CMS-1372-IFC-51

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

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

CMS-1372-IFC-52

Submitter : Dr. Lanny Hecker
Date & Time: 03/05/2004 12:03:00
Organization : Hematology & Oncology Associates
Category : Physician
Issue Areas/Comments GENERAL

See Attached Letters

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

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

CMS-1372-IFC-53

Submitter: Dr. Lanny Hecker
Date & Time: 03/05/2004 12:03:00
Organization: Hematology & Oncology Associates
Category: Physician
Issue Areas/Comments GENERAL

See Attached Letters

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

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CMS-1372-IFC-54

Submitter: Dr. Henry Lee
Date & Time: 03/05/2004 12:03:00
Organization: Hematology & Oncology Associates
Category: Physician
Issue Areas/Comments: GENERAL

See Attached

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

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4. CMS felt that in some cases, some information that had been provided should not be posted for the public, like patient information. At no time will we post anything that contains patient information or release it to the public.

If you wish to view any of these regulations, please feel free to contact us here at CMS by calling 410-786-9994 or 410-786-7195 Monday through Friday to schedule an appointment. Public comments can be view by Appointments only.

CMS-1372-IFC-55

Submitter: Dr. Paul Duncan
Date & Time: Hematology & Oncology Associates
Organization: 03/05/2004 12:03:00
Category: Physician
Issue Areas/Comments: GENERAL

This is in reference to CMS 1372-FC 3/5/04 I am a hematologist/oncologist member of a 5 person group in Albuquerque, New Mexico. Our group was formed 27 years ago and we see on average 900 new patients/year. At the current time (3/5/04) we pay more for: parenteral decadron;Taxol;parenteral pepcid and zoladex than Medicare allowable as of 1/1/04. It is not possible to run any business if the cost of sales is more than reimbursement. There has to be a margin to cover expenses of stocking, wastage, shipping costs etc. In New Mexico there still exists a gross receipts tax applied to sales of certain medical services (5.8%-some of these taxes have been recently rescinded by the state and for the most part (about 80% of tax) will disappear by January 2005. Main Medicare is exempted by managed Medicare does not totally disappear until 2005. A fair margin needs to be applied and this should be determined by a fair analysis of small businesses which are viable in the United States. Reimbursement for a pharmacist employed by an oncology practice should be provided because of the complexity of cancer pharmo-therapeutics. Nursing assessments are valuable and have been recognized in CPT-4(i.e. 99211)-they should not have arbitrarily been removed because infusion codes were reimbursed at a higher level. Our nurses continue to provide valuable cognitive evaluations and it is inappropriate to dismiss them. This in effect dilutes the important increases needed for administration codes. You might be interested in knowing that our charges in 1988 for a 99408 are almost identical to reimbursement from Medicare in 2003. Further reductions in 2005 for administration codes will be intolerable.

I predict practices will be unable to treat Medicare patients in the office if that is the scenario. This will have a chilling effect on clinical cancer research as well in the Medicare population where we need research data. The idea that the increase in administration code reimbursement offsets the loss in income from the pharmaceuticals is clearly false. If community practices fail there is not the capacity in University clinics or other facilities to take up the slack. The result will be a rather dramatic decrease in access for our seniors. We are already seeing some of this in 2004 but if the planned additional cuts for 2005 are carried out this will become readily apparent. Congress clearly does not wish to see a decreased access to care in the Medicare population (or any population for that matter) and they have authorized CMS to Act after April 1, 2004 to correct any errors in reimbursement. It is important that CMS does this responsibly and not risk under-reimbursement. It is better to err on the side of overpayment than underpayment because no model is perfect and the risk of underpayment is dissolution of an infrastructure that has taken years to build. Medicare does not have a large regional warehouse where oncology drugs could be stored and they don't wish to that. We are blessed by a pharmacy distribution system in this country which is phenomenonal. This is because of the efficiency of free enterprise which is the basic foundation of our economy. It is not perfect but it happens to be the best system devised yet by human societies. This works to Medicare's benefit as a payer of medical services. However, failure to

reimburse adequately for chemotherapy drugs and the safe administration of these drugs means that in the long run those drugs in which reimbursement is inadequate will not be used. Clinical research is done to determine the optimum treatment but it is possible that the optimum treatment cannot be afforded by the system. Please review in detail all chemotherapy administration polices. Multiple pushes of all agents should be allowed-not just chemotherapeutic agents.

Congress has given CMS the charge to get it right and not interfere with quality delivery of cancer therapy. Please do so.

Thank you.

CMS-1372-IFC-56

Submitter: Mr. Ann Donovan
Date & Time: 03/05/2004 12:03:00
Organization: Heartland Hematology-Oncology
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

In the 33 years of working in oncology, I have never felt so desperate for our patients. The impending changes for our Medicare population don't just threaten our ability to provide care it will stop the ability to provide care for many oncologists nationally. We are going from being progressive and able to provide the best cancer care in the world, to what we had over thirty years ago--only those who could afford to buy their own drugs, got treatment. A senator told me that "Medicare can't continue to pay for a person's "bad" lifestyle". Tell that to my farmer with lymphoma or the person who worked in a chemical factory among heavy metals that now has pancreatic cancer. I am sure that they would understand that their lifestyle just wasn't "good" enough! Until we get serious about cleaning up our environment, cancer numbers are only going to increase. I am attaching a copy of a spreadsheet that I have had to compile to make sure we could purchase drugs at a cost lesser than what Medicare is allowing. As you can see, there is no cushion. Even with the allowances in 2004, if a patient is underinsured, then the physician takes it at a loss. Other insurance companies are sniffing around like wild dogs. Once Medicare sets the standard, they try to follow.

The recent Medicare TV advertisements are misleading and I am sure they are meant to lull the population, it isn't the same Medicare-just better as the ads state. We are activating our patient population and they are frankly in disbelief that the government could do such a thing. We have been working with COA to give you accurate figures. Are you disbelieving? This year will be survivable; however, unless ASP is properly defined and the percentage is raised, the system will be broken. Once the system is broken, it cannot just be put back together. Our entire staffs are specialized in dealing with the terminally ill. So, once they are disbanded, there is no way to just hire new people off the street and be up and running again. CMS can't make up its mind and our patients suffer for it--first you want all treatments done in the office (which we obliged CMS with) and now, everything will switch back to the hospital. When January hit and we could not give four of our most common treatments, you just can't believe what we had to go through--patients wanting to pay the difference between our cost and what Medicare would allow, begging us not to transfer them to the outpatient department, tears, terror from the patient, fear of going to a new location--it was horrible! I only wish CMS could experience a fraction of what my patients go through. You're killing the messenger-the oncologist.

Years ago, there was no OSHA to comply to, CLIA to comply to, needless systems, hoods, expensive waste disposal, etc--now, we comply to all of this and yet our supply costs/ waste costs go up and up--and our reimbursement goes down. CMS needs to look long and hard at the figures being presented by those of us who are working oncologist!! Maybe we should get reimbursed for all of the services and supplies provided. That would at least help--to be able to bill for huber needles, tubing, special wraps, insyte catheters and waste disposal. I just don't see that happening. Next year, if the formula is not corrected, will be a disaster---many patients will not survive long enough for it to get straightened back out. It is hard for me not to be cynical--maybe this has been the plan all along. After all, cancer patients really can't be productive and add to society--they just drain away the financial resources, right? Until it happens to you.

CMS-1372-IFC-57

Submitter: Dr. William DeRosa
Date & Time: 03/05/2004 12:03:00
Organization: Hematology-Oncology Associates of Northern NJ, PA
Category: Congressional
Issue Areas/Comments General

Please see attached letter

THE ENDOCRINE SOCIETY®

8401 CONNECTICUT AVENUE, SUITE 900 ▪ CHEVY CHASE, MARYLAND ▪ 20815-5817 ▪ TELEPHONE 301.941.0200 ▪ FAX 301.941.0259 ▪ www.endo-society.org

March 5, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1372-FC
PO Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

On behalf of the physician members of the Endocrine Society and their patients in need of rhTSH (Thyrogen), we request an adjustment to the Medicare allowable amount for Thyrogen in the 2004 fee schedule. Under the Medicare Prescription Drug Improvement and Modernization Act, the proposed reimbursement rate does not even cover the cost of the drug itself, and there is no other way to cover the loss in revenue for the physician using it. This clearly jeopardizes access to Thyrogen for those thyroid cancer patients who are Medicare beneficiaries.

Early diagnosis and regular lifelong monitoring comprise effective treatment and management of well-differentiated thyroid cancer. Administration of Thyrogen in conjunction with thyroglobulin testing and/or radioiodine imaging has become the standard of practice in the follow-up management of such thyroid cancer patients. As responsible physicians, we are committed to providing all of our patients with the highest standard of care available.

The Medicare allowable for Thyrogen in 2004 is $1105.00 per kit when administered in the physician's office, as is often the case for purposes of cost-effective care. This amount was established using Average Wholesale Price figures that were in effect in April, 2003. This allowable is much lower than the current wholesale price of $1285.00 per kit. Physicians in private practice are not in the position to absorb an expense of this magnitude and should not be forced to lower their standard of care for Medicare patients because of the unreasonably low allowable rate. We are certain you will agree that the amount allowed by Medicare should be reasonable and accurately reflect the current purchase price of the drug.

We urge you to reconsider the methodology used to calculate the Medicare reimbursement rate for Thyrogen in 2004. Proper reimbursement will allow physicians to continue providing Medicare beneficiaries with the highest standard of care available.

Very truly yours,

E. Chester Ridgway, MD
President, The Endocrine Society

Richard A Dickey, MD
Chair, Clinical Affairs Committee
The Endocrine Society

CMS-1372-IFC-58

Submitter: Dr. Steven Papish
Date & Time: 03/05/2004 12:03:00
Organization: Hematology-Oncology Associates of Northern NJ, PA
Category: Congressional
Issue Areas/Comments: GENERAL

Please see attached letter

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

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CMS-1372-IFC-59

Submitter: Dr. Joni Tilford
Date & Time: 03/07/2004 12:03:00
Organization: Nebraska Hematology-Oncology
Category: Congressional
Issue Areas/Comments: GENERAL

Please see attached file for my comments - I thank you for your time.

Joni A Tilford MD

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

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CMS-1372-IFC-60

Submitter: Dr. Ray Peters
Date & Time: 03/07/2004 12:03:00
Organization: Ray E Peters DO
Category: Congressional
Issue Areas/Comments: GENERAL

I am commenting on Medicare reimbursement. I apologize if this is not a calm comment. Literally, I have been forced to consider the survival of my private practice of medical oncology. This is upsetting and unsettling. The reimbursement situation, as published, will put my practice into negative numbers even if I do not pay myself. We already have poor reimbursement in rural Missouri. You then cut chemotherapy drug payments. The increase in administrative reimbursement is touted as compensatory. Of course it is not for those of us who receive fractional reimbursement for our work. We are not guessing at this. My personnel have plugged the numbers into Excel spreadsheets and we find that we will lose this year. They don't tell me how bad next year is--fearing lose of employment. The real world of costs:

1) Billing costs 7%--just negotiated down from 8%.
2) Glitches in reimbursement cost 1-3%.
3) Delay in payment costs 2-3% in carrying costs which we regain by paying for drug up front. We carry Medicare and others while waiting for uncertain reimbursement.
4) Some drugs are "free" before we spend personnel time in acquisitions and don't recoup administration costs.
5). And some drugs are reimbursed below net acquisition costs.
6) We have forms and paperwork. We have to go to classes which explain the obscurities of governmental policy--like HIPA privacy policies.

You add to our work as regulators and reduce our payments as insurers. We are case managers, home health liaison & government apologists. We drown under your heavy burdens. And now you reduce reimbursement below cost.

Thanks.

CMS-1372-IFC-61

Submitter: Mrs. Sherry Lasher
Date & Time: 03/07/2004 12:03:00
Organization: N/A
Category: Congressional
Issue Areas/Comments: GENERAL

As an individual who has had a family member who was diagnosed with terminal cancer and an employee of an oncology group, I urge you to please think of more than money before you act. If you had ever had to hear a doctor tell you that your only chance (and sometimes a small one at that) of surviving cancer and that chemo was your only option, would you rather receive it at a physicians office or a hospital? Having been in the hospital recently, I have first hand experience that they are short-handed and you definitely do not get any extra care there. Dealing with a terminal illness is a harsh fact to face and every ounce of comfort you receive from your physician, staff and surroundings is appreciated. Our patients report that they are at the hospital for hours sometimes simply getting through registration. Would you want yourself or a family member to experience this ? Have a heart for a change and think of the person instead of the dollar. I'm quite sure there are many other avenues to go that do not affect so many very sick people.

Sincerely,
Sherry Lasher

CMS-1372-IFC-62

Submitter: Dr. Alan Israel
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Physician
Issue Areas/Comments: GENERAL

The Medicare reimbursement changes for 2004 have effected the administration of chemotherapy for Medicare recipients in my office. Because a number of the chemotherapy agents are not available to me at prices at or below the level of Medicare reimbursement I have been routinely sending patients to the Hospitals for this therapy. This specifically refers to Camptosar and Eloxatin used in colon cancer and Taxotere used in breast, lung and prostate cancers. Zometa is another drug with inadequate reimbursement. For 2005 because of anticipated reimbursement decreases resulting from the adoption of ASP+6% I plan on reducing the hours of my two chemotherapy nurses. Accordingly, additional patients will be treated in hospital. The explanation of benefits from the hospital admissions show how costly this is to the taxpayer. Finally, I wish to point out how unfair and inconsistent the Medicare reimbursement rules are to non-participating physicians. The cost of buying chemotherapy drugs DOES NOT DEPEND on whether you are a participating physician. I should be reimbursed the same amount for 40,000 units of Procrit for example which I purchased from a wholesaler as a participating physician who purchases from the same wholesaler. The lower reimbursements for chemotherapy agents received by non-participating physicians are unreasonable and entirely inconsistent. The chemotherapy reimbursement scheme for 2006 will withdraw significant revenues from oncology offices and will force most Medicare patients to receive chemotherapy in hospital. That is clear from looking at the cash flow of any oncology practice. Unfortunately, because the Medicare recipients are entitled to treatment it will not save the tax payer any thing.

Thank you for your attention

Alan Israel MD

CMS-1372-IFC-63

Submitter: Ms. Carol Riley
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Nurse
Issue Areas/Comments: GENERAL

Dear Mr. Smith,

I am writing in regards to the comment period for the rules and regulations on CMS-1372-FC. I am an oncology nurse with 19 years experience. I went into the field of oncology my senior year in nursing school due to the loss of my grandmother to metastatic breast cancer my freshmen year in college. However, for as long as I can remember she battled cancer. She is and remains my hero by her courageous battle and I know if she was diagnosis today she would be alive with all the progress we have made in our field. I support a balanced Medicare reform that addresses both cancer drugs and essential medical services. The changes for 2004 was a step in the right direction. However, the changes in the future have me greatly concern for what will happen to the oncology field. As a nurse I have experienced the shift of oncology from the hospital setting to the communtiy based setting. This shift has improved the quality of care given to patient. Less mistakes are made with dosing. Patients feel their quality of life are improved. Our patients beg not to be put in the hospital. It has enabled our patients to maintain control of their lives by also getting the best care for them. The community oncology has control. I like to give you example of some of the problems that will happen if the care is taken away from the community based doctor:

1. CBC's will take longer to run, delay in getting treatments started. In our office we can run a CBC in less than 3 mins, a stat cbc at the hospital takes 1-2 hours for the results.

2. Once at the hosptial, possiblity of other problems or 2nd hospital acquired infections increase. This is not a problem in our office.

3. Drug dosing errors or administration errors increase in the hospital. They do not have the quality staff that we have. Same nurses are not always taking care of the patients. Nursing shortage effects quality of care. Have you been in the hospital lately? The changes for 2005 puts in a system that is not tested but also includes sources that do not bill under Medicare Part B to be included in the ASP like wholesalers and hospitals. How is this fair? Secondly, it decreases reimbursement for administration codes. At the present time, there are numerous items we are not billed for

1. IVP of antiemetics.
2. Salline bags used to administered chemotherapy
3. all supplies-- pac needles, iv tubings, syringes, needles, etoh prep pads, betadine, jelco cathetars, just

to name a few
4. Many drugs are below reimbursed below cost
Decadron
Benadryl
Faslodex
Zometa
Lupron
Zoladex
Epirubicin
Camptosar
5Fu

5. Finally, pain management, symptom management such as help with control of diarrhea, constipaiton, diet, fatigue,mouth sores, dehydration, nausea and vomiting, loss of control, decrease in ADL's, and pyschological support given by nurses are not captured and reimbursed. In closing, the decrease in professional fees for 2005 and beyond is determintal to oncology practices . We have never been reimbursed for many of our services and when a change has finally been made to help rectify the practice expense portion in 2004, these amounts are then taken away in 2005 and beyond. Most oncology nurses went into the field to provide quality care to patients. These nurses become part of the extend family for many of the patients. What these nurses provide in physicians office has never been reimbursed adequately, and if the changes happen as proposed for 2005 and 2006 many of these nurses will lose their job and patients will be forced to go the hospitals where they are just a number not an individual. It would be jumping back in time by over 20 years. With the progress we are making in treating cancer this would be a giant step backward.

CMS-1372-IFC-64

Submitter: Dr. Brian Berry
Date & Time: 03/08/2004 12:03:00
Organization: Florida Cancer Specialists
Category: Physician
Issue Areas/Comments: GENERAL

Dear Sir,

As a practicing community oncologist in Florida, I believe that I have a unique perspective on the effects that these rules have had on my elderly patients. First, let me mention that my patients are generally quite elderly, with a median age of 71 and with 82% of our patients on medicare. We have been severely impacted by the changes for 2004 and have found that several chemotherapy drugs can no longer be administered to our patients in our office. One example is Sandostatin, a drug for patients with Metastatic Carcinoid. Patients are now suffering with severe flushing, sweats, diarhea and blood pressure changes because they can not recieve this drug through our clinic or the hospital. Why? Because it now costs more to buy the drug than we can get reimbursed for injecting it! There is not substitute for this drug. Other chemotherapy drugs such as Campath, Novantrone, Carboplatin, and Doxil have similar situations. Some pharmaceutical companies like Eli Lilly have responded by decreasing the cost of Gemzar to lower our acquisition expenses but not all companies are doing this. I am even more concerned about the 2005 regulatory changes and especially about the switch to ASP-based pricing. As I understand it now, ASP will mean that we will most likely not be able to acquire half of our drugs for more than it costs us now to administer them. This will result in great upheaval as our patients are refused chemotherapy with no alternative to recieve it elsewhere. Are the hospitals going to deliver the chemotherapy and lose money on each patient? No they won't and we won't either. If these rules are not changed or postphoned until adequate adjustments can be factored into the system, there will be many angry senior citizens not able to get appropriate treatment for their cancers. My own recommendation is to postphone the 2005 and 2006 changes until there is data available to truly assure the new regulations provide
continuing access to cancer care for all our seniors.

Sincerely,

Brian T. Berry, MD, PhD.

CMS-1372-IFC-65

Submitter: Mrs. Lisa Thompson
Date & Time: 03/08/2004 12:03:00
Organization: Purhcase Cancer Group
Category: Congressional
Issue Areas/Comments: GENERAL

First of all, I would like to say thank you for taking time to read the comments. I would ask that as you read my
comment you step back out of the congresssional mode and see what I see on a daily basis. I come from a small community
in Paducah. Each day I come into an office that our primary job is to tell people of how their lives are about to changed forever. They are given the devastating news that they have cancer. In the past 12 years that I have been at this practice, their ability to pay or not to pay has never been an issue for my doctors. You were treated the same whether you have insurance or whether you did not. I have always had the utmost respect for doctors who really have a desire to make a
persons life better versus how much money can I make. I work for three that have the desire to make a persons life better.
We have had to decide whether we can treat a patient in our office or whether they need to go to the hospital. This is a
very new concept for my office. I think the most gut-wretching comment I have heard regarding the cancer care cut has come from a patient that I personally overheard in the waiting room. She said, "I guess they (governement) just wants to give us
a shot and kill us". Another patient ask," Where am I going to get my treatment now?" That particular patient knows how much money in the last eight years that we have written off of her account. She knows that when we order her particular medication, we lose $1270 every month. That has been an issue for the past 8 years but now we must be careful of every
dollar we spend. But the hardest part was the fact that the hospitals were not willing to give the medication to her either. What do the patients do then? Fortunately, a local hospital has decided to give it. I don't know for how long. You don't
see the same battles as I do everyday. I also understand that I don't see your battles either. I know you job is difficult.
I am asking that congress at least not pull the administration codes for 2005 as stated in the bill. I also would ask that
you reconsider what you have done. You told your constituents that you would fix any problem that these cut would bring. But you are not planning of looking at that information until 2006. The year after all the admin codes have been done away with. The things that are being done to our senior and our sick are not fair to them.

Most of them have worked all their lives and deserve the best when they are faced with a life of cancer.

They would rather stay in our facility and be with nurses who know them rather than go to the hospital and sit twice as long for the same treatment. I can provide documentation that shows where a patient of ours went to the hospital for treatment @ 9am. He did not get a room until 5pm and his treatment was not finished until 1am the following morning. How can that be good for my patient? This is not the only incident like this. It will happen more and more if you continue down the road that you are on. I am very blessed to be in my office each and everyday. My goal is make a positive difference in their lives. Again thank you for taking time to read my thoughts and concerns.

CMS-1372-IFC-66

Submitter: Mrs. Lynn Foster
Date & Time: 03/08/2004 12:03:00
Organization: Palmetto Hematology Oncology, P.C.
Category: Other Health Care Professional
Issue Areas/Comments:GENERAL

1)Many of the drugs are reimbursed at a level lower than what we are currently able to purchase the drug for.

2)We are reviewing closing two of our three satellite offices (25-30 miles away from the main office) because of
the decrease in reimbursement and the fact that the patients are unable to step up to pay their 20%. The hospitals
in the area are unwilling and are not staffed to take patients in their center. So, the alternatives are that the
patients will travel 25-30 miles or choose to not continue treatment.

3)I am concerned that the change is causing physicians across this country to treat based on cost of treatment regimens
and not the best drug that is available. There simply must be a better way!

CMS-1372-IFC-67

Submitter: Dr. Leonard Kalman
Date & Time: 03/08/2004 12:03:00
Organization: Oncology Hematology Group of South Florida, PA
Category: Congressional
Issue Areas/Comments: GENERAL

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

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CMS-1372-IFC-68

Submitter: Mr. Clifton Osbourne
Date & Time: 03/08/2004 12:03:00
Organization: Transcript Pharmacy, Inc.
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

On January 8, 2004, CMS reduced their level of Medicare reimbursement for numerous drug products. Some of the cuts
were excessive and have resulted in significant lost revenue for pharmacy providers. Of particular importance are the
drugs that prevent organ transplant recipients from rejecting their new organ (immunosuppressants). If this class of drugs
is not exempted from the recent cuts, pharmacies may have to refuse to provide these medications to Medicare beneficiaries.
This will certainly be true if any of the manufacturers raise their current prices. The end result will be business failure for some of those pharmacies that have chosen to serve these vulnerable Medicare beneficiaries. If unable to obtain these drugs, patients will experience dramatic declines in overall health status, loss of function of their transplanted organs
and possibly death. We urge CMS to immediately reconsider this class of agents and exempt them from the recent reimbursement changes, then review the class and determine what constitutes reasonable and appropriate reimbursement. We ask CMS to comply with the law passed by Congress that requires a supply fee be paid for providing these medications. We calculate this cost
to be about $38 per prescription. This amount covers the costs associated with procuring and stocking these very expensive drug products, costs of labor (pharmacist, technician and support staff), costs of management of Accounts Receivable for Medicare patients and other business costs directly related to provision of pharmaceuticals (rent, utilities, insurance, etc.) We ask that CMS reimburse providers the difference that should have been paid for all claims from January 8, 2004 through the date that changes are made in reimbursement. We ask that CMS apply similar standards as do other payors, including Medicaid agencies and commercial insurers. This would mean that CMS would drop the onerous requirements that mandate:

1. Providers have a CMN or DIF completed for each prescription dispensed. This cumbersome requirement is used nowhere else
in the healthcare delivery system for prescription drugs.

2. Providers secure an original signed order before each prescription is dispensed. This burden is not placed on pharmacies by other payors. Pharmacists are only required to document the source of each prescription order.

Transcript Pharmacy, Inc.
2506 Lakeland Drive Suite 201
Flowood, MS 39232
601-420-4041 Phone
601-420-4040 Fax
March 5, 2004
Centers for Medicare and Medicaid Services
Room C5-14-03
7500 Security Blvd.
Baltimore, MD 21244-8013
Reference: CMS-1372-FC
Dear Sir or Ma'am:
On January 8, 2004, CMS reduced their level of Medicare reimbursement for numerous drug products. Some of the cuts were excessive and have resulted in significant lost revenue for pharmacy providers. Of particular importance are the drugs that prevent organ transplant recipients from rejecting their new organ (immunosuppressants).
If this class of drugs is not exempted from the recent cuts, pharmacies may have to refuse to provide these medications to Medicare beneficiaries. This will certainly be true if any of the manufacturers raise their current prices. The end result will be business failure for some of those pharmacies that have chosen to serve these vulnerable Medicare beneficiaries. If unable to obtain these drugs, patients will experience dramatic declines in overall health status, loss of function of their transplanted organs and possibly death.
We urge CMS to immediately reconsider this class of agents and exempt them from the recent reimbursement changes, then review the class and determine what constitutes reasonable and appropriate reimbursement.
We ask CMS to comply with the law passed by Congress that requires a supply fee be paid for providing these medications. We calculate this cost to be about $38 per prescription. This amount covers the costs associated with procuring and stocking these very expensive drug products, costs of labor (pharmacist, technician and support staff), costs of management of Accounts Receivable for Medicare patients and other business costs directly related to provision of pharmaceuticals (rent, utilities, insurance, etc.)
We ask that CMS reimburse providers the difference that should have been paid for all claims from January 8, 2004 through the date that changes are made in reimbursement.
We ask that CMS apply similar standards as do other payors, including Medicaid agencies and commercial insurers. This would mean that CMS would drop the onerous requirements that mandate:
1. Providers have a CMN or DIF completed for each prescription dispensed. This cumbersome requirement is used nowhere else in the healthcare delivery system for prescription drugs.
2. Providers secure an original signed order before each prescription is dispensed. This burden is not placed on pharmacies by other payors. Pharmacists are only required to document the source of each prescription order.
3. Providers secure a completed Assignment of Benefits document. No other payor places this

universal requirement on pharmacists.

Transcript Pharmacy, Inc.
2506 Lakeland Drive Suite 201
Flowood, MS 39232
601-420-4041 Phone
601-420-4040 Fax
We appreciate the opportunity to comment on this issue. Should your agency require additional information, please do not hesitate to contact me directly at 601-420-4041.
Sincerely,
Clifton Osbon, R.Ph.
Vice President
Transcript Pharmacy, Inc.
Medicare Provider 4595910001
Affected drugs include:
Drug Product HCPCS (Reimbursement Codes)
Tacrolimus (Prograf®) J7507 J7508
Mycophenolate mofetil (CellCept®) J7517
Prednisone J7506
Sirolimus (Rapamune®) J7520
Cyclosporine (Neoral®, Sandimmune®, etc.) J7502 J7515
Azathioprine (Imuran®) J7500

3. Providers secure a completed Assignment of Benefits document. No other payor places this universal requirement on pharmacists.

We appreciate the opportunity to comment on this issue. Should your agency require additional information, please do not hesitate to contact me directly at 601-420-4041.

Sincerely,

Clifton Osbon, R.Ph.
Vice President
Transcript Pharmacy, Inc.
Medicare Provider 4595910001

CMS-1372-IFC-69

Submitter: Mr. Fran Corona
Date & Time: 03/08/2004 12:03:00
Organization: Drs. Forte, Schleider & Attas, P.A.
Category: Health Care Provider/Association
Issue Areas/Comments: GENERAL

Please see the attached letter to CMS for comments on the Changes to Medicare Payment for Drugs and Physician FeeSchedule Payments for Calendar Year 2004. I feel it is crucial for CMS to fully understand how these changes willaffect Medicare. We have come a long way in the War on Cancer. Please do not let that change. This office has alreadychanged where some chemotherapy is being provided. Several drugs, listed in the attached letter, are under our costs.

We therefore, cannot afford to provide this treatment in our office and are sending patients to the hospital for their treatment. We also, unfortunately, have already had a reduction in staff and changed some office functions for 2004. Weare very concerned how these changes will affect all Medicare patients receiving cancer care. Thank you for your timeand consideration on this very critical matter.

CMS-1372-IFC-70

Submitter: Dr. Ana Lamas
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Physician
Issue Areas/Comments: GENERAL

Pleas see attachment below

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

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

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

CMS-1372-IFC-71

Submitter: Mr. Robert Gamble
Date & Time: 03/08/2004 12:03:00
Organization: Southeastern Medical Oncology Center
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

Comments to CMS:

First, CMS is to be commended in their attempts to transition the oncology community to a payment schema that does not involve ?Average Wholesale Price?. This is a mammoth task that impacts the entire outpatient cancer care community and
your courage to make this revision is to be admired. However, as an oncology four physicians serving five counties in
North Carolina, we have the following concerns:

1) Any revision to the payment system for outpatient oncology care should be budget neutral in order to protect the
quality and access to oncology care in a cost effective environment. The changes that were made for 2004 seem to accomplish your goal of shedding the AWP dependency while keeping us budget neutral with the payment increases for service. (Note: Our office is scheduled to have a deficit of $38,000 from the 2004 changes.) If the 32% transitional payment (for 2004) is reduced to the anticipated 3% our office can expect a decreased cash flow of $850,000. This deficit will be $1,200,000 if other payers follow this same payment structure. These types of deficits are likely to cause us to close our doors and 140 cancer patients pr day will not have access to care.

2) Average Sales Price is still not clearly defined and yet it is to be implemented within the next 9 months. The
ASP +6% model is also is also not properly described in that the health care provider will not realize all of the
6%. The drug distributor will receive some portion of the 6%. Regardless, it does not feasible for the community
oncology practice to survive based on the current understanding and definitions of ASP.

3) There continue to be many services that are under-reimbursed. This includes drugs, supplies and services. Further
study or effort is needed to make sure services and products are properly reimbursed.

4) There are also many services and product that are not reimbursed at all. These include, but are not limited, to the

time and effort for a professional health care provider to meet with patients and families to describe their therapy,
the risks and benefits and to get their authorization to pursue treatment. This time, and the other time spent answering patients can amount to several hours per patient. 90% of all of the supplies expensed to take care of patients is also
not reimbursed. This amounts to approximately $150,000 per year.

5) Lastly, the incentives to provide cost effective quality health care for 2005 do not agreement with the goals that our nation was founded on. The incentives seem to promote higher priced drugs and for the healthcare delivery to occur in higher cost environments such as the hospital. We prefer the incentives to placed on delivering the highest quality healthcare at the lowest possible cost.

We do not confess to know what the answers may be to the above. We are certainly willing to continue to provide information to support our concerns. We request that CMS give this issue due diligence by either continuing 2004 reimbursements in to 2005 and beyond , or at least delaying further changes until more information can be gathered.

Thank you in advance for this consideration.

CMS-1372-IFC-72

Submitter: Dr. William McGarry
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Congressional
Issue Areas/Comments: GENERAL

Dear Sirs;

The reductions in chemotherapy reimbursement will greatly limit my ability to provide chemotherapy in my office. Although there is an assumption that oncologists will be ableto shift these treatments to the hospitals or CMS designated mandatory vendors, that is not the case. There is a significant cost in the physician work component in planning, implementing and counseling cancer patients and their families which is not reimbursed under the current E'&'M system. When chemotherapy is made "revenue neutral" it will place financial pressure on oncologists to abandon treating Medicare patients and instead see primary care Internal Medicine patients.For example, I can see three patients with hypertension in the time it takes for me to write chemotherapy orders, answer nursing questions and oversee pharmacy inventories for chemotherapy--services for which I am currently not compensated by the E'&'M system. Under these proposals an oncologist will earn less practicing oncology than if he practices Internal Medicine, thus placing financial pressures on the oncologist to reduce the number of oncology patients he will take in his practice. These proposals will bring about an acute reduction in the access to care for Medicare recipients who have cancer.

Sincerely,

William McGarry, MD

CMS-1372-IFC-73

Submitter: Mr. Pamela Kassing
Date & Time: 03/08/2004 12:03:00
Organization: The American College of Radiology
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

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

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CMS-1372-IFC-74

Submitter: Mr. Rose Petrillo
Date & Time: 03/08/2004 12:03:00
Organization: Oncology Hematology Associates Of Northern Pa.
Category: Congressional
Issue Areas/Comments: GENERAL

To whom it may concern regarding CMS-1372-FC;

I would like you to please research before you give any final decsions regarding the cuts you have proposed for 2005. I feel you need to better look at the reimbursement model we are such a unique situation we take care of the patient has a whole mentally,physically,spirtually,we do alot of teaching to the patient and the family so every one has betterunderstanding of the process and the many bumps in the road ahead. Their are some drugsyou don't even reimburse me what I pay for them. How is that right? We are a rural cancercenter and give high quality, accessible and comprehensive cancer care close to home for
these patients.We provide state of the art cancer care so people do not have to drive 2 1/2 hours to Pittsburgh for treatments. We work in conjunction with the University of Pittsburgh offer access to clinical trials. The patient is able to receive all their cancer care in one place including chemotherapy and radiation.Some patients get treated twice a week, and I can't imagine these people traveling because we are forced to close due to reimbursement. We offer a van service free of charge to help these patients who have no one to come for their treatments and doctor appointments.I find it very hard to accept the impact your recommendations will make in cancer care in our community. Essentially forcing us to close our doors,because we can no longer give the care our patients deserve due to the reduction in reimbursement. It is unfair and unrealistic for the federal government to expect to reimburse community oncology clinics based solely on an acquisition cost of drugs that they procure. Cancer drugs cost more for storage,inventory, pharmacy, preparation and waste. I feel you do not understand what it takes to deliver cancer care.. What do you think we do with the patients who have no insurance we can't close the doors on them we treat and eat the costs,no one reimburses us for that. We treat regardless of insurance or lack of, these are human lives we are dealing with.

Cancer care is not simply counting out a few pills and administering them to the patient. It is a sophisticated process where highly toxic medications are infused in patients, under the most carefully controlled conditions.I don't know of any other speciality that has built the best health care system minimizing cost, maximizing quality, maximizing access and maintaining the autonomy of physician and patient relationship. Again I will say we provide nutritional, spirtual, social and other support services 24 hour on call for doctors and nurses to meet the needs of the patients and families.We continue to endure revenue cuts from our payers yet all our expenses continue to rise. My greatest concern is that you appear concerned with the "money amount " and that you are not thinking, about the effect your decision, has on the people who need cancer care services. We work hard to effectively

screen for and are able to treat cancer early in the disease process. We do screenings free of charge four times a year that to is a non billable service. I ask that you reconsider your changes please take everyones input and studies and what ever it takes so that cancer patients will not suffer for decisions that you make.

Consider the community you live in without cancer services. Cancer touches all of us in some way do not punish patients and families at a time of great need in their life with legislatives that will destroy the community cancer care systems. Thank you for taking the time and reading this I hope you reconsider the changes you want to implement.

Sincerely,

Rose Petrillo

CMS-1372-IFC-75

Submitter: Dr. William Jessee
Date & Time: 03/08/2004 12:03:00
Organization: Medical Group Management Association
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

Please see attached file

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

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March 8, 2004

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

Re: Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004

Dear Mr. Smith:

The Medical Group Management Association (MGMA) is pleased to provide the following comments in response to the interim final rule entitled "Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004," as published in the January 7, 2004 Federal Register. MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 19,000 members manage and lead some 11,500 health care organizations in which more than 237,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

MGMA appreciates the ongoing efforts of the Centers for Medicare & Medicaid Services (CMS) to update and clarify Medicare policies. We also recognize the substantial challenges the Agency faces in implementing the wide-ranging components of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). We have several concerns and recommendations related to this rule, as outlined below.

Definition of "physician services"

The statutory language of the Social Security Act defining the Medicare physician payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. We believe CMS' chosen definition for "physician services" in the sustainable growth rate (SGR) formula is inappropriate because it includes the cost of physician-administered outpatient prescription drugs. Medicare's coverage of prescription drugs has been a significant factor in the growth of Medicare expenditures. Since 1996 (the SGR base year), SGR spending for physician-administered drugs has more than doubled. These expenses reflect the acquisition of products, not services rendered by medical professionals.

Drugs are not “physician services,” and the definition of “physician services,” as required by the statute, does not include the cost of prescription drugs. The Administration’s inclusion of drugs in the definition of physician services runs counter to CMS’ longstanding goal of paying appropriately for both drugs and physician services.

A separate definition of physician services clearly distinguishes physician administered outpatient prescription drugs from services rendered by physicians. CMS adopted this definition in the December 12, 2002 “Inherent Reasonableness” rule (67 FR 76684). Plainly, in order to fairly administer the Medicare program, CMS ought to apply a consistent definition of physician services. The United States Senate endorsed such an interpretation in a Sense of the Senate resolution, passed as part of S.1, the Prescription Drug and Medicare Improvement Act of 2003, during the Medicare reform debate last year. Moreover, key House leaders, including the 2003 Chairmen of congressional authorizing committees for CMS, as well as the chairs of their respective health subcommittees, have written to the Agency encouraging the Administration to remove physician-administered drugs from the SGR calculation. MGMA agrees and strongly urges CMS to remove prescription drug expenditures from the definition of “physician services” used to calculate the physician payment update factor.

One consideration for CMS is that the recently reformed drug payment system potentially offers a separate venue for CMS to address the utilization and cost of drugs. Through the Average Sales Price setting mechanism, CMS could adjust prices to reflect utilization, novelty and cost. This may be a more appropriate way to achieve CMS’ goal of paying providers for actual costs incurred for the treatment of Medicare beneficiaries.

MEI Calculation

Another component of the Medicare physician reimbursement formula that needs improvement is the Medicare Economic Index (MEI). The MEI was established in 1973 to reflect the rising cost of practicing medicine. However, the current MEI calculation is showing its age, and fails to incorporate all of the costs a physician group practice bears to care for patients. MGMA agrees with a recent Practicing Physicians Advisory Council recommendation to CMS that the MEI be expanded to include costs such as compliance with extensive new billing regulations, including hiring new staff and increasing training for current staff to keep up with expanding regulations. The MEI also should reflect steps taken to improve patient safety and include those additional costs not included in the MEI in 1973, but which clearly ought to be a part of the calculation today.

MMA Recommendations

MGMA urges CMS to exclude from the SGR the program costs of prescription drugs now covered under MMA’s expansion of Medicare benefits. Clearly, the drug expenditures currently included in the SGR skew the calculation of growth in physician service utilization. As CMS implements the MMA, the new drug benefit will cover many more drugs that, like currently covered drugs, are not physician

services and therefore should be excluded in the SGR calculation.

We also note that the MMA's expanded coverage of prescription drugs, as well as preventive services, will lead to increased beneficiary utilization of physician services. While these new benefits will significantly improve Medicare for patients, and are important in continuing to improve the health of our nation's elderly and disabled, the new coverage will encourage more patient visits to physicians, negatively impacting physician reimbursements through the SGR. For instance, it is likely that more patients will visit their primary care physicians to obtain prescriptions, which in turn will drive up Medicare expenditures on both physician services and drugs. In addition, screening tests that will help to save lives also will increase Medicare spending on chronic care treatments as well as surgeries resulting from the discovery of acute health problems. It is imperative that CMS include both the direct and indirect costs of treating Medicare beneficiaries, including those resulting from the MMA, in its calculation of the SGR.

Reimbursement for Physician Administered Prescription Drugs

MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the physician's administration services. The MMA dramatically altered reimbursement in both of these areas, and MGMA remains concerned about the adequacy of reimbursement levels. Beginning in 2005, the cost of physician-administered drugs will be reimbursed at Average Sales Price (ASP) + 6 percent. It is our understanding that the ASP calculation will include the prices paid by large purchasers with the greatest abilities to leverage discounts, such as hospitals and health maintenance organizations. However, physician groups often must purchase these drugs at higher prices from wholesalers, who include a mark up in their pricing. It seems likely that such a calculation will leave smaller group practices, without access to such discounts, in the precarious position of being unable to cover the costs of buying these drugs.

There are several steps CMS can take to help facilitate the transition. Most importantly, where it has the discretion, CMS should take every reasonable step to ensure that reimbursement levels for these drugs are adequate for all physician group practices – not just the largest entities or the ones with access to the greatest discounts. Additionally, physician practices affected by these changes will need the earliest possible notification of the ASP of covered drugs, as well as the opportunity to comment on the adequacy of these prices as part of CMS' ongoing analysis of the appropriateness of these reimbursement levels. Moreover, CMS and its contractors should provide ample provider education on associated coding changes so that providers can bill accurately for both the drugs and their administration. All of this will help CMS to pay more appropriately for this care.

MGMA appreciates your consideration of these comments. If you should have any questions, please contact Jennifer Searfoss Miller in the Government Affairs Department at (202) 293-3450.

Sincerely,

CMS-1372-IFC-76

Submitter: Mr. Michael Sullivan
Date & Time: 03/08/2004 12:03:00
Organization: Northwest Medical Specialties, PLLC
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

SUBJECT: CMS-1372-IFC, Medicare: Physician Fee Schedule (2004 CY); Payment Reform For Drugs & Biologicals.

Our medical group with 12 oncology and infectious diseases physicians serves patients with serious infections, malignancies and immune disorders who reside in South King, Pierce, and Kitsap counties in Washington State through our 4 offices. We strongly support CMS' efforts to reform the current AWP payment methodology used to reimburse physicians for chemotherapy medications administered in the physicians office. However, payment reform must be both fairand equitable to preserve the ability of our clinic to continue to care for the acutely ill patients who walk through our doors. This is especially important given the high technical and staffing costs of operating a pharmacy and multiple infusion centers. We believe our ability to continue to care for such patients is threatened by the severe payment reductions for medications scheduled for 2004 and beyond.

We are especially concerned about the adoption of an Average Sales Price (ASP) payment methodology for 2005 and beyond. Due to the reductions in reimbursement for medications delivered in the physician office we project that our practice's Medicare drug reimbursement will decrease in 2004 by $1.54 million while reimbursement for practice expenses will increase by $.95 million for a net decrease of $.59 million. Assuming that 10% of our commercial payers will follow Medicare's lead we project that our practice willsee a total decrease of $.94 million in 2004.

We can survive these cuts for 2004 but will not be able to survive the cuts we anticipate in 2005 and beyond if the ASP+6% payment methodology is implemented. While ASP is not yet defined, some industry officials estimate it is equivalent to AWP-28 to 30%. Using these numbers and the decreasing payment for practice expenses, we project our total Medicare revenues will decrease by $1.98 million in 2005 and our total losses will be as much as $3.1 million from Medicare & Commercial payers combined. WE WILL NOT SURVIVE PAYMENT REDUCTIONS OF THIS MAGNITUDE. Due to the current payment reductions we no longer are ableto accept Medicare patients without secondary insurance. Though critically short of space,we have halted plans to open a new cancer treatment center in 2006. We have frozen our salaries. Also, already we see that we will need to curtail the use of a number of treatment options because the anticipated reimbursement is at or below our cost. Specific medications include Proleukin, Rituxan, Camptosar, Doxil, Gemzar, Hycamtin, Carboplatin and Zometa. These are primary drugs used in the treatment of cancer.

While a few manufacturers have lowered their pricing due to Medicare reimbursement cuts, this survival strategy will not work in 2005 and beyond. ASP by definition is an average which means half of the purchasers pay more than ASP and half pay less than ASP. CMS intends to utilize ASP data provided by the pharmaceutical industry which will have to include buyers not even compensated under Part B. Over time, community physicians who pay more than ASP will have to exit the delivery system. As providers cease providing chemotherapy the resultant ASP will decrease more since it is an average. Over time the ASP will erode to a level where all physicians will be forced to stop providing chemotherapy in their offices. Where will those patients go for cancer care? Initially physicians will admit them to the hospital for treatment as we are doing. However, we have already heard from our local hospital that they can not provide cancer care at a loss either. CMS must define ASP to include all of the costs associated with procuring and storing medications.Also, through valid studies of practice
expenses CMS must insure it adequately compensates community office based physicians for the high technical & staffing costs associated with providing these life saving complex medications.

CMS-1372-IFC-77

Submitter: Dr. Loren Tschetter
Date & Time: 03/08/2004 12:03:00
Organization: Sioux Valley Clinic- Oncology
Category: Congressional
Issue Areas/Comments: GENERAL

Please refer to attachment.

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

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CMS-1372-IFC-78

Submitter : Dr. Mark Lipshutz Date & Time:
Organization :
Category :
03/08/2004 12:03:00
Hematology Oncology Associates of W. Suffolk, P.C.
Physician
Issue Areas/Comments
GENERAL

We have attached our comment regarding CMS-1372-FC Changes to Medicare Payment for Drugs and Physician Fee Schedule.

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

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CMS-1372-IFC-79

Submitter: Ms. Barbara Smith
Date & Time: 03/08/2004 12:03:00
Organization:
Category:
03/08/2004 12:03:00
American Thyroid Association
Congressional
Issue Areas/Comments
GENERAL

To Whom it May Concern:
We are writing on behalf of the physician members of the American Thyroid Association to request an adjustment to the Medicare allowable amount for Thyrogen in 2004. Under the Medicare Prescription Drug Improvement and Modernization Act, the reimbursement rate does not even cover the cost of the drug. This clearly jeopardizes access to Thyrogen for thyroid cancer patients who are Medicare beneficiaries. Early diagnosis and regular lifelong monitoring comprise effective treatment and management of well-differentiated thyroid cancer. Administration of Thyrogen in conjunction with thyroglobulin testing and/or radioiodine imaging has become a standard of practice in the follow-up management of thyroid cancer patients. As physicians, we are committed to providing the highest standard of care to all of our patients. The Medicare allowable for Thyrogen in 2004 is $1105.00 per kit when administered in a physician office. This amount was established using Average Wholesale Price figures that were in effect in April, 2003. It does not reflect the current wholesale price of $1285.00 per kit. Physicians in private practice are not in the position to absorb an expense of this magnitude, nor do we want to lower our standard of care for Medicare patients. The amount allowed by Medicare should accurately reflect the current purchase price of the drug. An exception for Thyrogen has already been filed with CMS because of concern that low reimbursement rates may cause thyroid cancer patients to be denied access to Thyrogen.

We support this exception and urge you to reconsider the methodology used to calculate the Medicare reimbursement rate for Thyrogen in 2004. Proper reimbursement will allow physicians to continue providing Medicare beneficiaries with the highest standard of care available.

Yours truly,

Gregory A. Brent, M.D.
Secretary, American Thyroid Association

Paul W. Ladenson, M.D.
President-elect, American Thyroid Association
Michael Tuttle, M.D.
Chair, ATA Clinical Affairs Committee

Transcript Pharmacy, Inc.
2506 Lakeland Drive Suite 201
Flowood, MS 39232
601-420-4041 Phone
601-420-4040 Fax
March 5, 2004
Centers for Medicare and Medicaid Services
Room C5-14-03
7500 Security Blvd.
Baltimore, MD 21244-8013
Reference: CMS-1372-FC
Dear Sir or Ma'am:
On January 8, 2004, CMS reduced their level of Medicare reimbursement for numerous drug products. Some of the cuts were excessive and have resulted in significant lost revenue for pharmacy providers. Of particular importance are the drugs that prevent organ transplant recipients from rejecting their new organ (immunosuppressants).
If this class of drugs is not exempted from the recent cuts, pharmacies may have to refuse to provide these medications to Medicare beneficiaries. This will certainly be true if any of the manufacturers raise their current prices. The end result will be business failure for some of those pharmacies that have chosen to serve these vulnerable Medicare beneficiaries. If unable to obtain these drugs, patients will experience dramatic declines in overall health status, loss of function of their transplanted organs and possibly death.
We urge CMS to immediately reconsider this class of agents and exempt them from the recent reimbursement changes, then review the class and determine what constitutes reasonable and appropriate reimbursement.
We ask CMS to comply with the law passed by Congress that requires a supply fee be paid for providing these medications. We calculate this cost to be about $38 per prescription. This amount covers the costs associated with procuring and stocking these very expensive drug products, costs of labor (pharmacist, technician and support staff), costs of management of Accounts Receivable for Medicare patients and other business costs directly related to provision of pharmaceuticals (rent, utilities, insurance, etc.)
We ask that CMS reimburse providers the difference that should have been paid for all claims from January 8, 2004 through the date that changes are made in reimbursement.
We ask that CMS apply similar standards as do other payors, including Medicaid agencies and commercial insurers. This would mean that CMS would drop the onerous requirements that mandate:
1. Providers have a CMN or DIF completed for each prescription dispensed. This cumbersome requirement is used nowhere else in the healthcare delivery system for prescription drugs.
2. Providers secure an original signed order before each prescription is dispensed. This burden is not placed on pharmacies by other payors. Pharmacists are only required to document the source of each prescription order.
3. Providers secure a completed Assignment of Benefits document. No other payor places this

universal requirement on pharmacists.

Transcript Pharmacy, Inc.
2506 Lakeland Drive Suite 201
Flowood, MS 39232
601-420-4041 Phone
601-420-4040 Fax
We appreciate the opportunity to comment on this issue. Should your agency require additional information, please do not hesitate to contact me directly at 601-420-4041.
Sincerely,
Clifton Osbon, R.Ph.
Vice President
Transcript Pharmacy, Inc.
Medicare Provider 4595910001
Affected drugs include:
Drug Product HCPCS (Reimbursement Codes)
Tacrolimus (Prograf®) J7507 J7508
Mycophenolate mofetil (CellCept®) J7517
Prednisone J7506
Sirolimus (Rapamune®) J7520
Cyclosporine (Neoral®, Sandimmune®, etc.) J7502 J7515
Azathioprine (Imuran®) J7500

CMS-1372-IFC-80

Submitter : Mrs. Jo Ann Tucker Date & Time:
Organization :
Category :
03/08/2004 12:03:00
Central Alabama Oncology, LLC
Congressional
Issue Areas/Comments
GENERAL

I am the practice administrator for a single physician medical oncology practice in Alabama. While I appreciate the efforts of CMS to reform of the reimbursement system for drugs, I am deeply concerned about how the 2005 and 2006 changes will impact our practice. As a result of the changes in drug reimbursement in 2004, there are a number of drugs that are now being reimbursed at less that our practice can purchase them. Some of them are: carboplatin, carmustine, cladribine, ifosfomide, steptozocin, Zoladex, and Sandostatin. Other drugs that are being paid at just a few cents above cost are: Rituxan, gemcitabine, irinotecan, and Doxil. The 32% temporary increase in payment for the administration of these drugs is the only thing that has kept our practice solvent this year. As the current rule reads, this amount will be reduced to 3% in 2005. A 29% reduction in the amount presently paid for administration of cancer treatments would not cover the expenses involved with said administration, which include: specialized nurses, synringes, needles, IV tubing, drug storage, waste, patient and family counseling--not to mention rent, billing personnel, and many other expenses). If the rule is not changed for 2005 and beyond, our practice will be faced with a very tough decision. Do we send Medicare patients into the hospital setting for their cancer treatment or transfer their care to a University setting many miles away from our community or do we simply close our doors? Our number 1 concern is for the cancer patients in our community. Many of them already have transportation difficulties just getting to our office to receive their cancer treatment. If we are no longer available to treat them in this community, many of them will be unable to receive cancer treatment simply because they have no way of traveling an additional 40-50 miles to a metropolitan cancer center. I urge CMS to carefully review the impact the 2005 rule will have on Medicare cancer patients. I would be happy to discuss this issue with you at length. Your consideration of this very important matter is greatly appreciated.

Sincerely,

Jo Ann Tucker
Practice Administrator
Central Alabama Oncology, LLC
1024 First Street North

CMS-1372-IFC-81

Submitter: Mr. Owen Dahl
Date & Time:03/08/2004 12:03:00
Organization: Hematology & Oncology Specialists, LLC
Category: Physician
Issue Areas/Comments: GENERAL

I am the manager of a 23 medical oncology group in New Orleans. Our comments are attached.

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

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

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

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

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

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

CMS-1372-IFC-82

Submitter: Mr. Scott Taylor
Date & Time: 03/08/2004 12:03:00
Organization: Hematology & Oncology Associates of Eastern Idaho, PLLC
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

Please see our attached document, thank you

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

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

CMS-1372-IFC-83

Submitter: Dr. Bruce Kressel
Date & Time: 03/08/2004 12:03:00
Organization: Washington Oncology-Hematology Center
Category: Physician
Issue Areas/Comments: GENERAL

In response to rule CMS-1372-FC, we still have several drugs that we cannot provide or are barely making a profit on to include: Carboplatin, Doxil, Ellence, Fludarabine, Ifos & Mesna, Ferrlecit, IVIG's and Treisenox. If this continues and with what is coming down the pike for 2005 we will be unable to continue providing treatments for our patients. The reduction of services reimbursement by 29% in 2005 is simply not justified by my own costs. We are already sending several patients to the hospital for treatment and this will probably become the norm in the near future. Please reconsider the new 2005 cuts. We are a practice of 3 physicians and these comments are coming from all 3.

CMS-1372-IFC-84

Submitter: Mr. JOHN BARNEY
Date & Time: 03/08/2004 12:03:00
Organization: Medical Specialists of Fairfield
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

In the beginning of 2004 there were a handful of drugs that Medicare reimbursed for less than we paid for them.To an extent this has been rectified by the Drug Companies.I applaud the 32% increase in payments for infusion services ,but if this increase were to be dropped by 29% in 2005 our Practice would be decimated.We could not afford to treat Medicare patients in our office.I don't think I need to tell you that the administration of chemotherapy is a very expensive proposition and if we are not reimbursed fairly we could not afford the treatment in our office.Along these lines it's only a matter of time before the other Insurance companies get involved and if they follow Medicare reimbursement it will be the "death knell" to outpatient chemotherapy.Do I think we need to be reimbursed like we have in the past?No! However I feel that Community Oncology Alliance will offer a fair alternative whereby both the government will win and the outpatient treatment centers will remain viable and get back to taking care of patients.

CMS-1372-IFC-85

Submitter: Mrs. Jan Beach
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Health Care Professional or Association
Issue Areas/Comments:GENERAL

I've done the math and there is no way Community Based offices will be able to provide Cancer care without being reimbursed for all the services they provide. As it stands now, two Oncologist in our town no longer provide cancer care. The hospitals will not be able to absorb the care that is required for cancer patients and quite frankly, hospitals are not the least costly alternative! I do not believe Oncologist oppose being reimbursed for what services they provide, but you need to make sure all the services are reimbursed. Seems to me if the price of drugs could be controlled and offered to the Oncologist at a reasonable price AND ALL the services Oncologist provide, were reimbursed, the winner would be the Cancer Patients. What the Government and CMS have/are creating is NO care for cancer patients. Only the Government can stay in business on a deficient budget, deciding what is relevent and what is not.....hear the people....protect the elderly.....care for the people..... do your elected job and stop selling the American people out. Stop the flood of money out of our country.....Do you know that three times the amount is paid for medical care to people serving time verses people on Medicaid? Will next year be the year the Government can say we have costs under control because NO medicare patient will receive Cancer Care under the Medicare Program? The lives of many Cancer patients are in your hands.....since you have Government Benefits this might not concern you but for most of American this is a life and dealth issue! I ask you to work with Community Oncology Alliance (COA) as this is the only group that represents Community Based Practices and Cancer Patients in Community Based Offices.

CMS-1372-IFC-86

Submitter: Ms. Cynthia McGill
Date & Time:03/08/2004 12:03:00
Organization: Purchase Cancer Group, PSC
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

FILE CODE CMS-1372-F

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 costs 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 of 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 the patient's level of angst after a cancer diagnosis. We know that consistency, caring, and follow-up in the community oncology outpatient office helps to build a level of confidence with the patient that cannot be denied.

CMS-1372-IFC-87

Submitter: Mrs. Diane Lewis
Date & Time: 03/08/2004 12:03:00
Organization: N/A
Category: Psychiatric Hospital
Issue Areas/Comments: GENERAL

I work in a community based oncology practice and I have done the math and there is no way Community Based offices will be able to provide Cancer care without being reimbursed for all the services they provide. As it stands now, two Oncologist in our town no longer provide cancer care. The hospitals will not be able to absorb the care that is required for cancer patients and quite frankly, hospitals are not the least costly alternative! I do not believe Oncologist oppose being reimbursed for what services they provide, but you need to make sure all the services are reimbursed. Seems to me if the price of drugs could be controlled and offered to the Oncologist at a reasonable price AND ALL the services Oncologist provide, were reimbursed, the winner would be the Cancer Patients. Which should be everyones goal.

CMS-1372-IFC-88

Submitter: Ms. Mary Jo Carden
Date & Time: 03/08/2004 12:03:00
Organization: Transplant Pharmacy Coalition
Category: Association
Issue Areas/Comments: GENERAL

The Transplant Pharmacy Coalition submits comments regarding the interim final rule: Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004. Members of the Transplant Pharmacy Coalition are specialty pharmacies that provide critical immunosuppressive medications to prevent rejection of transplanted organs in nearly 84.000 Medicare beneficiaries. The members of the Transplant Pharmacy Coalition have already been negatively impacted by the Medicare Part B payment reductions for pharmaceuticals implemented in January 2004 before a final rule was ever promulgated. These pharmacies are experiencing economic hardships that make it nearly impossible to continue providing critical immunosuppressive medications for more than several weeks. The Transplant Pharmacy Coalition appreciates the opportunity to comment on the reductions but urges CMS to take immediate action to ensure that patient access to these critical medications is not further jeopardized. Each coalition member pharmacy will provide its own comments regarding the interim final rule. These comments will urge CMS to take the following three immediate actions that will ensure patient access is not jeopardized: Exempt all immunosuppressive agents from the recent reimbursement changes --while revisiting the regulations and determining what constitutes reasonable and appropriate reimbursements. Use First DataBank as the primary average wholesale price (AWP) reference source rather than RedBook. It is common pharmacy industry practice to use First DataBank rather than RedBook as a pricing reference for both purchasing and payment. Further, RedBook AWPs are typically 2-4% lower than First DataBank?s prices and unfairly lowers reimbursement even further. Immediately begin paying a supplying fee mandated by Congress under Section 303(a)(2) of the Medicare Prescription Drug, Improvement and Modernization Act (DIMA). CMS indicated that the supplying fee has not been paid to pharmacies because data are not available to support the
payment of the supplying fee at this time. Individual comments submitted by coalition members will provide CMS the data it needs to implement a supplying fee immediately. Implementing these immediate changes for this narrow category of immunosuppressive products will ensure continued patient access. Then, members of the Transplant Pharmacy Coalition will work with CMS, Congress, and other affected parties and organizations to develop an appropriate long-term solution to the provision of immunosuppressive medications under Medicare Part B.

If you have questions regarding the content of these comments, please contact Mary Jo Carden (Mcarden@dumbartonassociates.com) or Leigh Davitian (Ldavitian@dumbartonassociates.com), Principals in Dumbarton Group & Associates, LLC, (DG) and Legislative Counsel to the Transplant Pharmacy Coalition. DG?s phone number is 202-638-6994.

CMS-1372-IFC-89

Submitter: Mrs. Jenny Hass
Date & Time: 03/08/2004 12:03:00
Organization: Bend Memorial Clinc
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

The following attachment lists drugs where CMS reimbursement is less then cost. It is our understanding that as a Medicare provider it is CMS's intention to reimburse no less than the cost of drugs. Therefore, the following attached document identify drugs where Bend Memorial Clinic receives a negative reimbursement by CMS (less than cost). We would like CMS to reconsider the current reimbursement rate to cover at least our cost for each drug.

CMS-1372-IFC-90

Submitter: Mr. MARK E. SINGER
Date & Time: 03/08/2004 12:03:00
Organization: PROGRESSIVE CARE, S.C.
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

In regards to the changes in FY04 and beyond in reimbursement for community oncology, please be advised of its 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 a concommitant increase in administrative codes. Actual practice expenses continue to be unacknowledged and unpaid, and we have already been forced to eliminate the residual benefits to patient care by terminating our nutritionist, as well as 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 obstinent behavior not to recognize that every $1.00 in drug cost incurs an additional 15-20% in direct costs for ordering/warehousing, tax, transportation, mixing, spillage, spoilage, 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 the additional 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 permissable and considered safe to require our patients to "brown bag" temperature sensitive toxic drugs? Why does Medicare tolerate the fact that many drug prices that were initially cut in their reimbursement were simply reduced by their manufacturer to the new Medicare amount; thus, achieving our claim of the demise of cancer care by reimbursing acquisition cost only and deleting any margin to make-up the difference in what is not currently reimbursed on the practice expense side? How will you help us to explain to our patients that for the equivalent of 2-3 days in Iraq, this administration is intent on de-stabilizing our own health care system by de-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 increases 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 the high, out of control costs is not the practitioner, but the pharmaceutical and insurance industries?

CMS-1372-IFC-91

Submitter : Ms. Susan Treanor
Date & Time: 03/08/2004 12:03:00
Organization: Arena Oncology Associates
Category: Nurse
Issue Areas/Comments: GENERAL

To whom it may concern: I am an oncology nurse working in a private practice for 15 years. During these years cancer care has made some great progress. Most noteably, it has moved from in patient hospitalization to outpatient care. Patients are able to continue their lives with minimal disruption to the home or work routine. There has also been tremendous improvements in the quality of cancer fighting drugs. They are becoming less toxic to the patient and more targeted to the specific cancer. Unfortunately, this type of progress comes with a high price tag. I am deeply concerned that we will not be able to provide the new, truly lifesaving chemotherapy to our patients under the new reimbursement schedule. As it stands now, we are not being reimbursed even our cost on the following medications: Camptosar, Gemzar, Faslodex, Interleukin-2 and Streptozocin. The following drugs are being reimbursed at just 1-2% above our cost, they are: Campath, Doxil, Epirubicin, Hycamptin, Novantrone, Carboplatin, Rituxin and Zometa. I have also noticed some inconsistencies in reimbursement for the same drug at different doses. For instance, if we give interferon 3 million units, we will get back 18% LESS than we paid. However, if we give 5 million units, we will be reimbursed what we paid +4%. There is the same type of inconsistancy with Neupogen and Immunoglobin. I am in agreement that Medicare reimbursement should be reformed, but to decrease reimbursement to the point that private practices will no longer be able to provide the drug will only result in patients not being able to receive the cancer care that is available to them. The overhead expenses that are required to run a private oncology practice are tremendous. We need to employ specially trained nurses to administer the chemotherapy. We need a large facility in order to accomodate all the patients treatments which can last all day. We need specialized lab equipment to monitor the side effects of the chemotherapy and determine if it is safe to give the patient their chemotherapy. We have come so far in the 15 years I have been an oncology nurse. There are patients living longer and better quality lives. To continue on this current path of medicare reform will undoubtedly result in limited access to quality cancer care or a complete shift back to the required hospitalization, of which the costs would be significantly higher than they are now. Thank you for your consideration of the above matters.

Sincerely,

Susan Treanor, RN, OCN

CMS-1372-IFC-92

Submitter: Mrs. Alice Pickering
Date & Time: 03/08/2004 12:03:00
Organization: Associated Medical Specialist PA dba Coastal Cancer Center
Category: Health Care Professional or Association
Issue Areas/Comments: GENERAL

File CMS-1372-FC

In reference to the current decisions for 2004 and 2005 reimbursement of cancer care, we cannot continually serve patients at less than cost and remain in a viable business. Costs are hard to control on medications that are not highly utilized because of quantity purchased. It will be difficult, if not impossible, to continue to administer medications when reimbursement does not cover our costs.

To best serve our patients, we are continuously educating our RNs and encouraging and paying for them to become Oncology Certified. This vital education is a necessary ongoing expense to our practice. Continuing education for staff in matters of cancer care, compliance, new and changing regimens, new products on the market, how to safely mix and administer to the patient as well as staying current with documentation, billing and coding requirements is an additional, ongoing expense. We also maintain multiple facilities to accommodate our patients so they may receive extended hours of chemotherapy infusion in a comfortable environment close to home with easy access where realistically, family and friends are close by for support. In light of the 29% cut in 2005 we have revised and implemented all ways we know to cut costs and generate revenue without compromising quality or progressive care to our patient. Since 1982, Coastal Cancer Center (a division of Associated Medical Specialists, P.A.) has continued to try to do their part in providing and improving cancer care to our patients. Where we do believe that there was and is a need to revise the current system, our goal is to accomplish this while not tearing down what great cancer care that we all have worked so hard in this country to create.

I trust we can continue our mission if we work together to find solutions to this latest budget crisis. With all of the technology that we have today, we should be moving forward, not backward and are willing, while believing CMS is willing to work toward this end.

With kindest regards,

Alice Pickering
Administrator
Coastal Cancer Center

CMS-1372-IFC-93

Submitter: Dr. Myo Thant
Date & Time: 03/08/2004 12:03:00
Organization: Maryland Hematology and Oncology Associates
Category: Physician
Issue Areas/Comments: GENERAL

Please be informed that the current drug reimbursement affect the quality of care to our cancer patients.

1. We stopped giving Faslodex injection except when we had no alternative because it was a loss of income.

2. We also stopped giving Irinotecan to two of our patients because of the same low reimbursement resulting in a loss.

3. Two of the patients with Medicare only were sent to the hospital because we could not afford to take the loss of 20%. The patients who did not have co-pay were never able to pay the 20% out of their pockets and we had to write it off. In the past we were able to support it because the loss was bearable and the loss was compensated by the revenues received from other sources. With the decrease in the drug reimbursement we cannot afford to take the huge loss anymore.

4. 5-FU is also a loss for us.

5. Many of the supporting drugs such dexamethasone, benadryl are losses.

CMS-1372-IFC-94

Submitter: Dr. Gary Gross
Date & Time: 03/08/2004 12:03:00
Organization: Blood and Cancer Center of East Texas
Category: Physician
Issue Areas/Comments: GENERAL

Re CMS-1372-FC:

I support your efforts to develop a more rational approach to reimbursement for oncology services; however, your current approach will not reimburse our clinic enough to cover the costs of delivering cancer treatments to Medicare patients, thus forcing our patients to travel to already overcrowded outpatient facilities at local hospitals to spend hours receiving their treatments. What forces this move? Even including your increased reimbursement for chemotherapy delivery services, for our Medicare patients without a secondary insurance policy, every single drug we administer (save taxol, cisplatin, and leucovorin) would be delivered at a net loss to our practice. This does not even factor in the extraordinary overhead costs which we endure. I now have an associate, but until 3 months ago, to provided high quality and effecient cancer care, as a solo provider I required a staff of 10 with a monthly salary of $20,000. As well, we have the mortgage on a 5,000 square foot facility. And we have the cost of other unrecognized and unreimbursed highly specialized equiptment: sophisticated iv pumps, mixing hoods, drug management systems (Lynx). As of January 1 of this year, I have had to send the 20% of our Mediare patients without a secondary policy to the hospital oupatient facility for their treaments.. By next year, with your ASP system in place, I will not be able to afford to treat any Medicare patients in the office. I am one of 13 oncologists in Tyler Texas. We will all be in the same situation. If I extrapolate my average of 12 Medicare chemo treatments times 13 physicians, that would be 156 outpatient treatments per day. Between our two hospitals we have 5 chairs and 2 nurses to provide these services...an impossiblity in a 24 hour work day. This isn't just about money. I would love to have the time to share with you the physical and emotional stresses of my 14 hour work day. Why do you begrudge me a fair salary? Make changes, but please take into account our costs of purchasing chemotherapy drugs and providing high quality services, and make realistic changes.

Gary GRoss, MD, FACP

CMS-1372-IFC-96

Submitter : **Dr. Mark Hutchins M.D.** **Date & Time:** **02/24/2004 12:02:00**

Organization : **Nebraska Hematology Oncology**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs.
You have a big job. You do it pretty well considering. I and my colleagues have an important job. We see and care for cancer patients. We try to maximize their time at home and minimize their time in the hospital. They may not have long to live.
We deliver nearly 100% of our chemotherapy in our office. Patients come and receive same day treatment and go home.
We do receive more in drug reimbursement then the drugs cost us. That is true. This excess over cost quite honestly pays the physicians. Without this we would have to work for nothing. The money we get for seeing the patient, for administering the drugs, and a little from lab, pays the cost of running an outpatient chemo administration office. We support 15-17 employees with salary, health insurance and retirement plans. We are only 3 doctors, but we need this back up to deliver care to our patients.
Your proposed rules for 2005 will essentially eliminate any chance of us continuing to care for cancer patients in the outpatient setting.
All of the Medicare patients will be sent to the inpatient wards of hospitals and wait for their treatments (what we did in 1980). The idea of taking back the increase in administration fees that were authorized for 2004 is insane, absolutely insane.
Being a cancer doctor is a rewarding life pursuit. But none of us can continue this work if you remove our ability to control our treatments (mandatory vendor) or eliminate our ability to pay our nurses (reduce the administration fees) and if you remove our ability to pay ourselves (reduce drug reimbursement to acquisition cost).
Dr. Mark Hutchins M.D.