for drugs must be based on what we are actually paying for drugs plus a reasonable percent.
In summary, please do not implement these sweeping decreases in reimbursement that will create problems with access to modern cancer care and treatments. Instead, gradually implement your reimbursement changes over several years and utilize real life data based on the impact these changes will have on oncology practices. We recommend that you work closely with ASCO to accomplish this. Based on the real decreases in reimbursement that we are seeing in 2004, we know that 2005 will only maginfy the problems for our oncology practice and force us to seek ways to cut our social work, pharmacy and RN staff to the detriment of patient care.
Thank you for the chance to comment on your proposals.

CMS-1372-IFC-29

Submitter : Mrs. Kristine Hartigan **Date & Time:** 03/04/2004 12:03:00

Organization : Redwood Regional Oncology Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir, Re CMS-1372-FC
I know what you know, Medicare does not have the funds to keep up with the demand of medical care needs for its enrollees. As the 77 million baby boomers hit Medicare eligibility age in the next few years this will only worsen.
The Medicare Prescription Drug Improvement and Modernization Act passed in 2003 has devastating reimbursement cuts that effect cancer patients beginning this year and worsening in 2005 and 2006. You set reimbursement of several drugs below acquistion price. Desferal, Interferon, Irinotecan, Sandostatin LAR, Pentostatin and Streptozocin are examples of drugs that cost us more to purchase than you reimburse. These patients are having to go to the hospital to receive these drugs. We know that your costs are even greater when you pay for this care in the hospital setting. In addition, the burden on patients to have to go to the hospital, process through all the complexity of checking in, etc. is insanity. Especially given that an incredibly well organized system is in place for the patients to receive the treatment in their Oncologist's office. The first things we are having to cut this year to out-pt cancer care in the community setting are things like paying licensed Therapists to facilitate support groups for patients and families; significant decreases in our subsidies of the cost of running clinical trials in our community (we have an NCI funded CCOP but we subsidize the funding to the tune of $200,000 a year); to decrease operating costs of our out-patient chemotherapy infusion centers we have to now force patients to come at specific times of day for treatment in order to achieve efficient utilization of all the resources it takes to operate the infusion centers - this is very difficult for patients and those they depend on, family/neighbors/friends, to drive them to the infusion center for treatment. In the past we were able to always accomodate the patient's needs which often could lead to nurses staying at work on overtime,etc. We no longer can afford to do this.
The nursing shortage, particularly bad in California, creates tremendous challenge for us to employ the RNs to administer the chemotherapy. Having to compete with high salaries that hosptials pay is impossible and now with less reimbursement coming in this will magnify the problem. Without specially trained RNs patients cannot safely receive chemotherapy treatments. It takes 6-12 months to train a RN to the point that he/she can carry a patient load. This is a huge financial burden to the Oncology practice.
The analysis of the 2005 and 2006 reimbursement changes in the law will mean millions less in reimbursement. The reality is, patients who do not have secondary insurance to their Medicare cannot pay the 20% of Medicare's allowable. We carry tremendous "bad debt" to be able to treat patients. While Medicare is not set up to cover 100% of the allowable, you need to know that the "profit" we use to get on drugs was used to help offset this loss. We will no longer be able to carry the loss without jeopardizing our ability to pay our bills, salaries, etc and remain open to serve the cancer patients in our communities.
By the end of this year we will be forced to close some of our offices. Currently we serve cancer patients in six different communities, in 4 counties in Northern California. One of those areas is a rual community with a large percentage of uninsured and underinsured people. The loss of that office will mean loss of access to cancer care as those people have no ability to travel the 90 minutes to the nearest cancer care facility. The local hospital in that community tells us they are unable to serve these patients at this time.
In the 31 years I have been an oncology nurse, I never thought it possible that cancer care would come to a point when there are therapies available but not the money to pay for it. We need you to do better for our citizens.
Thank you.

Submitter : Mrs. aleta kilborn **Date & Time:** 03/04/2004 12:03:00

Organization : maine center for cancer medicine

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS Decision Maker,
I would like to take this opportunity to comment on the Interim Final Rule with Comment Period CMS-1372-FC, "Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004," published in the January 7, 2004 Federal Register (hereafter the "Interim Final Rule"). Specifically, I would like to address my urgent hope that the Centers for Medicare & Medicaid Services (CMS) will take all possible steps to ensure that cancer care does not fall off the reimbursement "cliff" currently embedded in Public Law 108-173, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).
I am deeply concerned about what will happen to access to cancer care in 2005 when the transitional adjustment for drug administration services is dropped precipitously. As you know, MMA established a 32% transitional adjustment level for 2004, which then drops to 3% in 2005 and is completely eliminated in 2006. At the same time, drug reimbursement levels are set to be further reduced by the switch to ASP reimbursement.
I understand that CMS does not have the authority to change the fact that Congress established a steep drug administration services transitional payment schedule or mandated work GPCI adjustments that are temporary. I am, however, extremely concerned about the adverse impact that the payment reductions flowing from these statutory provisions, coupled with the reductions inherent in the planned changes in drug reimbursement methodologies beginning in 2005, will have on cancer care and patient access.
Like many, I appreciate Congress' willingness to include provisions in MMA calling for a number of studies designed to assess such unintended consequences of the legislation. I fear, however, that none of the Congressionally mandated studies will be completed in time to protect patients who face access problems in 2004 and 2005 because of MMA changes.
As a result, I encourage CMS to begin a dialogue with patient advocacy groups working to identify any developing access problems in 2004. I would also like to recommend that the agency begin using its website and other outreach initiatives to monitor the impact of MMA so that it can make changes in the discretionary rules implementing the law, if necessary. CMS also should assume responsibility for alerting Congress to impending problems requiring a legislative fix before the mandated reports are ready.I
n light of this situation, the American Society of Clinical Oncology (ASCO) has adopted a policy position that Congress should enact legislation in 2004 that would revise the MMA's transitional adjustment payment for drug administration services to an amount that will maintain the net revenue available to physicians from 2004 payment policy to drugs and drug administration services in 2005 and 2006. ASCO has also called on Congress to create an exceptions or similar process under which CMS would be required to ensure that the payment amounts for drugs in 2005 and later years are sufficient to cover the costs that physicians incur in purchasing the drugs.
I am grateful for your consideration of my concerns and would like to extend my appreciation for your efforts to implement MMA in a manner that strengthens patient access to covered drugs.Respectfully submitted,
Aleta M. Kilborn
100 Campus Drive
Scarborough, Maine 04074

CMS-1372-IFC-31

Submitter : **Dr. Robert Folman** **Date & Time:** **03/04/2004 12:03:00**

Organization : **N/A**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,
I am writing you as a medical oncologist in private practice to comment on CMS-1372-FC. I should first tell you that I agree with the concept of reforming the system for cancer chemotherapy reimbursement and that I believe that reimbursement should be based on average sale price (ASP) rather than average wholesale price (AWP.) The changes effected in 2004 have not prevented me from treating Medicare patients in my office. Some drugs however were being reimbursed below my cost. For example, initially my group sent patients requiring gemcitabine or irinotecan to the hospital outpatient department to receive their treatment there rather than elect to subsidize the treatment ourselves (a typical dose of irinotecan would cost us $64 to administer, after reimbursement.) However, we decided to accept the loss and cover it with the revenue provided by the drug administration charges. We hated to send our elderly patients to the hospital. It was a great inconvenience for some of them. We changed our policy early in the month of January. A number of other drugs are being reimbursed below their cost. At times this may encourage physicians to favor the use of more expensive alternative drugs because of their inherent profitability. Each dose of Neupogen that I administer costs me a few dollars. I sometimes have to decide between giving a few doses of Neupogen (and billing $344 per dose) or just giving one dose of Neulasta, which generates a $130+ profit, is convenient for my patients, and results in billing Medicare $3000. This is illogical. The fact that patients requiring Neupogen have to come to my office each day to receive it rather than self-administer it at home is also absurd. It greatly inconveniences them, sometimes impeding the quality of their care, and it results in unnecessary drug administration fees for Medicare. On weekends, it makes it necessary for them to go to the hospital for a subcutaneous injection. Patients should be allowed to self-administer growth factors provided by a physician's office.
Many of the drugs that we now administer are being given at our cost - with no real profit. We can only continue to do this because of the revenue received for drug administration services. We need this to cover the many costs associated with our ability to provide these treatments, to bill for them, and then successfully collect what we are owed; not to mention the unreimbursed educational, counselling and supportive services that we provide all of our patients as they cope with this devastating disease.
We understand that this 32% increase in reimbursement for services will be cut back by 29% next January and anticipate that ASP + 6% drug payments will be no better than what we currently receive. It is important for you to understand that removal of these service reimbursements will likely lead to the return of my patients to the hospital for their care - a burden that my hospital will not be able to handle. The provision of chemotherapy in the community setting must be supported. This is a worthwhile service that physicians can provide in their office clinics more effectively and more economically than is possible in most hospitals.
I hope you will consider some of these comments. I thank you for taking the time to read them.
Most sincerely,
Robert S. Folman, MD

CMS-1372-IFC-32

Submitter : Dr. Vance Browne **Date & Time:** 03/03/2004 12:03:00

Organization : Florida Cancer Specialists

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

The new payment schedule by Congress will change the face of Oncology in a negative way. The new fee schedule have essentially made the use of older medications unprofitable and in some cases an actual loss, and so there is a rush to use newer and more expensive medications which are still paid at 95% AWP. This will push up the cost of care overall.The system should reward the use of older medications if equivalent in efficacy. Why can't Medicare pay fairly for services rendered and not ' nickel and dime' the system to death?. To refuse to pay for chemotherapy on the day a patient sees the doctor does not mean you won't pay. It means the patient will come back another day for treatment. There is no 'free lunch'. Medicine, like everything else is a business. It has to be profitable. It also has to have fair reimbursement. If Medicare would stop playing games with the fee schedule and reimburse fairly for services rendered, then the current poisionous atmosphere where physician is viewed as the enemy and a racketeer will improve, as would the delivery of care to the patient As long as Medicare continues to scapegoat doctors and take action that tries to avoid fair payment for services rendered, the current mayhem will continue.

CMS-1372-IFC-33

Submitter : **Dr. Dean Tsarwhas** **Date & Time:** **03/03/2004 12:03:00**

Organization : **North Shore Oncology Hematology Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for full comments

Department of Health and Human Services
Centers for Medicare and Medicaid (CMS)
7500 Security Blvd
Baltimore, Maryland 21244

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CMS-1372-IFC-34

Submitter : Dr. Dean Tsarwhas **Date & Time:** 03/03/2004 12:03:00

Organization : North Shore Oncology Hematology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See new attachment

Department of Health and Human Services
Centers for Medicare and Medicaid (CMS)
7500 Security Blvd
Baltimore, Maryland 21244

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CMS-1372-IFC-35

Submitter : **Dr. Dwight Oldham** **Date & Time:** **03/03/2004 12:03:00**

Organization : **Lynchburg Hematology Oncology Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mr. Dennis G. Smith
Acting Administrator Centers
For Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1372-FC
P.O. Box 8013
Baltimore, Maryland
21244-8013
Dear Mr. Smith:
I am the managing partner for Lynchburg Hematology Oncology Clinic, a five physician group of medical oncologists practicing in Lynchburg, Virginia. We are the only providers of medical oncology services in the Lynchburg area. I am writing with comments regarding CMS-1372-FC Medicare program changes to Medicare payment for drugs and physician fee scheduled payments for calendar year 2004. We have compared reimbursement to our practice under the new fee schedule versus our reimbursement in 2003. We do not believe this is a revenue neutral rule. We estimate our reimbursement to decrease by four hundred and forty four thousand dollars in 2004 or approximately eighty thousand dollars per physician. There are five drugs where reimbursement is less than actual invoice costs and these include Carboplatin, Gamimune, Doxorubicin, Camptosar and Faslodex. As you know, Medicare does not pay all of the drug costs. They pay 80% and we are responsible for collecting the additional 20%. We practice in a rural area where approximately 20% of our Medicare population has no co-insurance. Our actual collections for drugs average 92% of allowed charges. Using this formulation, there are additional drugs where we are paying drug companies more than we are collecting. These include Gemcitabine, Rituxan, Herceptin, Velcade and Epirubicin. Because of these decreases in reimbursement, we have begun to admit a small number of patients to the hospital for treatment. These are patients who are receiving expensive therapies, who do not have co-insurance. We also would comment that while 2004 is causing some disruptions, the outlook for 2005 is significantly worse. While it is not absolutely clear to us what average sales price or ASP would be, it would appear likely that most drugs will be reimbursed less than our costs. We are currently spending nine million dollars a year on drugs at our practice and even relatively small losses on any given drug are going to translate into very substantial dollar losses very quickly. Given that reimbursement for chemotherapy administration services is also supposed to decrease, it is apparent that next year is going to be very difficult. We had been negotiating with the local hospital regarding building a cancer center and we have just finished notifying them that we are going to be unable to proceed with that. Continuing our practice under its current organization of a independently owned entity is going to be impossible with the regulations for 2005 are implemented as currently worded. Our choices are going to be to either allow Medicare patients to leave the area or to consider selling or merging our practice with an entity that can offset losing money on providing chemotherapy services with revenue from other areas. Possible buyers would include the local hospital or a national company such as U.S. Oncology . We are currently evaluating those options.
Page 2
Thank you for your attention.
Sincerely,
Dwight S. Oldham, M.D.
DSO/rtg

CMS-1372-IFC-36

Submitter : Dr. Dean Tsarwhas **Date & Time:** 03/03/2004 12:03:00

Organization : North Shore Oncology Hematology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See updated attachment

Department of Health and Human Services
Centers for Medicare and Medicaid (CMS)
7500 Security Blvd
Baltimore, Maryland 21244

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Submitter : Mrs. Jane Steinkamp **Date & Time:** 03/03/2004 12:03:00

Organization : Oncology Hematology Associates of West Broward, PA

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I can not believe that CMS would give us a 32% increase for our chemo admin charges to help defer the loss in the sub-standard reimbursement for chemotherapy drugs and then take 29% of it back the next year. I am an Administrator for a practice and we are making only pennies on the drugs we are administering through our office. Something that has been completely eliminated in your drug analysis is the inventory, proper care & temperature of the drug, time to mix the drug for each individual patient by a professional that the practice must employ. The time for quality patient care, & patient and family education has been totally omitted when you think of your 29% cut in chemo administration for 2005. How can you make decisions that affect millions of patients and could very likely put the medical oncologists out of business to supply patient care without understanding all of the hidden overhead costs and time that goes into chemo administration. These patients need a tremendous amount of care, education, support, and time.

Oncologists are not looking to be unfair in anyway, but having practiced oncology, supporting patients, and realizing the time and money involved to bring new drugs to the marketplace we also know that our profit margins are much slimmer than you calculate. The additional staff, space, and equipment that oncology must maintain carries far higher overhead costs than any other specialty. Before you make a decision that could be catastrophic to oncology patients and to the entire medical oncology delivery system you need to be more educated in your decisionmaking. Once you make a poor decision and the industry falls apart it will not be easy to rebuild knowledgeable staff, facilities, and physicians.

IS THAT WHAT YOU TRULY WANT FOR THE PATIENTS IN THE UNITED STATES OF AMERICA? Please do not reduce our medical delivery system, research, and quality of life down to a socialized medical system that the rest of the world DOES NOT enjoy. We have always been better than that and provided the citizens of this country with better than that.

CMS-1372-IFC-38

Submitter : **Mr. Richard Lam** **Date & Time:** **03/03/2004 12:03:00**

Organization : **N/A**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Congressperson:
The proposed changes in physician re-imbursement for practicing oncologists will deeply affect patient care. As an oncologist specializing in the care of prostate cancer patients, I devote a tremendous amount of un-reimbursed time outside the office setting (phone calls, house calls to long distances, coordinating care with other physician specialist/ancillary services).
We not only treat the ill patients, but we spend just as much time (free) treating and helping the family members cope with the hardships. We are able to continue this high level of care under the current system. However, if the oncology drug costs are not re-imbursed fairly, then we will be operating at a loss and therefore will have to cut back drastically, the extra time and energy we devote to our patients.
Please take my humble comments seriously and not allow the pending cut-backs take effect.
Thank You
Richard Lam

Submitter : Dr. Kasra Karamlou **Date & Time:** 03/03/2004 12:03:00

Organization : Oregon Hematology Oncology Associates, PC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This letter is in response to the request for comments regarding CMS-1372-FC, Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004. I am a medical oncologist in practice in Portland, Oregon. I belong to a multi-physician, single specialty group owned by 7 of the physicians of the practice. We have 8 sites in the Greater Portland area, 12 physician providers and 4 nurse practitioners, and employ approximately 125 other employees including nurses, medical assistants, medical technologists, billers, receptionist/schedulers, etc.
As an oncologist in a community-based practice, I support balanced Medicare reform that appropriately reimburses for both oncology drugs and medical services for cancer patients in my practice. However, the changes that have been proposed are being implemented as a result of the Medicare DIMA of 2003 will continue to be detrimental to my ability to continue to provide care for Medicare patients in my office. With the change in drug reimbursement from 95% of AWP to 85% of AWP (or less in several cases), there are many drugs where reimbursement is less than our acquisition cost for the drug. The list is as follows:
List of Drugs Reimbursed At or Below Acquisition Cost (*=per Noridian information, **=per Medicare information as published in the Federal Register as of 2/5/04, ***=per both Noridian and Medicare information)
Arsenic trioxide (Trisenox)*
Phytonadione (Aqua Mephyton)*
Carboplatin (Paraplatin)*
Ranitidine (Zantac)*
Ceftazidime (Fortaz)*
Sodium Bicarbonate*
Cytarabine Liposome (Depocyt)*
Sodium Chloride*
Dactinomycin (Cosmegen)*
Sodium Thiosulfate*
Denileukin (Ontak)*
Testosterone Cypionate*
Dexamethasone (Decadron)*
Testosterone Enthanate*
Fluconazole (Diflucan)*
Thyrotropin (Thyrogen)*
Hydrocortisone Sodium Succinate (Solu-Cortef)*
Interferon alpha 2a (Roferon)***
Lorazepam (Ativan)*
Magnesium sulfate*
Medroxyprogesterone acetate (Depo-Provera)*
Meperidine (Demerol)*
Mesna (Mesnex)**
Methylprednisolone Sodium Succinate (Depo-Medrol)*
Metoclopramide (Reglan)*
Morphine Sulfate*
Nandrolone (Deca Durabolin)*
Octreotide LAR (Sandostatin in LAR Depot)***
Panhematin (Hematin)**
This ?upside down? reimbursement situation makes it impossible to provide care for patients in my office for those drugs.
The increase in reimbursement for services in 2004 has helped to offset the decrease in drug reimbursement. Although it still does not cover total costs to provide services to patients, I believe it is a step in the right direction to fairly pay for all of the essential services required for my Medicare patients with cancer and hematological diseases. I strongly suggest additional identification of actual and current costs on which to base future

practice expense decisions. I have participated in submission of actual cost data through membership in such organizations as Community Oncology Alliance and ASCO.
I am very concerned about reimbursement for services in 2005. If the service reimbursement is decreased to 2003 levels by taking away the transitional year increase and projections related to ASP + 6% for drug reimbursement are realized at a reduction to my practice of over 17% of profit, I will not cover my costs and will not be able to treat Medicare patients in my office. The drug reimbursement at ASP + 6% is also of concern to me for 2005 and beyond. ASP has not been well-defined and the other purchasers of drugs who might affect the average sales price are not and have not been paid previously under the same Part B Medicare system as physicians practices (such as hospitals, the Veteran?s Administration, etc.). Furthermore, I have estimated the cost of acquiring drugs to be ASP + 12% in order to cover the cost of procurement, storage, waste, inventory, etc. This substantial decrease in drug reimbursement in 2005 is of great concern for the practice.
Regards, Dr. Karamlou

CMS-1372-IFC-40

Submitter : Dr. Fred Ey **Date & Time:** 03/03/2004 12:03:00

Organization : Oregon Hematology Oncology Associates, PC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This letter is in response to the request for comments regarding CMS-1372-FC, Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004. I am a medical oncologist in practice in Portland, Oregon. I belong to a multi-physician, single specialty group owned by 7 of the physicians of the practice. We have 8 sites in the Greater Portland area, 12 physician providers and 4 nurse practitioners, and employ approximately 125 other employees including nurses, medical assistants, medical technologists, billers, receptionist/schedulers, etc.
As an oncologist in a community-based practice, I support balanced Medicare reform that appropriately reimburses for both oncology drugs and medical services for cancer patients in my practice. However, the changes that have been proposed are being implemented as a result of the Medicare DIMA of 2003 will continue to be detrimental to my ability to continue to provide care for Medicare patients in my office. With the change in drug reimbursement from 95% of AWP to 85% of AWP (or less in several cases), there are many drugs where reimbursement is less than our acquisition cost for the drug. The list is as follows:
List of Drugs Reimbursed At or Below Acquisition Cost (*=per Noridian information, **=per Medicare information as published in the Federal Register as of 2/5/04, ***=per both Noridian and Medicare information)
Arsenic trioxide (Trisenox)*
Phytonadione (Aqua Mephyton)*
Carboplatin (Paraplatin)*
Ranitidine (Zantac)*
Ceftazidime (Fortaz)*
Sodium Bicarbonate*
Cytarabine Liposome (Depocyt)*
Sodium Chloride*
Dactinomycin (Cosmegen)*
Sodium Thiosulfate*
Denileukin (Ontak)*
Testosterone Cypionate*
Dexamethasone (Decadron)*
Testosterone Enthanate*
Fluconazole (Diflucan)*
Thyrotropin (Thyrogen)*
Hydrocortisone Sodium Succinate (Solu-Cortef)*
Interferon alpha 2a (Roferon)***
Lorazepam (Ativan)*
Magnesium sulfate*
Medroxyprogesterone acetate (Depo-Provera)*
Meperidine (Demerol)*
Mesna (Mesnex)**
Methylprednisolone Sodium Succinate (Depo-Medrol)*
Metoclopramide (Reglan)*
Morphine Sulfate*
Nandrolone (Deca Durabolin)*
Octreotide LAR (Sandostatin in LAR Depot)***
Panhematin (Hematin)**
This ?upside down? reimbursement situation makes it impossible to provide care for patients in my office for those drugs.
The increase in reimbursement for services in 2004 has helped to offset the decrease in drug reimbursement. Although it still does not cover total costs to provide services to patients, I believe it is a step in the right direction to fairly pay for all of the essential services required for my Medicare patients with cancer and hematological diseases. I strongly suggest additional identification of actual and current costs on which to base future

practice expense decisions. I have participated in submission of actual cost data through membership in such organizations as Community Oncology Alliance and ASCO.
I am very concerned about reimbursement for services in 2005. If the service reimbursement is decreased to 2003 levels by taking away the transitional year increase and projections related to ASP + 6% for drug reimbursement are realized at a reduction to my practice of over 17% of profit, I will not cover my costs and will not be able to treat Medicare patients in my office. The drug reimbursement at ASP + 6% is also of concern to me for 2005 and beyond. ASP has not been well-defined and the other purchasers of drugs who might affect the average sales price are not and have not been paid previously under the same Part B Medicare system as physicians practices (such as hospitals, the Veteran?s Administration, etc.). Furthermore, I have estimated the cost of acquiring drugs to be ASP + 12% in order to cover the cost of procurement, storage, waste, inventory, etc. This substantial decrease in drug reimbursement in 2005 is of great concern for the practice.
Regards,
Dr. Fred Ey

CMS-1372-IFC-41

Submitter : **Dr. anthony coscia** **Date & Time:** **03/03/2004 12:03:00**

Organization : **norwalk medical group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

i appreciate the work done by congress in preserving cancer care in 2004. the changes in administration reimbursement codes help offset the decreased payments for medications and allow us to remain fiscally sound rather than going out of business. however, even now many drugs that are exceptionally expensive, such as carboplatinum, taxotere, rituxan, gemzar to mention a few, are reimbursed at or nearly at cost. life would be simple if we got paid on each and every drug with just a small mark-up above cost. but there are many other costs that go into providing a drug beyond the cost of the drug. factors such as patients being poor and not having secondary insurance or assets results in our losing the 20% copay since medicare pays for only 80% of its approved charges; patients in nursing home, because of a crazy quirk in medicare, are allowed coverage for some but not all chemo drugs and supportive care drugs in our offices which often results in major losses to us; errors on medicare's part or our part resulting in underpayment of medicare payments to us; non coverage for off label use of drugs for which there is lots of data proving its value but it's not covered unless it's listed and therefore approved in various official publications; the list can go on and on as to why just reimbursing us our costs or slightly above (as is planned for 2005 and often happens now in 2004 with reimbursement at 80-85%AWP) is a receipt for financial disaster especially when infusion/administration code reimbursement is decreased more than 20% in 2005. we need a reasonable mark-up of at least 12% over average selling price in order to remain financially sound, and we must maintain our current reimbursement rates for administration services at the 2004 level. otherwise, the crisis of late 2003 re: the future of outpatient chemotherapy services will repeat itself in the fall of 2004. thank you.
anthony g. coscia, md

CMS-1372-IFC-42

Submitter: Ms. Joan Zaro
Date & Time: 03/05/2004 12:03:00
Organization: The Endocrine Society Association
Category: N/A
Issue Areas/Comments GENERAL

See attached comment letter

Department of Health and Human Services
Centers for Medicare and Medicaid (CMS)
7500 Security Blvd
Baltimore, Maryland 21244

Below you will find a brief explanation why an attachment can not be provided at this time on a particular document at this time, which was as indicated by the commenter. If you wish to view those attachments that have not been posted, please call CMS at 410-786-9994 or 410-786-7195 Monday through Friday to schedule an appointment.

1. The commenter failed to complete all steps required in order to process their comments. All required fields must be completed in order to attach an attachment.

2. The commenter was referring to another comment received, but did not attach the information they were referring to.

3. The commenter intended to attach more then on attachment. But for some reason, CMS only received one or neither of their attachment.

4. The commenter provided sensitive information, that CMS felt was inappropriate to be posted on the web site.

CMS-1372-IFC-43

Submitter: Mrs. Carol VanSickle
Date & Time: 03/05/2004 12:03:00
Organization: Purchase Cancer Group
Category: Congressional
Issue Areas/Comments: GENERAL

I work in an oncology practice, my patients are voicing concerns and worries regarding the Medicare cuts and already changes to their treatments. They find cancer treatment hard enough without having to start over at another facility and some have even considered stopping treatment as a result. They want to stay where they start and just get through it. They need our support and understanding in going through such a traumatic experience without worrying about how to pay for it. Please think twice about the Medicare cuts for oncology.

Everyone knows someone affected with cancer, this is a major problem.

Sincerely,
Carol VanSickle

CMS-1372-IFC-44

Submitter: Ms. SANDRA RODGERS
Date & Time: 03/05/2004 12:03:00
Organization: PURCHASE CANCER GROUP
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

I am asking CMS on behalf of our cancer patient's to remove the cancer care cuts out of the Medicare prescription drug package. This is the only way to ensure the senior's will continue to receive the proper care, and to receive the appropriate drugs that their type cancer requires. The 2004 cuts have been devastating enough for them, some not being able to receive their treatment in the office setting by professional oncology nurses as they have been use to. Some having to go to the hospital, setting where they have to wait for hours just to receive their treatment. Our patients are usually weak and not feeling well and they are having to leave our comfortable office setting to go over to a hospital
and wait for hours somtimes, for their treatment. This is very heart breaking to watch, and to know it's only going to get worse if something isn't done in 2005. We need to strengthen cancer care, not dismantle it. we need real medicare reform that addresses concerns without endangering senior's from receiving the cancer drugs and care they so deserve and have been used to. Please, do not let these drastic oncology cancer cuts remain in the medicare prescription drug bill. Truly reform medicare, not criple it. These cancer patient's are in your hands. Please protect them.

Respectfully,

Sandra Rodgers

CMS-1372-IFC-45

Submitter: Dr. David Clarkson
Date & Time: 03/05/2004 12:03:00
Organization: Radiation Therapy Oncology
Category: Physician
Issue Areas/Comments: GENERAL

Regarding CMS-1372-FC,

Several drugs are currently reimbursed below my cost: Zometa, Leukine, Carboplatin, 5-Flourouracil. The 29% reduction in administrative fees due in 2005 will not support the nurses needed to provide good care to patients in my office. The "transitional" 32% increase in administration fees for 2004 should remain in place if oncologists are going to be able to pay support staff. We can not provide care for patients in our offices without these individuals as their contribution is invaluable.

In the past, I have never felt the need to ask about a patient's insurance because I wanted to treat all patients equally. Now, with current Medicare changes, I am forced to identify Medicare patients. This is because I have to consider, not if I will make money but, if my costs for the treatment that I feel is medically appropriate are going to be reimbursed. Almost without exception, I lose money treating patients in my office who have Medicare and who can not afford their co-pay or do not have secondary insurance. I believe this is wrong for myself and the patients I care for.

I invite you to review my costs and come to my clinic to see what is done here for our patients. These people need and deserve quality care and this is being jeopardized by current trends. Please consider making changes to the current Medicare reimbursements for cancer care before it is too late. Let me know if you have any recommendations on how to deal with this issue that I may have overlooked.

Thank you.

Dr. David Clarkson

CMS-1372-IFC-46

Submitter: Dr. Denis Fitzgerald
Date & Time: 03/05/2004 12:03:00
Organization: Hematology Oncology of CNJ
Category: Congressional
Issue Areas/Comments GENERAL

The revision in the drug pricing for chemotherapy will not reimburse practices for the true cost of ordering, inventory and payment. The single vendor idea is a monumental hassle and administrative nightmare and would be wasteful of time as well as wasteful of drugs that are ordered and not used when a regimen changes. We provide counseling services to our patients from our oncology certified nurses. Each nurse spends 2 hours per day calling patients, reviewing side effects, providing nutritional counseling, speaking with families and supporting patients emotionally. These services are not reimbursed. In the metro north east, these nurses with employer taxes, benefits, education, vacation coverage etc cost practices over $50 per hour and that does not include cost of office space, telephone etc. We will have to curtail these unreimbursed services if the 2005 practice expense/ drug administration cuts are not changed. We were to hire another physician associate to help with patient care and anticipated growth based on aging of the baby boomers but cancelled that due to reimbursement issues. The proposed ASP price severely discriminates against small practices and sets the price at the level of the largest few intermediaries who then resell the drugs to the community oncologists. This will result in our practice purchasing drugs at the same cost or with a margin of 1-2% price markup at best which cannot cover the administrative costs of obtaining and paying for them. Many common drugs are now generic(5 FU, leucovorin, etoposide, pamidrinate) and inexpensive so that the cost of obtaining and stocking far exceeds the 1-2% margin. The price of one phone call to order 5FU for 1 month for 15 patients exceeds the margin of that entire amount of our most commonly used drug!! The Medicare reform bill is moving in the right direction but severely curtailing reimbursement for these life saving medications will cause patients to go to overburdened hospital facilities that simply do not have the room or manpower to care for them! Please interpret the ASP to be the price that 90-95% of what oncology practices (NOT INTERMEDIARIES) pay for the drug and support the concept that 12% above ASP is needed to pay for the drug costs alone. This will balance out between the very inexpensive but commonly used drugs where even that percentage is inadequate because of the very low cost and the more expensive drugs where the 12% will pay for the administrative burden of obtaining these drugs. The federal government does not expect its other vendors to supply any product or service at 1% above the vendor's cost of that product and payment for chemotherapy drugs should be treated equitably.

Thank you.
Denis Fitzgerald, MD
Hematology-Oncology of Central New Jersey

CMS-1372-IFC-47

Submitter: Dr. Keith Logie
Date & Time: 03/05/2004 12:03:00
Organization: N/A
Category: Physician
Issue Areas/Comments GENERAL

Dear CMS;

The Medicare reform act for 2004 and 2005 has a progressively negative impact on my ability to practice Medical Oncology and offer treatment to Medicare patients. Most oncology drugs are now breakeven if we collect both Medicare and the 20% coinsurance. As you are aware, many patients do not have coinsurance or their coinsurance does not pay fully on the 20% not covered by Medicare. This places my practice in a position in 2004 of having to pay out of pocket for these patients. Hospitals are not willing to accept these patients. In 2005, the cuts become even more drastic in drug and infusion revenue. The risk of treating Medicare patients at a loss is very high and will force us to limit our Medicare book of business severely. We often times begin a treatment expecting full payment only to find the patient supplement does not pay fully, the patient cannot meet their copay, drug reimbursement by CMS may be denied or need to be appealed, or the formula for calculating AWP-15% is below our cost (as occurred with taxotere, Gemcitabine and irinotecan thus far this year). Please take this into account when going forward into 2005.

Sincerely,
Keith Logie, MD

CMS-1372-IFC-48
Submitter: Ms. Karen Neihoff
Date & Time: 03/05/2004 12:03:00
Organization : N/A
Category : Individual
Issue Areas/Comments: GENERAL
Please STOP any proposed laws that will keep cancer patients from receiving the best cancer care.

CMS-1372-IFC-49

Submitter: Mrs. Kathey Parker
Date & Time: 03/05/2004 12:03:00
Organization: Highlands Oncology Group
Category: Congressiona
Issue Areas/Comments GENERAL

Please see attached comment letter.

March 4, 2004

Mr. Dennis G. Smith
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1372-FC
P. O. Box 8013
Baltimore, MD 21244-8013

Dear Mr. Smith:

Pursuant to the instructions posted in the Federal Register/Vo. 69, No. 4/Wednesday, January 7, 2004/Rules and Regulation, what follows in this letter are comments regarding CMS-1372-FC, Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004. This letter is written on behalf of the physicians at Highlands Oncology Group located in Northwest Arkansas. We are the only provider of cancer care in this area and fear that, with the new changes to be implemented January 1, 2005, people diagnosed with cancer will have their care severely disrupted or even prohibited.

We have been fortunate to have both Senators Blanche Lincoln and Mark Pryor and Congressman John Boozman visit our practice to see first hand how cancer care is delivered in the community outpatient oncology clinic. There is a concept that oncologists have been overpaid for pharmaceutical drugs when in fact the so called overpayment has been used to provide services previously not otherwise covered or paid by CMS. We support the concept of balance Medicare reform as contemplated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Only with balanced reform will seniors covered by Medicare be ensured the ability to continue to have access to a cancer care delivery system that works very well in the community outpatient setting. We appreciate the effort of CMS in openly talking with the community oncology physicians and advocates in 2003 to understand the service reimbursement increase needs.

Although the 2004 system retains the AWP-based system, there is generally adequate payment for most cancer drugs. However, there are several very commonly used cancer drugs where the reimbursement for these drugs is now less than actual acquisition costs. Some of these drugs for our practice are:

- Carboplatin (Paraplatin)
- Gemzar
- Melphalan
- Ethyol
- IL2 (Aldesleukin)
- Faslodex
- Ontak
- Lovenox

At least two pharmaceutical manufacturers have responded to this situation by lowering prices. We believe that this situation is best addressed by CMS and it was not your intent for reimbursement to be less than acquisition price.

On the services side, the increase for 2004 in no way creates a balance for the decrease in drug reimbursement. There are many areas of cancer care where payment is substantially inadequate or non-existent. To be specific, the planning and management of complicated cancer treatments, complex drug reconstitution services provided by trained oncology nurses and nutritional counseling. The current Medicare payment system has not kept pace with modern-day cancer care and does not pay for all the essential services required by cancer patients.

We understand that CMS welcomes comment on the interim final rule and its implementation for 2004. However, we would be remiss if we did not comment on changes dictated for 2005 and beyond by MMA. We estimate that for 2005, Medicare reimbursement for cancer care will be decreased nationwide by $890 million. This calculation is substantially different than the CBO score for all of Part B, which was a decrease of $200 million. Unfortunately, although we would hope that the CBO score was correct, we trust our estimate because it is based on actual market data. Our practice has performed it own independent analyses and wonder why the national and individual clinic analyses can be so different than the CBO calculations? It is because we are using real market data, especially relating to a realistic estimate of Average Selling Price (ASP), data that is not accessible by CBO?

Relating to drug reimbursement changes for 2005, we are extremely concerned about implementing a system (ASP) this is totally new and untested. There are several key aspects of the ASP system, as currently crafted in MMA, that are flawed and need to be changed:

- ASP will be the basis for reimbursement to community oncology clinics (that are reimbursed under Part B) but the calculation of ASP (As currently contained in MMA) will include purchasers that are not reimbursed under Part B (such as hospital that are reimbursed under Part A). We understand and appreciate the concept of Medicare paying for drugs based on competitive market value, but that value should be based on those providers covered under Part B only.
- ASP as defined in MMA will be a price paid by large purchasing intermediaries (e.g., wholesalers), not community oncology clinics that purchase drugs from these purchasing intermediaries. As such, ASP is a price “one step removed” from community oncology clinics that will be reimbursed based on ASP.
- If ASP (the average or “mean” price) is equal to the median price, by definition at least 50% of the intermediary purchasers will be purchasing at a price above ASP. The percent of community oncologists purchasing above ASP increased when the purchases of large non-Part B providers (hospitals, wholesalers) are included in the ASP formula.
- COA, a large national organization, has calculated that at least a 112% multiplier is required above drug acquisition cost to cover the direct drug costs (storage,

inventory, pharmacy, procurement, capital, waste, and reimbursement) not adequately reimbursed by Medicare.

Using current, actual drug acquisition costs, community oncology clinics have estimated ASP. These analyses arrive at the conclusion that there will be a substantial decrease in Medicare reimbursement in 2005. Given the points made above, theses estimates of ASP are undoubtedly on the high side, thus making the order of magnitude of these reimbursement cuts on the low side.

In addition to the problems with ASP, the transitional increase to services reimbursement will be decreased from 32% in 2004 to 3% in 2005. It is especially disconcerting and perplexing as to why services reimbursement would be increased in 2004 and then decreased one year later when inflation increases.

Certainly, we acknowledge the efforts of CMS to reexamine the payment of services issue and the possible use of existing and new codes to more adequately capture all essential cancer care services rendered; thus, negating use of a transitional payment. We will continue to identify and explain services that cancer patients receive, especially seniors covered by Medicare, and having services more adequately defined by codes – not just lumped under a few codes. We strongly recommend that Medicare reimbursement for services should not be decreased in 2005 until more data and analysis is available.

In summary, there are numerous uncertainties surrounding Medicare drug and services reimbursement for 2005. However, community oncology practices are certain of one thing based on actual market data – the massive, historic cuts to cancer care from Medicare alone will cause access to patient care problems. Unfortunately, because most private (commercial) payors follow the Medicare reimbursement system, there is close to a doubling impact of these cuts as private payors are now pushing for draconian reimbursement cuts. The net result is that the cancer delivery system is at risk and, therefore, the hopes of every American battling cancer or helping a loved one do so, when there are many, many unknowns. It seems as though cancer care has been targeted and is regarded as a way to save the federal budget, but that is just not the case. With cancer claiming the lives of an average of 1,500 Americans daily, how can CMS risk jeopardizing the cancer care delivery system until you have more information?

We welcome the opportunity to work openly with CMS and the Congress in a spirit of cooperation, sharing data and arriving at equitable solutions that maintain the community cancer care delivery system in this country. We need to strengthen cancer care, not dismantle it.

I have personally been involved in the reimbursement discussions since they started in December 2002. I have lost my only brother to cancer and see how the dying process cripples the one with this deadly disease and also the family. The last thing patients need to add to their already existing anxiety is money. My physicians have been very vocal with our state senators and congressman and find it tough to look in the eyes of cancer

patients – who place their lives in their hands – and realize the realities of patient care disruptions that will continue to occur because no clinic can viably provide patient care that is reimbursed for less than cost. One local hospital system has refused since January 1st to treat certain Medicare only patients where we are upside down on costs because they realize they are also upside down on costs. Politics aside, this should not be happening in the United States. Advances in research and treatment options have come so far and we deserve for it to continue.

We understand that CMS has been charged with the task of implementing 2004 Medicare reimbursement changes for 2005 with a mandate in certain areas and discretion in others. The biggest issue facing community oncology clinics across the country is that we need to start planning right now for 2005, especially given the enormity of the cancer care cuts we face. We thank CMS for its openness and cooperation and we pledge the same as we move forward.

Sincerely,

Kathey Parker
Administrator

CMS-1372-IFC-50

Submitter: Dr. Gerald Feuer
Date & Time: 03/05/2004 12:03:00
Organization: Southeastern Gynecologic Oncology, LLC
Category: Physician
Issue Areas/Comments GENERAL

The attached letter comments on "Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004, CMS-1372-FC." We hope these comments provide insight as you contemplate the changes to the Medicare program.