

CMS-1371-IFC-1

Submitter : Dr. Angela Sandlin Date & Time:

Organization :

Category :

02/09/2004 12:02:00

Baptist Hospital Northeast

Individual

Issue Areas/Comments

GENERAL

GENERAL

Please note that the hospital outpatient payment rate of \$37.95 per gram of intravenous immune globulin (IVIG) is far below our hospital's acquisition cost! We cannot afford to obtain, dispense, administer and monitor this treatment for our Medicare patients when the payment is less than the medication costs! Please research the cost of this drug further and adjust the payment rate to a more appropriate amount. Thank you very much.

Angela Sandlin, Pharm.D. Director of Pharmacy Baptist Hospital Northeast email:

asandlin@bhsi.com

CMS-1371-IFC-2

Submitter : Mr. Dennis Jackman Date & Time:

Organization :

Category :

02/09/2004 12:02:00

Aventis Behring

Individual

Issue Areas/Comments

GENERAL

GENERAL

Aventis Behring believes that the following therapies should be classified as sole source as they are all biologics. The Medicare Prescription Drug Improvement and Modernization Act as well as the Social Security Act explicitly state that biologics are to be treated as sole source therapies. J 1563 Immune Globulin, 1g APC 0905 J 1564

Immune Globulin, 10mg APC 9021 J 7190 Factor VIII APC 0925 J 7192 Factor VIII recombinant

APC 0927 J 7193 Factor IX non-recombinant APC 0931 J 7194 Factor IX complex APC 0928 J 7198 Anti-inhibitor APC 0929 P 9041

Albumin (human) 5%, 50ml APC 0961 P 9045 Albumin (human) 5%, 250ml APC 0963

P 9046 Albumin (human) 25%, 20ml APC 0964 P

9047 Albumin (human) 25%, 50ml APC 0965 Q2022 Von Willebrand Factor Complex per IU APC 1618 Our complete comments are attached.

Thank you.

CMS-1371-IFC-3

Submitter : Mr. Christopher Higgin Date & Time:

Organization :

Category :

02/10/2004 12:02:00

POH Medical Center

Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS-1371-IFC Interim Final Rule Part 419 Regarding the ruling I am requesting a re-evaluation of the reimbursement rate. We are currently paying \$37.24 per gram of IGIV and at the \$37.95 reimbursement rate we will not be able to cover the cost of providing IGIV to patients. We have a small but significant number of patients each month who desperately need this agent for treatment of their various conditions. It is an innovative agent which has greatly improved the quality of life of patients who can not get relief with other modalities. Please reconsider the reimbursement rate.
Thank you.

CMS-1371-IFC-4

Submitter : Dr. Dean Tsarwhas Date & Time:

Organization :

Category :

03/02/2004 12:03:00

North Shore Oncology Hematology Associates

Physician

Issue Areas/Comments

GENERAL

GENERAL

Pursuant to instructions posted in the Federal Register published 1/06/04 [FR Doc.03-32322], what follows in this letter are comments regarding Docket ID:CMS-1371-IFC, Medicare Program; Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004. I am writing on behalf of North Shore Oncology Hematology Associates, a six-physician specialty practice in northern Illinois. Please see attached document

ATTACHMENT

March 2, 2004

Mr. Dennis G. Smith
Acting Administrator

Centers for Medicare & Medicaid Services
Department Of Health and Human Services
Attention: CMS-1371-IFC
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Mr. Smith

Pursuant to instructions posted in the Federal Register published January 06, 2004 [FR Doc. 03-32322], what follows in this letter are comments regarding Docket ID: CMS-1371-IFC, Medicare Program; Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004. I am writing on behalf of North Shore Oncology Hematology Associates, a six-physician specialty practice in northern Illinois. We employ fifty clinical and business support staff and have over 432,000 patient encounters per year. Our three offices are dedicated to caring for cancer patients in a compassionate and service-oriented environment close to their homes and places of work.

Our practice understands that changes are needed to the methods that Medicare pays for chemotherapy drugs and that payment for administration services of chemotherapy drugs need to more closely align with the costs involved. However, we have serious reservations and concerns about the provisions contained within the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) pertaining to cancer chemotherapy drugs.

Although the 2004 payment system for cancer drugs retains the Average Wholesale Price (AWP) based model, with payments reduced from 95 percent of AWP to 80-85 percent of AWP, the payment amounts for some drugs are lower than the prices at which we can purchase them. Specific drugs for which we lose revenue on office administration include:

- Doxil: used to treat breast and ovarian cancer
- Gemzar: used to treat pancreatic and lung cancer
- Rituxan: used to treat non-Hodgkins lymphoma
- Hycamtin: used to treat ovarian and lung cancer
- Irinotecan: used to treat colorectal carcinoma
- Novantrone: used to treat breast and prostate cancer

Carboplatin: used to treat multiple cancer types

Lupron: used to treat prostate cancer

Sandostatin: used for carcinoid tumors and chemotherapy related diarrhea

Although the Centers for Medicare & Medicaid Services (CMS), has the authority to increase the payment amounts in such circumstances, CMS takes the position that it cannot legally do so until April 1, 2004. This process is flawed and payment amounts should be revised as soon as possible to allow all physicians to purchase drugs without

incurring losses. There is significant impact on Medicare beneficiary access to care, in that we will no longer be able to treat Medicare patients in the office with these drugs and will need to refer them to the hospital for more costly and inconvenient care.

Regarding chemotherapy services-related reimbursement (chemotherapy administration), the increase payment amounts for 2004 are a step in the right direction for equitable payment for all of the essential services required by seniors covered by Medicare. CMS need to understand that the administration of chemotherapy agents involves highly specialized nurses and pharmacists working with potentially toxic chemicals that require careful storage, handling, reconstitution, and administration to patients with cancer. These patients are looking to us, to our staff, and these chemotherapy drugs to cure their disease, extend their life, or reduce the pain that their cancer is causing. That is why it is especially disconcerting and perplexing to us why chemotherapy services would be increased in 2004 and then decreased significantly in 2005. This is simply not justified.

Finally, we have extreme concerns about implementing a system for reimbursing chemotherapy drugs based on Average Sales Price (ASP), scheduled to take effect on 1/1/05. This is a novel, untested, and methodologically flawed proposal. ASP is not the market price at which our office can purchase cancer drugs. In the cancer drug market, there are large wholesalers and other purchasing intermediaries that purchase the majority of cancer drugs, and resells these drugs to community cancer offices. This means that the ASP represents the average market price available to these purchasing intermediaries and not the average market price available to oncologist's offices. The market price available to our offices would be higher than ASP and we would therefore incur losses. Purchasing intermediaries and hospitals buying larger drug volumes than our offices would be able to purchase drugs below ASP, putting smaller community practices at a disadvantage. In addition basing Medicare drug reimbursement on drug acquisition alone ignores the total drug costs incurred by community cancer offices. ASP +6% does not cover costs of procurement, storage, safe handling, inventory, disposal, billing and reimbursement processing, documentation, pharmacy, overhead and management of these drugs. Conservative estimates from our accountants project that our practice would lose \$2.7 million dollars on an ASP +6% reimbursement system in 2005. If this were to take effect as planned, in order to continue serving cancer patients, we would need to restrict Medicare beneficiary access, reduce our workforce, and refer patients to the hospital for higher cost care.

In summary, we believe that Congress needs to create a process in which CMS would be required to ensure that the payment amounts for chemotherapy drugs are sufficient to cover all the costs that oncologists incur in purchasing these drugs. CMS needs to revise the MMA's transitional payment for drug administration services, which is 32% in 2004, to an amount that will maintain the net revenue available to physicians from drugs and drug administration services in 2005 and 2006 at the same level as 2004. ASP needs to be correctly defined, and a realistic add-on of at least 12% needs to be in place to provide appropriate drug reimbursement.

Thank you for your consideration.

Sincerely,

Dean G. Tsarwhas, M.D.

CMS-1371-IFC-5

Submitter : Mr. Maryann Roefaro Date & Time:

Organization :

Category :

03/04/2004 12:03:00

Hematology-Oncology Associates of CNY

Congressional

Issue Areas/Comments

GENERAL

GENERAL

The proposed Medicare changes for 2005 will be catastrophic for our practice. We are an independent group practice comprised of 11 physicians and we treat thousands of cancer patients per year. Over the last 4 years, we have rendered over 7 million Dollars of free treatment to patients. These patients are on Medicaid, managed Medicaid products, or do NOT have insurance. We gladly give of our time and talents - but we have paid for over a million dollars in drugs over the last 4 years without reimbursement. After 25 years, we have to turn away NEW patients without insurance or who have Medicaid. If the provisions for 2005 become a reality - we will need to reexamine our patient population, our staffing and everything we do. It will be extremely difficult for patients to get care if they don't have the right insurance ... WHY?? Because the margin on drugs will no longer be sufficient to cover these losses. Our government just THINKS the doctors are making tons of money that they shouldn't. The fact is that the margin on drugs, without adequate increased in administration, don't cover our costs to take care of the WHOLE person.

CMS-1371-IFC-6

Submitter : Mrs. Linda McNeil Date & Time:

Organization :

Category :

03/04/2004 12:03:00

Central Georgia Hematology Oncology Associates

Congressional

Issue Areas/Comments

GENERAL

GENERAL

There are many drugs that we the allowable is below our cost and many more where the margin is pennies to just a few dollars above our cost . meaning we lose money because of the acquisition,storage, waste that is incurred, not to mention the special equipment it takes for mixing, including trained personal as well as diluents etc. The medicare allowable is less than cost on J9017 arsenic trioxide 1 mg., J9065 Cladarabine 10 mg., J9157 Daunorubicin liposomal 10 mg, J9178 Epirubicin 2 mg, J9202 Groserelin 3.6 mg, J9206 Irinotecan 20 mg, J9214 Interferon alpha 2 b 1 MU, J9350 Hycamtin 4 mg, J9395 Fulvestrant 25 mg, Q2017 tenoposide 50 mg. Biologicals and supportive care drugs allowable below: J1100 dexamethsone 1 mg, J2060 lorazepam 2 mg, J2353 Octereotide LAR 1 mg, (20 mg size) , J3420 Vitamin B-12, J3430 Vitamin K, J3480 potassium chloride 2 meq, J9062 Maxipime 500 mg. We are not reimbursed adequately for maintenance of porta a cath devices or using them to administer chemotherapy. We have to use a special non -coring needle sterile gloves, special hexachlorehexidine gluconate swabs (recommended by the CDC) to prevent infection (keeping the patient out of the hospital) and sterile dressings. We use an item called coban to keep the peripheral IV site stable , preventing infilltration of drugs that can cause serious damage and also to prevent the loss of the IV site keeping the patient frombeing stuck again. We are sending 30 % more patients to the out patient hospital for chemotherapy treatments as a result of the losses to our practice the cuts have caused this year . Our patients are complaining the personnel at the hospital is not trained to administer chemotherapy and they are being delayed in getting their treatment because they don't have enough space and have to come back another day.They are also spending many more hours at the hospital waiting on orders to be sent filled etc. than they did in the office. Some regimens are being compromised an because the hospital cannot give the treatments 3or 4 days in a row as is required by the regimen. The outcomes for these patients may also be less than optimal because of this. In our office we often have patients who have delayed nausea and vomitintg from chemotherapy who need IV antinausea medications which are not reimbursed by CMS since chemotherapy is not given on the same day. We have started sending them to the hospital for this service. The only reason more of our patients aren't going to the hospital for treatment is we are trying to hang on and keep them in our office while being proactive for reasonable changes. We are taking a loss on them just not so catastrophic that we have to close our practice. This is because finally we are getting reimbursed at the reasonable rate for chemotherapy administration in 2004. Services we provide for our patients that aren't reimburseable are we have a registered nurse available to speak with our patients during office hours so their problems can be handled in a timely manner maintaining continuity and quality patient care. We assist patients in obtaining drugs through patient assistance programs when possible. (Many we don't expect

to get reimbursed for - providing blankets, drinks, coffee, sodas, fruit drinks, variety of crackers and individual love and care. We celebrate with them when they complete a chemotherapy regimen giving them a handsome certificate, singing, blowing bubbles and giving them hugs. The proposed cutbacks on drugs and on the administration fees in 2005 will cause us to have to send all the medicare patients to the hospital which will cause us to cut staff, and possibly close. I'm sure many practices will close. This is at a time when statistics say there is a shortage of oncologists and it will be worse in a few years. Who indeed is going to provide quality care for the large population of oncology patients? I will leave oncology after 25 years if changes aren't made in the 2005 proposal.

CMS-1371-IFC-7

Submitter : Dr. susan greenberg Date & Time:

Organization :

Category :

03/04/2004 12:03:00

self employed doctor

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

CMS: I have had the privilege of practicing medicine in the U.S. for 20 years. During that time I have seen to wonderfull progress oncology has made in extending the lives and quality of life for my patients. I have also seen the cost of practicing medicine rise incredibly secondary to the cost of medication, nursing, overhead in general. I have read the proposed new CMS ruling with great concern. The cuts that are proposed along with the proposed payments for drugs are less than what I pay for the drugs. This "cost" is independent of the soft costs that are not included in the "actual cost." Knowing that this proposed reimbursement will force oncologists to either cost shift to the hospital which is more expensive or force offices to close makes me believe that the true reason for the change in policy is that CMS needs to contain costs by having our senior citizens die sooner. A more reasonable approach is to have the patient's share expenses; they have no concerns of cost containment when things are as they are now. A global payment for a diagnosis code along with a payment co-pay would help the doctors, patients, and CMS realize that ALL play a role. Thank you. Susan Greenberg

CMS-1372-IFC-15

Submitter : Mr. robert stackpole Date & Time:

Organization :

Category :

03/04/2004 12:03:00

UrologicalGroupOfUnionCounty

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 patients 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:

Organization :

Category :

03/04/2004 12:03:00

Atlanta Cancer Care

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:

Organization :

Category :

03/04/2004 12:03:00

Community Oncology Alliance

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:

Organization :

Category :

03/04/2004 12:03:00

Michael S. Buchholtz, MD, PC

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 forecast 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:

Organization :

Category :

03/04/2004 12:03:00

CHARLESTON CANCER CENTER

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:

Organization :

Category :

03/04/2004 12:03:00

Southwest Oncology Associates Ltd.

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 recipients 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:

Organization :

Category :

03/04/2004 12:03:00

ohio and west virginia hematology and oncology society

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 distinguish 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. Finally 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 dispensing fee for staying in this difficult business. Thanks, Steve Roshon, MD

CMS-1372-IFC-22

Submitter : Mr. dolores meals Date & Time:

Organization :

Category :

03/04/2004 12:03:00

N/A

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:

Organization :

Category :

03/04/2004 12:03:00

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

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 acquisition (85% of AWP) price for the following agents: Doxil, Carboplatin, Iron dextran, Gemzar, Camptosar, Lupron,

Navelbine and Faslodex. If not for the 2004 increment 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 reimbursement for services coupled with this insufficient drug pricing will be disastrous 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 :

Category :

St. Louis Cancer Care

Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir: I am a medical oncologist 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 anti-nausea 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, handling 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 incredible strides in cancer treatment.

CMS-1372-IFC-25

Submitter : Dr. David Hetzel Date & Time:

Organization :

Category :

03/04/2004 12:03:00

Hope:A Women's Cancer Ctr

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:

Organization :

Category :

03/04/2004 12:03:00

HEMATOLOGY ONCOLOGY ASSOCIATES

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 per diem 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:

Organization :

Category :

03/04/2004 12:03:00

Santa Barbara Hem Onc Med Group

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 hospital 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 patinets 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 contemplotate 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:

Organization :

Category :

03/04/2004 12:03:00

Broome Oncology

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 magnify 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:

Organization :

Category :

03/04/2004 12:03:00

Redwood Regional Oncology Center

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 acquisition 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 hospitals 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 rural 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.

CMS-1372-IFC-30

Submitter : Mrs. aleta kilborn Date & Time:

Organization :

Category :

03/04/2004 12:03:00

maine center for cancer medicine

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:

Organization :

Category :

03/04/2004 12:03:00

N/A

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-1371-IFC-8

Submitter : Dr. Dean Tsarwhas Date & Time:

Organization :

Category :

03/03/2004 12:03:00

North Shore Oncology Hematology Associates

Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment for full comment

CMS-1371-IFC-9

Submitter : Mrs. DeAnna Bagwell Date & Time:

Organization :

Category :

03/03/2004 12:03:00

Baptist Cancer Center-Walker

Congressional

Issue Areas/Comments

GENERAL

GENERAL

Because of recent cuts in Medicare reimbursement (CMS - 1371- IFC), we have already discharged 1patient from our clinic who was receiving Sandostatin-LAR. If we had continued to treat this man, we would loose approximately \$200.00 per month on him alone.

CMS-1371-IFC-10

Submitter : Mrs. Melody Edgington Date & Time:

Organization :

Category :

03/03/2004 12:03:00

N/A

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

CMS-1371-IFC - the cuts to practice expense of 29% in 2005 will be devastating to our practice. In 2004, we have already had to stop extending credit to all of our patients. Now all patients must pay any co-insurance amounts or non-covered amounts at the time of service, or treatment is denied. If the projected cuts to practice expense are implemented in 2005, our office will be forced to close our doors. If that happens there will be no cancer care in our communities.

CMS-1372-IFC-32

Submitter : Dr. Vance Browne Date & Time:

Organization :

Category :

03/03/2004 12:03:00

Florida Cancer Specialists

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 poisonous 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:

Organization :

Category :

03/03/2004 12:03:00

North Shore Oncology Hematology Associates
Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for full comments

CMS-1372-IFC-34

Submitter : Dr. Dean Tsarwhas Date & Time:

Organization :

Category :

03/03/2004 12:03:00

North Shore Oncology Hematology Associates
Physician

Issue Areas/Comments

GENERAL

GENERAL

See new attachment

CMS-1372-IFC-35

Submitter : Dr. Dwight Oldham Date & Time:

Organization :

Category :

03/03/2004 12:03:00

Lynchburg Hematology Oncology Clinic
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 coinsurance. 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:

Organization :

Category :

03/03/2004 12:03:00

North Shore Oncology Hematology Associates

Physician

Issue Areas/Comments

GENERAL

GENERAL

See updated attachment

CMS-1372-IFC-37

Submitter : Mrs. Jane Steinkamp Date & Time:

Organization :

Category :

03/03/2004 12:03:00

Oncology Hematology Associates of West Broward, PA

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:

Organization :

Category :

03/03/2004 12:03:00

N/A

Congressional

Issue Areas/Comments

GENERAL

GENERAL

Dear Congressperson:

The proposed changes in physician re-imburement 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

CMS-1372-IFC-39

Submitter : Dr. Kasra Karamlou Date & Time:

Organization :

Category :

03/03/2004 12:03:00

Oregon Hematology Oncology Associates, PC

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 multiphysician, 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

CMS-1372-IFC-39

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:

Organization :

Category :

03/03/2004 12:03:00

Oregon Hematology Oncology Associates, PC

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 multiphysician, 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

CMS-1372-IFC-40

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:

Organization :

Category :
03/03/2004 12:03:00
norwalk medical group
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-1371-IFC-6
Submitter : Mrs. Linda McNeil Date & Time:
Organization :
Category :
03/04/2004 12:03:00
Central Georgia Hematology Oncology Associates
Congressional
Issue Areas/Comments
GENERAL
GENERAL

There are many drugs that we the allowable is below our cost and many more where the margin is pennies to just a few dollars above our cost . meaning we lose money because of the acquisition,storage, waste that is incurred, not to mention the special equipment it takes for mixing, including trained personal as well as diluents etc. The medicare allowable is less than cost on J9017 arsenic trioxide 1 mg., J9065 Cladarabine 10 mg., J9157 Daunorubicin liposomal 10 mg, J9178 Epirubicin 2 mg, J9202 Groserelin 3.6 mg, J9206 Irinotecan 20 mg, J9214 Interferon alpha 2 b 1 MU, J9350 Hycamtin 4 mg, J9395 Fulvestrant 25 mg, Q2017 tenoposide 50 mg. Biologicals and supportive care drugs allowable below: J1100 dexamethsone 1 mg, J2060 lorazepam 2 mg, J2353 Octereotide LAR 1 mg, (20 mg size) , J3420 Vitamin B-12, J3430 Vitamin K, J3480 potassium chloride 2 meq, J9062 Maxipime 500 mg. We are not reimbursed adequately for maintenance of porta a cath devices or using them to administer chemotherapy. We have to use a special non -coring needle sterile gloves, special hexachlorexidine gluconate swabs (recommended by the CDC) to prevent infection (keeping the patient out of the hospital) and sterile dressings. We use an item called coban to keep the peripheral IV site stable , preventing infilltration of drugs that can cause serious damage and also to prevent the loss of the IV site keeping the patient frombeing stuck again. We are sending 30 % more patients to the out patient hospital for chemotherapy treatments as a result of the losses to our practice the cuts have caused this year . Our patients are complaining the personnel at the hospital is not trained to administer chemotherapy and they are being delayed in getting their treatment because they don't have enough space and have to come back another day.They are also spending many more hours at the hospital waiting on orders to be sent filled etc. than they did in the office. Some regimens are being compromised an because the hospital cannot give the treatments 3or 4 days in a row as is required by the regimen. The outcomes for these patients may also be less than optimal because of this. In our office we often have patients who have delayed nausea and vomitintg from chemotherapy who need IV antinausea medications which are not reimbursed by CMS since chemotherapy is not given on the same day. We have started sending them to the hospital for this service. The only reason more of our patients aren't going to the hospital for treatment is we are trying to hang on and keep them in our office while being proactive for reasonable changes. We are taking a loss on them just not so catastrophic that we have to close our practice. This is because finally we are getting reimbursed at the reasonable rate for chemotherapy administration in 2004. Services we provide for our patients that aren't reimburseable are we have a registered nurse available to speak with our patients during office hours so their problems can be handled in a timely manner maintaining continuity and quality patient care. We assist patients in obtaining drugs through patient assistance programs when possible. (Many we don't expect to get reimbursed for - providing blankets, drinks, coffee, sodas, fruit drinks, variety of crackers and individual love and care. We celebrate with

them when they complete a chemotherapy regimen giving them a handsome certificate, singing, blowing bubbles and giving them hugs. The proposed cutbacks on drugs and on the administration fees in 2005 will cause us to have to send all the medicare patients to the hospital which will cause us to cut staff, and possibly close. I'm sure many practices will close. This is at a time when statistics say there is a shortage of oncologists and it will be worse in a few years. Who indeed is going to provide quality care for the large population of oncology patients? I will leave oncology after 25 years if changes aren't made in the 2005 proposal.

CMS-1371-IFC-7

Submitter : Dr. susan greenberg Date & Time:

Organization :

Category :

03/04/2004 12:03:00

self employed doctor

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

CMS: I have had the privilege of practicing medicine in the U.S. for 20 years. During that time I have seen to wonderfull progress oncology has made in extending the lives and quality of life for my patients. I have also seen the cost of practicing medicine rise incredibly secondary to the cost of medication, nursing, overhead in general. I have read the proposed new CMS ruling with great concern. The cuts that are proposed along with the proposed payments for drugs are less than what I pay for the drugs. This "cost" is independent of the soft costs that are not included in the "actual cost." Knowing that this proposed reimbursement will force oncologists to either cost shift to the hospital which is more expensive or force offices to close makes me believe that the true reason for the change in policy is that CMS needs to contain costs by having our senior citizens die sooner.

A more reasonable approach is to have the patient's share expenses; they have no concerns of cost containment when things are as they are now. A global payment for a diagnosis code along with a payment co-pay would help the doctors, patients, and CMS realize that ALL play a role. Thank you. Susan Greenberg

CMS-1371-IFC-8

Submitter : Dr. Dean Tsarwhas Date & Time:

Organization :

Category :
03/03/2004 12:03:00
North Shore Oncology Hematology Associates
Physician
Issue Areas/Comments
GENERAL
GENERAL
See attachment for full comment

CMS-1371-IFC-9
Submitter : Mrs. DeAnna Bagwell Date & Time:
Organization :
Category :
03/03/2004 12:03:00
Baptist Cancer Center-Walker
Congressional
Issue Areas/Comments
GENERAL
GENERAL
Because of recent cuts in Medicare reimbursement (CMS - 1371- IFC), we have already discharged 1patient from our clinic who was receiving Sandostatin-LAR. If we had continued to treat this man, we would loose approximately \$200.00 per month on him alone.

CMS-1371-IFC-10
Submitter : Mrs. Melody Edgington Date & Time:
Organization :
Category :
03/03/2004 12:03:00
N/A
Other Health Care Professional
Issue Areas/Comments
GENERAL
GENERAL
CMS-1371-IFC - the cuts to practice expense of 29% in 2005 will be devastating to our practice. In 2004, we have already had to stop extending credit to all of our patients. Now all patients must pay any co-insurance amounts or non-covered amounts at the time of service, or treatment is denied. If the projected cuts to practice expense are implemented in 2005, our office will be forced to close our doors. If that happens there will be no cancer care in our communities.

CMS-1371-IFC-11

Submitter : Ms. DONNA THOMAS Date & Time:

Organization :

Category :

03/05/2004 12:03:00

N/A

Congressional

Issue Areas/Comments

GENERAL

GENERAL

I FEEL THE CANCER CUT BILL SHOULD BE CHANGED BECAUSE IT IS MAKING IT VERY HARD ON OUR PATIENTS. BECAUSE MOST OF OUR PATIENTS ARE WORE OUT FROM THE CHEMO TREATMENTS AND ARE NOT ABLE TO GO TO THE HOSPITAL AND DRIVE A LONG DISTANCE TO GET TREATED. THEY LIKE TO BE TREATED IN OUR OFFICE. ALSO THE PATIENTS ARE HAVING A HARD ENOUGH TIME DEALING WITH THE CANCER THEY SHOULD NOT HAVE TO BE WORRIED ABOUT HOW THEY ARE GOING TO PAY FOR THE TREATMENT AND ALOT OF PEOPLE DO NOT HAVE ALOT OF MONEY TO PAY FOR THE HIGH PRICES . THE PEOPLE THAT SUPPORT THE CANCER CUT BILL SHOULD PUT THEIR SELVES IN THE PATIENTS POSITION OR HAVE SOME IN THEIR FAMILY TO BE IN THE POSITION OF OUR PATIENTS.

CMS-1371-IFC-12

Submitter : Mrs. MICHELLE GIBSON Date & Time:

Organization :

Category :

03/05/2004 12:03:00

N/A

Physician

Issue Areas/Comments

GENERAL

GENERAL

I WORK IN A CANCER THERAPY CENTER, AND THE NEW RULES UNDER MEDICARE HAS CAUSED LOTS OF ANGER WITH OUT PATIENTS. THEY ARE USE TO OUR DOCTORS AND NURSING STAFF. THEY COME HERE AND ARE TREATED BY FIRST NAME BASIS AND THEY LIKE THE PERSONAL FEEL THEY GET. NOW SOME OF THOSE PATIENTS ARE HAVING TO GET THEIR CARE AT THE HOSPITAL BECAUSE OF THE CUTS IN MEDICARE. THEY ARE HAVING TO WAIT 4-6 HOURS BEFORE THEIR TREATMENT IS EVEN STARTED. THEY ARE BEING TREATED BY DIFFERENT FACES EACH TIME AND JUST DONT FEEL LIKE

THE CARE IS AS GOOD. PLEASE CONSIDER REMOVING THE CANCER CUTS FROM THE RX BILL. THE PATIENTS ARE GETTING HURT BY THIS.

CMS-1371-IFC-13

Submitter : Ms. DONNA DONALDSON Date & Time:

Organization :

Category :

03/05/2004 12:03:00

PURCHASE CANCER GROUP

Congressional

Issue Areas/Comments

GENERAL

GENERAL

I THINK THE MEDICARE CUTS TO CANCER CARE ARE VERY BAD FOR OUR PATIENTS. THEY HAVE TO GO TO THE HOSPITAL AND WAIT HOURS (UP TO 8) FOR A TREATMENT THAT WE COULD DO IN TWO HOURS. THESE PEOPLE ARE SICK AND TIRED AND DO NOT NEED TO WAIT ALL DAY IN A WAITING ROOM WITH OTHER SICK PEOPLE (THEIR WHITE COUNTS MAY BE DOWN AND ARE PRONE TO INFECTIONS).. IT IS JUST SAD THE WAY WE TREAT OUR SICK.... HOW WOULD YOU LIKE TO BE TREATED LIKE THAT...

CMS-1371-IFC-14

Submitter : Ms. Cathy Collins Date & Time:

Organization :

Category :

03/05/2004 12:03:00

Purchase Cancer Group

Congressional

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1371-IFC As a cancer survivor I feel it is imperative that the Medicare cuts anticipated in 2005 that will directly impact oncology patients must be revamped. This is NOT in the best interest of the patient! Patient's rely on doctors, staff and facilities they know and trust. In rural locations patients may have to travel several hours to get chemotherapy treatment and this is NOT a viable option. People are weak, their

immune systems are down and to expect them to travel to larger facilities who can incur the loss that this plan will incur is not acceptable. Please take a closer look and get a full understanding of the negative impact this will have on cancer patients!!!

CMS-1371-IFC-15

Submitter : Dr. dean gesme Date & Time:

Organization :

Category :

03/05/2004 12:03:00

N/A

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

These comments pertain to file: CMS 1371-IFC.

The 2005 reimbursement for parenterally administered drugs is based on a severely flawed formula that will result in most small medical practices being unable to break even on obtaining these drugs for the treatment of Medicare patients. I can only assume that CMS has not fully assimilated this fact and considered the ramifications for the Medicare patients for whom CMS is responsible.

The 2005 changes will result in site of care changes that will certainly need to be carefully considered in the budgetary projections as well as considering patient out-of-pocket expenditures along with increased inconvenience when these services are provided in non-office settings.

Oncologists are already despondent over CMS' intent to disassemble the caring office treatment environment and I have witnessed the defensive attitude that the prospect of these adverse changes has produced. This is very worrisome as a wholesome and optimistic environment is a key ingredient in offering quality healthcare to cancer patients. It is hard for patients to maintain hope in a care setting where the care providers have no hope for the system of care.

CMS must not wait to witness the 2005 devastating changes that will certainly occur but rather should thoughtfully encourage Congress to delay the changes for 2005 until CMS and Congress have more carefully weighed the true unintended consequences of MMA for 2005 in terms of both real costs to CMS and to cancer patients.

CMS-1371-IFC-16

Submitter : Ms. Sandra Conner Date & Time:

Organization :

Category :

03/05/2004 12:03:00

Purchase Cancer Group

Congressional

Issue Areas/Comments

GENERAL

GENERAL

American citizens who suffer from cancer are already being affected adversely by the legislation that was voted into effect for 2004. Our patients are being pulled from the comfort and personal care of our office and trained nurses to have their chemotherapy in local hospitals (who are already understaffed). They sometimes have to wait for hours just to get a bed. They are frequently exhausted by by this treatment and this additional stress and travel takes its toll on them as they fight for their very lives against this devastating disease. The provisions for 2005 - 2006 in the bill that is in now in effect will have a tremendous detrimental impact on the cancer patient in America. Cancer care must be kept intact and available at the community level. This is not an option - to protect and serve the American people, we must do this.

CMS-1371-IFC-17

Submitter : Mrs. KARA ROBINSON Date & Time:

Organization :

Category :

03/05/2004 12:03:00

PURCHASE CANCER GROUP

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

NEED TO STOP AND THINK WHAT WE ARE DOING TO THE PATIENTS, IF THIS GOES ON ANY FUTHER. OUR PATIENTS DO NOT LIKE GOING TO THE HOSPITALS FOR THEIR TREATMENT. THEY ARE THERE FOR LONGER PERIODS AND SOME ARE NOT GETTING THE CARE THAT THEY SO DESERVE. PLEASE TAKE INTO CONSIDERATION OF THIS AS WE LOOK FUTHER INTO CANCER CARE FOR THE FUTURE.

CMS-1371-IFC-18

Submitter : Mrs. DEBBIE MCCUE Date & Time:

Organization :

Category :

03/05/2004 12:03:00

N/A

Other Technician

Issue Areas/Comments

GENERAL

GENERAL

THIS IS IN REGARDS TO CANCER CARE BILL. PATIENT CONSTANTLY COMPLAINT ABOUT TRANSPORTATION PROBLEMS, GETTING TO THE HOSPITAL. MOST PATIENTS ARE TOO WEAK AND SICK TO DRIVE THEMSELVE, AND DEPEND ON FAMILY AND FRIENDS. THE AVERAGE WAIT FOR CHEM IN THE HOSPITALS IS DOUBLE OUR TIME IN A CLINIC. ARE YOU WILLING TO ALLOW MEDICARE/INSURANCE CO TO DECIDE WHAT CHEM YOU SHOULD BE GIVEN BASED ON PRICE? THEY IS EXACTLY WHERE THIS IS HEADING. YOU WILL NOT GET THE NEWEST OR BEST DRUG BUT THE CHEAPEST . RECONSIDER THE CANCER CARE BILL, I HAVE WORKED IN ONCOLOGY 10 YEARS, I CAN GUARANTEE THIS WILL EFFECT YOU AND YOUR FAMILY MORE THAN YOU REALIZE TODAY. DO YOU THINK PHARMACEUTICAL COMPANIES WILL CONTINUE RESEARCH AND DEVELOPING NEW DRUGS IF ONLY OLDER CHEAPER DRUGS WILL BE PRESCRIBED?????

CMS-1371-IFC-19

Submitter : Mr. Walt Moyer Date & Time:

Organization :

Category :

03/05/2004 12:03:00

Utah Cancer Specialists

Congressional

Issue Areas/Comments

GENERAL

GENERAL

As the CEO of Utah Cancer Specialists a group of 9 medical oncologists and 6 midlevels in Utah with 45,000 cancer patients vists in 2003, I speak for our entire group when I express our grave concerns with the reimbursement changes proposed in CMS-1371-IFC. Medicare reimbursement for cancer care is already lower than that of any commercial payer. These additional cuts will make it impossible to continue to provide care to Medciare patients. Fully one third of our practice is Medicare patients as the elderly get cancer more often than the rest of the population. If commercial payers follow suit, (as several are already indicating that they will) community cancer care will cease to exist and patients will have no alternative but to go to the hospital for care. Hospitals are ill equipped to handle these volumes and I can assure you that they cannot provide care as economically as community care clincis can. We (and the majority of the cancer care community) are not opposed to moving reimbursement away from the current

methodology of marking up drugs. The proposed system of ASP + 6% as defined however is a disaster. We support the "Community Oncology Alliance" proposal of ASP (properly defined) +12% with appropriate increases in administration codes. I cannot overemphasize how critical it is that this issue be resolved appropriately. The current plan will leave millions of people without access to cancer care.

CMS-1371-IFC-20

Submitter :

Ms. Katherine Grigsby

Date & Time:

03/05/2004 12:03:00

Organization :

Category :

Oncology Consultants, P.A.

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

March 5, 2004

Mr. Dennis G. Smith

Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

RE: CMS-1371-IFC

P.O. Box 8018

Baltimore, MD 21244-8018.

Dear Mr. Smith,

I am writing in regards to the instructions posted in the Federal Register/Vol. 69, No. 4 Wednesday January 7, 2004/Rules and Regulations, pertaining to CMS-1372_FC, Medicare Program: changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004.

Oncology Consultants, P.A. provides medical services for numerous of cancer patients in the local community. Our practice has six locations in the surrounding Houston Texas area. Oncology Consultants, has always taken into consideration in our business strategy to provide quality services and convenient locations to our Medicare and Commercial patients. Easy accessibility, consistency and stability are very important in the treatment of cancer patients. In fact we are scheduled to open another clinical this year in an area where there is a demand due to population growth. Although, this area is underserved for cancer services sadly these plans may be discontinued depending on the outcome of the debate of reimbursement from CMS.

Our intention is to bring to your awareness the complex issues surrounding the delivery of cancer care. With so many new treatments and advances in cancer it would be a disgrace to disrupt what has taken years to build and the approach of cancer treatments centers geographically accessible to all patients in this country. If we do not take the time to properly study the adequate reimbursement for cancer services Community Oncology Clinics will not be able to continue and operate in this country. Patients would be forced to find treatment in the large facilities which are normally located in the center of big cities. The dilemma of traveling 30 to 50 miles in traffic, spending all day in a Hospital for your chemotherapy plus, not feeling well could very well be a deterrent for many cancer patients not to seek, miss or discontinue their treatments.

Therefore, we would asked that your department carefully exam and analyzed the Medicare reimbursement changes for 2005. In 2004, we have had to turn patients away to county Hospitals for treatment when certain drugs where necessary because the reimbursement for these drugs are now lower than our acquisition costs incurred by our clinic. These drugs are as followed:

Campath Parrboplatin (Paraplatin)
Doxil (Doxorubicin Liposome) Gemzar
Hycamtin Irinotecan
Novantrone Rituxin
Temodar

Currently, we would request that CMS do their due diligent in accumulating additional information from the pharmaceutical manufacturers pertaining to the pricing of these drugs to the Community Oncology Clinics. CMS is in an excellent position to foresee and properly determine the correct allowable to enable the relief for these drugs and allowing the reimbursement issued to be resolve pertaining to this situation.

Next, I would like to bring to your attention some of the services not currently paid by Medicare. Examples are following; the planning and management of complicated cancer treatments, the nursing time for certified Oncology nurses, patient education and consulting, plus this is not taking into account the supplies used in giving chemotherapy that are not reimbursed by Medicare. In addition, supportive care of consulting face to face and through the numerous phone calls cancers patients have regarding their disease that is essential to patients with cancer. Performing these services are vital to the care of the cancer patient and if changes in reimbursement take place these necessary services would not be able to continue.

We appeal to CMS to capture the many services provided by Community Cancer Clinics to determine the exact payment for the delivery of treating cancer.

Katherine M. Grigsby
Oncology Consultants, P.A.

CMS-1371-IFC-21

Submitter : Mrs. Julia Haner, RN, OCN Date & Time:

Organization :

Category :

03/05/2004 12:03:00

Purchase Cancer Group

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am an Oncology Certified RN working in a community based practice in Western Kentucky. We have Medicare patients that must now go to one of our local hospitals to receive their chemotherapy treatments thanks to the new medicare guidelines. My patient's are going through the most difficult time in their lives-battling cancer. Now they must be burdened with the governments decision to longer provide enough reimbursement for our practice to give them their chemotherapy in our office. Now they can spend their entire day waiting until the local hospital has a room, chair or bed for them, go through hospital registration, get to the right department, wait for the hospital pharmacist to get their chemotherapy and antiemetics, wait their turn in line for IV access, hope the pharmacy has their meds ready by now, finally get their treatment and then trek back to their car in the hospital parking lot. I had a patient tell me her treatment, that normally took one and a half hours in our office, took a total of 8 hours. THESE PATIENTS DO NOT HAVE THAT KIND OF TIME TO WASTE!!!! They are forced to pay with their time and ultimately their quality of life because the government had no idea (do they really care?) the impact the Cancer Care Cuts would have on Medicare patients.

The cancer community is not cut and dry. You cannot put it in neat boxes to stack, store away and forget. This area of medicine need its own special guidelines and considerations. Don't lump us in with the anti-allergy drugs and antibiotics. Chemotherapy IS NOT the same and cannot be treated that way.

My patient's are concerned a time might come when they have to go to larger hospital/university settings in order to receive their therapy. That would mean a 2-4 hour drive in addition to the time of the office visit and chemotherapy administration. I cannot offer them much comfort other than hopefully things will change before it comes to that.

I ask you to put a face, your mother, father, sibling or best friend, with the rat-race scenerio I gave above. Would you want that to happen to them?

Wouldn't you want them to have the best care possible, in a familiar setting, with nurses that not only administer their chemotherapy, but can talk with them about their side effects, concerns, fears and offer some comfort to them? These patients are experiencing enough stress with their cancer diagnosis and changes in their life, without having to put up with government regulations that in no way take into consideration their needs. It's

just really sad.
Thank you
Julia Haner,RN, OCN

CMS-1371-IFC-22

Submitter :

Ms. Lee Horton

Date & Time:

03/08/2004 12:03:00

Organization :

Category :

CCI

Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

I am commenting on behalf of a group of five medical oncologists practicing in Huntsville, Alabama. There are currently three drugs for which our reimbursement by Medicare is less than our actual cost: Gemcitabine, J9201; Sandostatin LAR J2352; and Zoladex, J9202. There are several services that we currently provide to our patients that are not billable. If the 29% cut in reimbursement is allowed to remain in regulation for 2005, we will not be able to afford to continue to provide these services. These services include: providing licensed Social Workers to assist the patients with disability, applying for patient assistance programs for prescription drugs, and managing the mounds of governmental paperwork associated with a life threatening illness; Genetic Counseling ? we currently employ a genetic counselor to assist patients and their families with the familial risks of cancer to ensure proper screening and testing; we currently have an extensive research effort bringing the latest clinical trials to our community. These trials require extensive paperwork and tracking, which we will not be in the position to support. Also, if the cuts of 2005 stay as written, including removal of the practice expense increase and ASP plus 6% , we will be forced to close our practice to Medicare patients. We have done extensive analysis of the proposed regulation, and the effects would be devastating to our Medicare reimbursement. We are a large volume practice, and I can only estimate that the effect to smaller practices will be greater. All of this will drive Medicare patients to hospitals for their chemotherapy treatments. This will result in a drastic increase in costs to the Medicare program, as hospital costs for providing the same services are

40-60% higher. . In addition, the restructuring of Medicare reimbursement for chemotherapy drugs is restricting access to the newest chemotherapy regimens, which are more effective and less toxic. A clinical example is that there is a newer drug, Epirubicin, that should replace Doxyrubicin. Both are common drugs used to treat Breast Cancer. Epirubicin is more effective and less cardiotoxic. However, Medicare reimburses Epirubicin at a rate that barely covers the actual cost, much less any other costs. This leaves Medicare patients with older, less effective, more toxic drugs. Many costs associated with providing chemotherapy are not currently reimbursed by Medicare. The items include specialized IV tubing, IV pumps, daily cleaning required after chemotherapy treatments, highly skilled nurses, pharmacists and pharmacy technicians. There are also overhead costs associated with providing chemotherapy treatments such as specially designed coats for nurses, protective gloves, flooring in the treatment area, and many other items too numerous to name. I strongly encourage CMS to seek as many opinions from Oncology Physicians actually treating Medicare patients before they allow the 2005 regulations to remain.

CMS-1371-IFC-23

Submitter : Dr. Charles Winkler Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Purchase Cancer Group

Physician

Issue Areas/Comments

GENERAL

GENERAL

March 4, 2004

We are a three-physician oncology practice in Western Kentucky. Our base office is in Paducah, Kentucky. We have two satellite offices in

Northwestern Tennessee and two satellite offices in Western Kentucky. We treat approximately 50% of our patients in the satellite practice and 50% in our main office in Paducah, Kentucky. The recent changes in payments for oncology drugs and services have been a hardship on our patients.

Because of these changes, we have been unable to treat approximately 15% of our practice in the office. These treatments have been transferred to the hospital outpatient chemotherapy setting. Treatments in the hospital outpatient clinic are delayed by 1-3 days due to space constraints. Their treatments are prolonged, at times taking 12 hours or longer, for a treatment which would be administered in 3-4 hours in the office. Many of our patients have to travel a prolonged distance at night after their treatment is completed. Several patients have been discharged from the hospital at midnight.

Because of these changes, our practice has had to lay off two full-time nurses. In addition, there has been reduction of other ancillary staff as well.

Our ability to counsel patients effectively and to respond to their needs in a timely fashion has been reduced by our lack of personnel. Because of these changes, more of our patients are referred to hospital emergency rooms for assessment and treatment. This was normally done via telephone communication with our nurses and home health agencies.

The following drugs cost us more than Medicare reimburses in Kentucky and Tennessee:

Liposomal doxorubicin; Campath; Interleukin; Trisenox;
Carboplatin; BCNU; Leustatin; epirubicin; Gemzar; Camptosar; Roferon; Intron-A;
pentostatin; Rituxan; Hycamtin; Faslodex; Solu-Medrol;
Solu-Cortef; Zometa; Sandostatin; amifostine; Gamimune.

These drugs used singly or in combination regimens preclude their administration in an office setting. These patients are admitted to the hospital for their outpatient treatment.

As all medical oncologists, I favor a balanced reform for oncology care. The changes in 2004 have impacted our practice to a point that I feel we can no longer deliver the type of care our Medicare patients deserve.

I ask that you review the recently imposed Medicare regulations and work toward balanced reform with the American Society of Clinical Oncology patient advocacy groups and Community Oncology Alliance.

Thank you for allowing me to comment.

Sincerely,

Charles F. Winkler, M.D., F.A.C.P.

CMS-1371-IFC-24

Submitter : Mr. Linda Thornrose Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Gainesville Hematology Oncology Associates

Congressional

Issue Areas/Comments

GENERAL

GENERAL

Reference: CMS-1371-IFC. This comment is regarding the interim final rule on the implementation of Medicare reimbursement changes for 2004.

I am a practice administrator for a five-physician oncology practice with two office locations. In the thirteen years I have been with our practice, I have watched patient care go from treatment in the hospitals (85-90% in the early 90's) to now having that same percentage being treated in the office setting now. This provides a vastly improved quality of life to the patient that is phenomenal! If you are the patient faced with a lifethreatening disease, your quality of life takes on a whole new importance.

Unless you have been touched by cancer in some personal way, you cannot know the importance of a community cancer care practice to patients undergoing treatment for their life-threatening disease. Our patients come to our office on a regular basis building relationships with our doctors, nurses and staff. They see the same familiar faces in the same familiar environment. This provides a comfort level and support system, often from other patients being treated alongside them, that aids in their healing process. With the proposed changes facing oncology and hematology practices in 2005, we may be forced to revert back to treating patients in the hospital setting. They do not see the same faces, do not usually get to home the same day, are exposed to dangerous germs when they are already immunosuppressed, and they have a higher out of pocket cost. In other words, the patients' standard of care will be compromised due to budget restraints because we cannot afford to treat them in the office any longer.

While I recognize the need for Medicare Reform, I maintain it needs to be well-balanced, addressing the appropriate payment for both cancer drugs and essential medical services required by patients who are battling cancer. I do appreciate the efforts of the Members of Congress in trying to achieve this goal. The 2004 increase in the administration reimbursement is a long overdue adjustment that finally addresses the costs of providing drug treatment for the patients. It has certainly helped alleviate the sharp reduction in most of the drugs. There are several drugs for 2004 that are reimbursed at less than we pay for them: Carboplatin (Paraplatin), Tituxin, Hycamptin, Gemzer, Doxil, Irinotecan and Novantrone that we use in our offices. We have had at least one pharmaceutical company lower their price for one of these drugs, but that does not fix the problem. CMS must address this problem as soon as possible. Services related reimbursement has increased about \$500 million, which is lower than the \$718 million under-reimbursed for services that practices need to cover their patient services costs. Planning and managing complicated cancer care has evolved over the last decade without any recognition of needed reimbursement for services and supplies necessary to provide this very labor intensive and time-consuming care.

Thus far for 2004, we are surviving, but with the 2005 proposed changes with ASP and the 32% transitional increase in administration costs being decreased to 3% , I am afraid for our practice, that we will be unable to continue providing the same excellent care to our patients. I have watched our costs continue to rise along with other inflation while reimbursement continues to decrease at an alarming rate. Please reexamine the payment of services issue in addition to the use of existing and new codes to more adequately capture all essential cancer care services that are rendered. Please recognize that I am willing to do whatever is required to help CMS come to a fair and equitable solution to this huge challenge facing all of us. In this spirit, I am offering my willingness and abilities to assist in this effort. Thank you for allowing me to voice my opinion.

Sincerely,

CMS-1371-IFC-25

Submitter : Mrs. Denise Pierce Date & Time:

Organization :

Category :

03/08/2004 12:03:00

D K Pierce & Associates

Other

Issue Areas/Comments

GENERAL

GENERAL

Section 621 (a)(1) of the Medicare Modernization Act (MMA) amends the Social Security Act by adding section 1833(t)(15), requiring payment at 95% of AWP for new drugs and biologicals until a HCPCS code is assigned. My comments submit a process for consideration that enables hospitals to document and bill new drugs, and Medicare fiscal intermediaries to make payment that reflects each drug's appropriate utilization. Hospitals cannot bill and receive payment using the current miscellaneous HCPCS codes (J9999, J3490, and J3590) which all drugs utilize until drug-specific HCPCS code assignment. Hospital outpatient drug pass-through designation, allowing hospitals to receive separate drug payment, may require up to six months for the review process and coding designation. Therefore there may be up to six months that CMS would be out of compliance with the MMA provision to pay for new drugs at 95% of AWP.

We recommend that CMS initiate a "temporary" C-code designation process for new FDA-approved drugs, integrating the following steps:

1. A drug manufacturer would submit an abbreviated form of the transitional pass-through application upon the drug's FDA approval, providing information on:
 - Drug name (brand and generic);
 - FDA approval date;
 - Brief clinical vignette, including indication of use;
 - Dosing and administration (including average per patient dose);
 - CPT codes that would be billed with the drug;
 - Suggested C-code unit of use for billing purposes (e.g., "per 500mg"), and;
 - Published Redbook AWP pricing.
2. CMS would review each application and, within 30 days of application submission, issue a temporary C-code for the drug.
3. Using the temporary C-code, required drug detail and Pharmacy Revenue Code 636, a given hospital could bill use of a new drug retroactive to the date of FDA approval (for services on or after 1/1/04).
4. A list of approved codes, drug names, unit of use billing and Medicare allowable would be published on the CMS website, under the HOPPS

references, and communicated to providers via the fiscal intermediaries via website access (or links to the CMS website), listserv communications, and provider bulletins.

5. The temporary C-code list would be updated on a monthly basis, if any abbreviated transitional pass-through applications are submitted to and reviewed by CMS.

6. CMS could request additional information from the manufacturer (if necessary) to fulfill a complete transitional pass-through review, and consider changes to the coding and unit of use billing within six months of the temporary code assignment.

By modifying the current C-code process to expedite review and code assignment, CMS would maintain compliance with the provisions of the MMA, and minimize the need to integrate a more complex coding and documentation system for hospitals.

CMS-1371-IFC-26

Submitter : Dr. Ian Anderson Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Redwood Regional Medical Group

Physician

Issue Areas/Comments

GENERAL

GENERAL

To CMS,

I am in a group of 11 medical oncologists serving a mostly rural area of Northern California. We feel strongly that the changes to 2004 and 2005 Medicare reimbursement will significantly affect the quality and access to cancer care. In 2004, under the new rules, we are losing money when we treat patients with certain drugs such as oxaliplatin and irinotecan among others. As a result, we have been forced to send these patients to our local hospital to receive therapy. This approach to care results in extra trips by the patient, and increases the risk of medical errors as we must fax orders and are not on site when treatment is delivered. In 2004, the reduction in drug reimbursement is partially offset by payment for "practice expenses". However, in 2005 these payments virtually disappear and drug reimbursement will also drop to ASP + 6%, resulting in approximately a 3 million dollar loss for our practice.

We are already a fairly efficient practice, so there will be no easy way to further cut costs and keep our doors open. We anticipate in 2005 that our most rural offices which serve a high proportion of indigent patients will halt any infusional services. These patients will need to travel 100 miles

to receive outpatient treatment, and many will be unable to do so. Furthermore, our clinical research program which provides access to promising drugs will have to be closed, since we will no longer be able to subsidize it. Finally, we fear that the drastic cuts for 2005 will force us to close our outpatient infusion centers completely, laying off our nurses, lab staff, and support staff who provide critical services for our patients.

We currently provide very high quality care for our cancer patients and believe that quality and access to such care are in jeopardy with the planned Medicare cuts. Several years ago, we suffered through the bankruptcy of a major local HMO and barely survived. We always place patient care first, but learned that a healthy business plan is critical to providing that care. A loss of 3 million dollars in revenue will be insurmountable. We urge you to reconsider Medicare reimbursement for 2005 and beyond.

Sincerely,

Ian C Anderson, M.D.

CMS-1371-IFC-27

Submitter : Dr. Gary Stein Date & Time:

Organization :

Category :

03/08/2004 12:03:00

American Society of Health-System Pharmacists

Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1371-IFC-28

Submitter : Mr. Susan Schutz Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Horizon Hematology Oncology

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

CMS-1371-IFC-29

Submitter : Mrs. Gwenda Alexander Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Purchase Cancer Group

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

CMS-1371-IFC

I am the Laboratory Manager at Purchase Cancer Group. I am in contact with cancer patients daily. Many of our patients are now required to receive chemotherapy in the hospital setting. They must come to the office, have lab work, be evaluated by the doctor and if chemotherapy is indicated, set up a time with the hospital to receive the treatment. This is sometimes on the same day but because of the limitations at the hospital it may be days later. This delays treatment, causes increased anxiety due to waiting and additional scheduling needs.

In the past we were able to do all processes of evaluation and treatment in our office on the same day. I am asking you to introduce a new bill that would remove cancer care from the existing policies and allow our patients to continue getting the high quality care they have always received in our facility. Our patients experience so many difficulties just with the disease, let's not cause more by preventing them the best care in the quickest time frame possible.

Thank you for your attention.

Gwenda Alexander, M.T. (ASCP)

CMS-1371-IFC-30

Submitter : Ms. Cynthia McGill Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Purchase Cancer Group, PSC

Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

FILE CODE CMS-1372-FC

I am employed as Practice Administrator for Purchase Cancer Group in Paducah, Kentucky. My position allows me the unique opportunity to experience both the clinical and financial aspects of a medical oncology community practice.

The cut in reimbursement for chemotherapy agents has negatively impacted the decision-making for treating our patients in the outpatient setting in

2004. The treatment decision-making process for the year 2005 and beyond is grim, at best.

Due to extensive research on the issue, we are deeply concerned regarding the ASP model of drug reimbursement proposed. It is simply inappropriate for Medicare drug reimbursement to be based on acquisition cost alone. The additional cost of storage, inventory, procurement, etc., are linked to the purchase of the cancer drug. Therefore, drug reimbursement needs to be based on ALL of the costs associated with cancer drugs.

Additionally, CMS proposes that the services associated with the administration of chemotherapy agents will be cut by close to 30% in the year 2005 and even more dramatically in 2006. This is not an acceptable practice. Our request is that ASP, properly defined, plus an additional 12% AND \$550 million dollars allocated to the practice expense module is the only acceptable option. This will assure that our patients continue to receive the best possible care in the community outpatient setting.

Furthermore, it is in the best interest of community based oncology practices that a SEPARATE bill be introduced to carve out chemotherapy drugs and administration for all Medicare recipients.

We believe that, overall, the Medicare Prescription Drug Plan may benefit many seniors; however, the cuts in reimbursement for chemotherapy drugs and treatment should never have been made a part of the current legislation.

My hope is that each individual involved in the decision-making process for this issue would have an opportunity to actually visit a community oncology clinic. You will find that the best care available is delivered in this setting. The patients and staff build a rapport that is beyond compare.

The patient care in a community oncology setting allows the patient to maintain consistency throughout their treatment cycle and to have a partnership with the physicians and caregivers.

Our patients have experienced a 10-12 hour wait for treatment in the hospital outpatient setting. The majority of hospitals are ill equipped to administer chemotherapy drugs and perform the follow-up necessary for quality patient care. Oftentimes, patients may have to wait for an extended period of time to even begin the treatment regimen. Of course, this places all patients at risk.

Our sole desire is that patients receive the best care possible. We certainly do not want to add to their level of angst after a diagnosis of cancer. We know that consistency, caring, and follow-up build a level of confidence with the patient that cannot be denied.

Thank you.

CMS-1371-IFC-31

Submitter : Mr. MARK E. SINGER Date & Time:

Organization :

Category :

03/08/2004 12:03:00

PROGRESSIVE CARE, S.C.
Health Care Provider/Association
Issue Areas/Comments

GENERAL
GENERAL

In regards to the changes in FY04 and beyond in reimbursement for community oncology, please be advised of its actual impact:

Although we have witnessed over the past year the non-Medicare carriers sliding down to the Medicare rate of reimbursement, it is obvious that going forward they intend to mimic Medicare's decrease in drug reimbursement without the concomitant increase in administrative codes.

Actual practice expenses continue to be unacknowledged and unpaid. We have already been forced to eliminate the residual benefits to patient care by terminating our nutritionist and considering cutting back on our oncological psychologists. To reduce such expenses another 29% in FY05 will only expedite the demise of the most efficient delivery model for oncology.

ASP remains undefined by trade level; thus, assuring the pushing down on and elimination of all community practices in quick order, as we do not purchase the same volume as a Humana, etc.

Given the increasing cost of drugs, the lack of appropriate and timely payment on new drugs, and the government's obstinate behavior not to recognize that every \$1 in drug cost incurs an additional 15-20% in direct costs for administration, storage, mixing, tax, spillage, wastage, etc., we will be required to hospitalize more patients. However, the hospitals currently lack sufficient capacity to handle the meager 15% load they currently enjoy.

How have you planned for the hospitals to acquire experienced staff, space, equipment, etc. to handle this surge? As well, how have you planned with the states to take on more debt as a result of more people forced onto welfare because they can no longer hold onto their jobs due to the systemic hospitalizations required? How have you planned with Congress to take on the higher cost and lower outcome for cancer care in America when it is re-directed back into the hospital?

In view of the prohibited cost of drugs due to the lack of any Federal guidelines, why are the states prevented from securing the same drugs from Canada at a lower cost; yet, it is permissible and considered safe to require patients to "brown bag" temperature sensitive drugs?

Why does Medicare tolerate the fact that many drugs that were initially cut in reimbursement were simply reduced by their manufacturer in price to the new Medicare amount providing no margin to make-up the difference in what is not currently fully reimbursed on the practice expense side?

How will you help us explain to our patients that for the equivalent of 2-3 days in Iraq, this administration is intent on de-stabilizing our own country's health care system by dis-funding community cancer care; forcing the practitioner to ration health care by electing not to use expensive

new drugs that are not reimbursed properly; losing highly trained, competent oncology nurses because their health insurance goes up 35% per year?

To succumb to special interests, such as rural health care, is ridiculous, as this will be the first area to witness Medicare's "neutron bomb" that will eviscerate community oncology practices.

Before we destroy a model that can never be replicated again, to what extent will Medicare ever consider that the true contributor to high, out of control costs is not the practitioner, but the pharmaceutical and insurance industries?

CMS-1371-IFC-32

Submitter : Mrs. Dawn Holcombe Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Oncology Network of CT, LLC

Congressional

Issue Areas/Comments

GENERAL

GENERAL

Re: file code CMS-1371-IFC

please see attached letter for errors and flaws in logic. I'd love to go in more detail. We have dozens of drugs now priced upsidedown and at a loss.

CMS-1371-IFC-33

Submitter : Mr. LINDA HUNT Date & Time:

Organization :

Category :

03/08/2004 12:03:00

PURCHASE CANCER GROUP

Congressional

Issue Areas/Comments

GENERAL

GENERAL

I THINK CUTTING THE CANCER CARE PROGRAM IS SO HORRIBLE. I WORK AT PURCHASE CANCER GROUP AT THE FRONT DESK IN PADUCAH, KY. I WISH THAT YOU AND OTHERS WOULD COME TO OUR OFFICE AND SIT NEXT TO MY DESK OR IN OUR CHEMO ROOM. SO MANY OF OUR PT.,NOW HAVE TO GO TO THE HOSPITAL TO GET THEIR CHEMO. WE HAVE A NICE ROOM AND THE PT. ENJOY AND LIKE THAT THEY ARE HERE FOR ONLY 1HR. TO MAYBE 6HR., DEPENDING ON THE TYPE OF TREATMENT THEY HAVE.PT. SAY SOME TIME THEY ARE TOLD TO BE AT THE HOSPITAL AT 8AM AND WILL END UP SITTING FOR HRS. BEFORE THEIR TX. IS STARTED, GETTING DONE AT MIDNIGHT OR LATER.MANY OF OUR PT. ARE ELDERLY,HAVE

TROUBLE DRIVING AT NIGHT,IN COLD,DAMP OR SNOWY,ICY WEATHER OR
HAVE TO DEPEND ON SOMEONE TO DRIVE THEM
WE HAVE MANY PT. THAT LIVE OUT OF TOWN.I AM 55YRS. OLD I LIVE
9MILES FROM WHERE I WORK AND I KNOW WHAT IT'S
LIKE AT MY AGE DRIVING IN BAD WEATHER. THERE ARE SO MANY
SOMETIME SAY THEY AS SOON DIE THAN HAVE TO LOSE
THE WARMNESS,CARING,LOVING FRIENDLNESS OF OUR OFFICE STAFF
AND THE OFFICE AS THE COLDNESS OF THE
HOSPITAL.SOMETIME THEY ARE STUCK IN ROOMS NOT CHECKED ON AS
THEY SHOULD OR NEED TO BE. SO PLEASE PUT
YOURSELF IN THE PATIENTS SHOES AND CHEMO CHAIR AND SEE HOW
YOU THINK YOU WOULD FEEL, THESE PEOPLE
DESERVE BETTER . SO PLEASE RECONSIDER THE CANCER CARE CUT.

CMS-1371-IFC-34

Submitter : Mr. John Waite Date & Time:

Organization :

Category :

03/08/2004 12:03:00

Virginia Physicians, Inc

Individual

Issue Areas/Comments

GENERAL

GENERAL

I am submitting my comments to rule CMS-1372-FC Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004. As an administrator of a medical oncology practice, I have witnessed first hand that these changes have negatively impacted the way we practice medicine in a community-based clinic. With at least one protocol for the drug rituximab, we have had to send the patients to the hospital infusion center because our overhead costs on the administration were too great in comparision to the Medicare reimbursement.

The reimbursement changes for this year do not severly impact us now as they will for 2005. The drastic cuts for next year will send community oncology spinning. The proposal to have office administered drugs reimbursed at Average Sale Price plus 6% will mean that physician groups will lose money on at least half of the drugs that we order. ASP will include the manufacturer's prices to hospitals and large corporate groups like US Oncology and Kaiser Permanente all of whom enjoy price discounts far greater than independent physician groups. To make the issue even more precarious, CMS wants to retract the 32% increase in administration fees that went into effect for this year. Oncology groups will lose money on the

chemotherapy drugs and be unable to cover the overhead in administration. If we can stay in business, groups such as ours will be forced into sending all Medicare patients into the hospital which will be a detriment to their care. I implore you to keep the monies (\$500 million a year) for chemotherapy administration and incorporate Average Sale Price plus 12% which studies have shown can keep community oncology operating to provide the excellent care to all of our patients. Thank you for your consideration to this matter