Submitter : Ms. phyllis thompson **Date:** 08/31/2007

Organization : university of cincinnati heart and vascular center

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

Please continue to provide seperate reimbursement for echo contrast agents in 2008. There are many patients that we would not be able to define the endocardial borders without this very useful tool. We can definitely make a more accurate assessment of wall motion abnormalities in our obese patients more readily because of contrast. The purchase of contrast is quite costly, and without the seperate reimbursement I am afraid that sonographers would see the cost as a disincentive to using the contrast agent. Additional time and personnel is also a factor in the use of contrast agents, we need the seperate reimbursement to cover all of the different elements involved. Using contrast agents is a very useful noninvasive way to diagnose cardiovascular disease. Please don't make us lose it because of seperate reimbursement issues. Thank you for your time. Phyllis Thompson RDCS Hamilton,OH

Submitter : **Dr. Franklin Schneider** **Date: 08/31/2007**

Organization : **Cardiovascular Associates of RI**

Category : **Physician**

Issue Areas/Comments

OPPS Impact

OPPS Impact

Dear CMS-

I strongly oppose CMS-1392-P which will bundle payment for intravenous echocontrast with stress echo or transthoracic payments. Intravenous echocontrast is a medication which is extremely useful under the proper circumstances - It can take a non-diagnostic echocardiographic study and provide diagnostic quality images.

We do not use echocontrast with every study. It is used very selectively. However, when used it has great value. To use intravenous echocontrast properly requires s significant amount of additional effort. A nurse must start an intravenous line, and administer the medication. A physician must be present when we give the echocontrast. We also must change the ultrasound machine settings to allow us to optomize the image quality. All this takes extra time and effort. This doesn't even include the added cost of the contrast agent.

All this proposed policy will do is make physicians less apt to use intravenous echocontrast. This will ultimately result in higher costs because additional studies will need to be performed to get adequate diagnostic data about the patient.

I think the proposal is extremely short sighted.

Thank you for your time.

Sincerely,

Franklin Schneider, MD, FASE, FACC, FASNC
Director, Non-Invasive Imaging Labs
Cardiovascular Associates of RI

#298

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

#299

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

#300

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : Dr. Orlando Santana **Date:** 08/31/2007

Organization : Mt. Sinai Medical Center

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I do stress echo. To eliminate payment for contrast agent for outpatient is a big mistake. In limited studies, adding a contrast agent actually saves money by not having to repeat the test with other imaging modalities. Contrast agents are extremely underused, and this will only exacerbate that problem. Numerous studies have been published that show that contrast agents SAVE MONEY!!!!!!

#302

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

Submitter : Dr. Joshua Prager **Date:** 08/31/2007

Organization : N. American Neuromodulation Society (NANS)

Category : Physician

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

On behalf of the North American Neuromodulation Society (NANS), I am writing to urge CMS to create a separate ambulatory payment classification (APC) for rechargeable neurostimulators under its Proposed Changes to the Hospital Outpatient Prospective Payment System (CMS-1392-P).

NANS is the leading medical professional society for physicians dedicated to advancing the science and clinical application of neuromodulation therapies, including neurostimulation for chronic, intractable pain.

As you know, special, new technology pass-through payments for rechargeable neurostimulators are scheduled to expire in 2008. CMS already recognizes that rechargeable neurostimulators represent a substantial clinical improvement. Because of the advancements in battery power for rechargeable neurostimulators, this therapy results in far fewer clinical interventions (i.e., battery replacement and related complications). The higher initial cost of rechargeable neurostimulators is certainly more than offset over the patient s lifetime, resulting in long-term cost savings to Medicare over non-rechargeable systems. In January 2006 CMS began providing reimbursement to hospitals for the cost differential between rechargeable and non-rechargeable neurostimulators through the pass-through payment.

In the proposed rule, CMS proposes to pay hospitals the same rate ($12,314) for rechargeable and non-rechargeable neurostimulators when implanted in hospital outpatient departments in 2008. The cost differential (according to CMS s claims data) between the two therapies is approximately $6,500 a substantial difference that warrants separate reimbursement. Further, we do not believe that new coding requirements to support classification within a new APC would prove overly burdensome for facilities. However, the differential cost would clearly and negatively impact patient access to rechargeable neurostimulation.

At this rate, however, it will be financial infeasible for many facilities to offer their patients rechargeable neurostimulator technology, despite its demonstrated clinical and economic advantages.

Without a separate APC for rechargeable neurostimulators, we are deeply concerned that the proposed rules would substantially and negatively impact patient access to this vital therapy. Again, we urge CMS to recognize this shortcoming in the proposed rule by establishing an APC that reflects the true device and facility overhead costs of procedures that use rechargeable neurostimulators and allows facilities to continue offering this important therapy option to their patients.

Should you have any questions concerning these comments and implantable neurostimulation, please do not hesitate to contact me directly at paindoc@ucla.edu or (310) 264-7246. Thank you for your consideration on this important issue.

Sincerely,

Joshua Prager, M.D., President
North American Neuromodulation Society

Submitter : Ms. Becky Littke **Date:** 08/31/2007

Organization : Kadlec Medical Center

Category : Hospital

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

OPPS: Specified Covered Outpatient Drugs

This proposed rule would be difficult to implement at the hospital level because of operating systems. Each entry would have to be manually corrected in our Information Systems to present it as you described in the proposed rule on the UB-04. To quantify the amount of manual labor involved, this would require our hospital to edit 23,000 lines per month in outpatient pharmaceutical charges. With our current I/S program this is not achievable with the use of manual entry.

This rule creates greater opportunity for error and increases overhead for hospitals. The other factor you may consider is that this rule is inconsistent with the attempt to package services. The use of pharmaceuticals is packaged because the administration of the drug is billed in the drug price. This practice is consistent with the rest of the 2008 proposed rule.

Proposing to separate the cost of the drug and overhead fees involved in administration is contrary of your goal to package services. I understand you are hoping to pinpoint which drugs are used for which procedures, however, the administration costs do not vary by procedure. The pharmacist must still review the order, provide instructions to the nursing staff, and then the drug is administered to the patient before, during, or after a procedure.

Submitter : **Ms. Sue Hill** **Date: 08/31/2007**

Organization : **Banner Health Care**

Category : **Nurse**

Issue Areas/Comments

Wound Care Services

Wound Care Services

Skin Substitutes:
Please retain the same or improved reimbursement that you provided in 2007 on the 15340 code or APC 25.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Packaged Services

See Attachments

#306

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. TERESA LECHEL-SIREKIS **Date:** 08/31/2007

Organization : ST JOSEPH MERCY OAKLAND, MICHIGAN

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I JUST DISAGREE WITH THE WHOLE THING. JUST ANOTHER WAY FOR THE GOVERMENT TO DICTATED PROCEDURES.

Submitter : Miss. Maria Nicosia **Date:** 08/31/2007

Organization : St Joseph Mercy Oakland

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a technician who makes the decision to use or not use a drug on a patient. I bill for the product as used. It is not ethical to charge a patient for something that they did not recieve. It is also not ethical to not charge a patient for a procedure they did recieve. It should be billed as used.

Submitter : Mrs. Valerie Rinkle **Date:** 08/31/2007

Organization : Asante Health System

Category : Hospital

Issue Areas/Comments

Relative weights

Relative weights

Asante requests CMS to eliminate the requirement that hospitals use new patient visit codes. Originally on page 18451 of the April 1, 2000 Final OPPS Rule, CMS defined an established patient as a patient that already had a medical record and there was no reference to a timeframe or 3 years. Then in 2006, CMS added that the patient was considered established if the medical record was created in the last 3 years. This was an effort to align the hospital definition of a new patient with the CPT definition.

This definition is a problem for hospitals. Medical record numbers and the actual medical record or chart associated with such numbers is unique for each patient and it is fixed and not renewed. So a baby born at a hospital and seen periodically throughout childhood into adulthood retains the exact same medical record and number. Once assigned, the medical record number never changes regardless of the frequency or infrequency of patient encounters. Many hospital safety precautions are dependent on unique medical record numbers.

Whether or not each hospital outpatient has to obtain a new medical record number or not is known only to the hospital s registration staff when an outpatient visit is scheduled. Whether a medical record number is new or if there has been an entry into a medical record (meaning a hospital visit in the past 3 years) is not known to hospital staff that choose the visit charge codes based on the services rendered at the visit.
If a patient had one clinic outpatient hospital visit five years ago and got a medical record number, then had one inpatient admission two years ago and now 5 years from the first outpatient visit has another outpatient visit would that patient be a new outpatient to the hospital? Remember, the medical record number and chart remain the same throughout this 5-year period. Is the definition the mere existence of a medical record number/chart as in the 2000 definition or is it an entry into the constant medical record number/chart within the past 3 years. Does an inpatient entry within the 3-years count toward whether an outpatient can be considered a new patient underthe 3-year definition?
For all these reasons, we believe the current definition of an established patient versus a new patient cannot be consistently and appropriately operationalized by hospitals. We believe the median cost data CMS has from claims is highly suspect and may reflect hospitals that merely match physician E/M coding and the physician s choice of a new or established patient. We think that the OIG will be very interested to audit hospitals now that there is a payment differential between new patient CPT codes and established patient CPT codes and APC payments. We do not think many hospitals would be able to withstand such an audit.

As CMS is clearly aware, in general, the use of CPT E/M code definitions and guidelines are problematic for hospitals. Last year CMS made the policy decision that hospitals no longer report consultation CPT codes and should a consultation require more hospital resources, that the hospitals visit guidelines incorporate this and use it in assigning visit levels. We believe the same policy should be made for new patient visit codes. CMS should change the status indicator to B for 99201-99205 and only assign five APC payment rates to 99211 99215.

Asante would rather take the one-time reduction in APC payment rates due to CMS blending the median cost data for new and established visits rather than a continuation of the current practice to report new and established patient visit codes. This change saves hospitals from trying to operationalize the current unworkable definition. We also know that the cost data will be much more accurate and robust after two years when CMS has the data based on this coding change.

Submitter : Mrs. Valerie Rinkle **Date:** 08/31/2007

Organization : Asante Health System

Category : Hospital

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Pleasc scc thc attachment for comments on packaging observation services.

CMS-1392-P-310-Attach-1.DOC

#310

Proposal to Package Observation

As an overall concept, Asante is not opposed to the concept or principle of packaging. However, we are concerned about the application of this concept to Observation Services. Observation is not a "dependent service" as CMS defines it: "We [CMS] have defined observation care as a well defined set of specific, clinically appropriate services which include ongoing, short-term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether a patient will require further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital." CMS also states "Observation status is commonly assigned to patients who present to the emergency department and who then require a significant period of treatment and monitoring before a decision is made concerning their next placement or to patients with unexpectedly prolonged recovery after surgery." From a hospital and clinical care perspective, the medical monitoring performed hour by hour IS the primary, independent service in observation cases. Asante does not believe observation is ideal for packaging and we are concerned about the interactions of CMS' multiple packaging proposals on observation cases in combination with the proposal to package observation for chest pain, asthma and congestive heart failure.

Please find below a simple analysis on several observation cases where Asante compares the 2007 payment to the proposed 2008 payment. For chest pain cases, the significant negative impact of the other six proposed packaged areas in addition to the observation-packaging proposal is evident. The interplay between all 7 packaging proposals dramatically compounds the poor OPPS reimbursement for observation cases. OPPS payment for these cases covers less than half the estimated cost of care and this would decrease further under the 2008 proposal. For cases eligible for APC 0339 payment, OPPS payments would decrease around 10%. For cases not eligible for APC 0339, OPPS payments appear flat or to decrease slightly. While this is not a large sampling of cases, for Asante, we are greatly concerned because of QIO initiatives to push more 1-2 day inpatient stays to outpatient status.

Observation Case #1		2007 Payment	Prop 2008 Payment	Difference in % Pmt
	90765	$116.34	$116.62	
	90775	$51.03	$51.42	
	71010	$44.20	$46.23	
	78465	$417.75	$765.25	
	78478	$96.73	$0.00	

	78480	$96.73	$0.00	
	A9500	$371.76	$0.00	
	99284	$219.52	$224.14	
	93017	$162.80	$182.36	
	93307	$206.60	$419.79	
	93325	$102.63	$0.00	
	93005x3	$73.05	$72.57	
	G0378	$462.90	$0.00	
Total OPPS Payments		$2,422.04	$1,878.38	
Diagnosis: Chest Pain				
	Total Charges	$13,685.70		
	Est Cost (Total Charges * OP CCR)	$5,433.22		
	Difference between Est Cost & Pmt	-$3,011.18	-$3,554.84	
	Payment as a % of Cost	44.58%	34.57%	-10.01%
	Observation Case #2	**2007 Payment**	**Prop 2008 Payment**	
	90774	$51.03	$52.93	
	90775x4	$204.14	$211.72	
	99285	$340.01	$348.81	
	G0378	$462.90	$0.00	
	90471	$25.35	$25.71	
Total OPPS Payments		$1,083.43	$639.17	
Diagnosis: Chest Pain				
	Total Charges	$10,014.65		
	Est Cost (Total Charges * OP CCR)	$3,975.82		
	Difference between Est Cost & Pmt	-$2,892.39	-$3,336.65	
	Payment as a % of Cost	27.25%	16.08%	-11.17%
	Observation Case #3	**2007 Payment**	**Prop 2008 Payment**	
	71020	$67.77	$46.23	
	78465	$417.75	$765.25	
	78478	$96.73	$0.00	
	78480	$96.73	$0.00	
	A9500	$371.76	$0.00	
	71275	$155.99	$336.41	
	94760x5	$113.32	$124.35	
	99284	$219.52	$224.14	
	93307	$206.60	$419.79	
	93320	$102.63	$0.00	
	93325	$102.63	$0.00	
	93017	$162.80	$182.36	
	Q9949	$37.00	$0.00	
	93005	$24.35	$24.19	
	G0378	$462.90	$0.00	
Total OPPS Payments		$2,638.48	$2,122.72	
Diagnosis: Chest Pain				
	Total Charges	$13,255.68		
	Est Cost (Total Charges * OP CCR)	$5,262.50		
	Difference between Est Cost & Pmt	-$2,624.02	-$3,139.78	
	Payment as a % of Cost	50.14%	40.34%	-9.80%

Observation Case #4	2007 Payment	Prop 2008 Payment	Change in Payment
71010	$45.58	$46.23	
94640x4	$90.64	$99.48	
99284	$219.52	$224.14	
G0378	$0.00	$0.00	
G0376	$11.35	$10.57	
Total OPPS Payments	$367.09	$380.42	
Diagnosis: Diarrhea			
Total Charges	$7,138.56		
Est Cost (Total Charges * OP CCR)	$2,834.01		
Difference between Est Cost & Pmt	-$2,466.92	-$2,453.59	
Payment as a % of Cost	12.95%	13.42%	0.47%
Observation Case #5	**2007 Payment**	**Prop 2008 Payment**	
90760	$116.24	$116.62	
74020	$45.58	$46.23	
71020	$67.77	$46.23	
99284	$219.52	$224.14	
93005	$24.35	$24.19	
G0378	$0.00	$0.00	
Total OPPS Payments	$473.46	$457.41	
Diagnosis: Altered Awareness			
Total Charges	$7,021.99		
Est Cost (Total Charges * OP CCR)	$2,787.73		
Difference between Est Cost & Pmt	-$2,314.27	-$2,330.32	
Payment as a % of Cost	16.98%	16.41%	-0.58%
Observation Case #6	**2007 Payment**	**Prop 2008 Payment**	
90761	$25.35	$25.71	
90774	$51.03	$52.93	
73510	$45.58	$46.23	
73550	$45.58	$46.23	
74020	$45.58	$46.23	
94640x13	$294.62	$323.31	
99283	$135.90	$138.32	
93005	$24.35	$24.19	
62311	$408.68	$454.58	
G0378	$0.00	$0.00	
Total OPPS Payments	$1,076.67	$1,157.73	
Diagnosis: Joint Pain			
Total Charges	$11,383.37		
Est Cost (Total Charges * OP CCR)	$4,519.20		
Difference between Est Cost & Pmt	-$3,442.53	-$3,361.47	
Payment as a % of Cost	23.82%	25.62%	1.79%

Observation is a critical hospital service. The Institute of Medicine's committee on the future of Emergency Care in the US recommends that

CMS remove current limitations on medical conditions that are eligible for observation. Hospitals are concerned that with the expansion of services eligible for payment in the ASC setting, there will be an increase in observation care in hospitals from direct admits from ASCs. These visits have few, if any, separately payable services. Furthermore, CMS has several initiatives with QIOs to reduce 1-2 day inpatient stays and ensure these cases are admitted as observation cases. Hospitals are asked to continue to provide medically necessary patient care and medical monitoring for these patients over 1-2 days, but accept significantly reduced payment that does not even cover half the cost of care.

The duration of observation care is ordered by physicians and controlled by physicians. Physicians have no initiatives from CMS to change their admitting or discharging behavior for these cases. Observation is a medically necessary, crucial, and "independent" service which represents significant outpatient cost to hospitals. The medical monitoring or hourly cost represented by HCPCS G0378 should be separately reimbursed because this is the "independent" service that should be explicitly recognized with an OPPS payment.

Note that since 2002, the APC Advisory Panel and CMS have worked with providers to make the billing requirements for separately payable observation easier. It is logical that the number of claims would grow with increased leniency and increased understanding of the billing requirements. It is also logical that observation would increase with CMS' initiatives to reduce 1-2 day inpatient stays. Has CMS compared the increase in the number of claims with G0378 with the decrease in one-day inpatient stays? In addition, the APC Panel and hospitals have repeatedly commented to CMS that hospitals under report observation care due to the packaged status and the complexity of billing rules prior to 2006.

Asante urges CMS to continue paying for observation for chest pain, asthma and CHF. We also urge CMS to expand separately payable observation to syncope and hypovolemia. At a minimum, we urge CMS to delay any change in observation payment policy until more analysis is performed.

We believe the following analyses should be performed and presented to hospitals.

	CY2003	CY2004	CY2005	CY2006
# Claims for Separately Payable Observation	56,000	77,000	124,300	271,200
Complexity of Rules to Bill for Separately Payable Observation	Highest	Highest	Moderate	Lowest
CMS/QIO Driven Decrease in One-Day Inpatient Stays	? !	? !	? !	? !

Percentile	25th Percentile	50th Percentile	75th Percentile
Number of 2006 Claims	? !	? !	? !
Total claim cost of 2006 Claims w/G0378	? !	? !	? !
Sum of 2007 APC Payments for Claims	? !	? !	? !
Difference from Cost	? !	? !	? !
Sum of 2008 Proposed APC Payments for these claims	? !	? !	? !
Difference from Cost	? !	? !	? !

CPT Codes	% of claims with G0378	% of claims paid with APC 0339	2007 APC Payment	2008 Proposed APC Payment
G0378	100%	30%	$442.81	$0.00
99285	57%	?	$325.26	$348.81
?	?	?	?	?
?	?	?	?	?

?	?	?	?	?

Valerie Rinkle
Revenue Integrity Director
Asante Health System

Submitter : Dr. David Orsinelli **Date:** 08/31/2007

Organization : The Ohio State University

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a practicing Cardiologist with extensive experience in the field of Echocardiography and frequently employ ultrasound contrast agents in my practice. These agents are an invaluable asset in this field. I am writing in regard to the proposal to eliminate separate payment for contrast agents used in echo procedures performed in hospital outpatient settings beginning in 2008. The packagng of payment for these agents into the amount received for the principal procedure billed with the contrast agent is in my opinion inappropriate. These agents do add cost to the procedure. The agents cost money and there are additional resources utilized (both personnel and supplies) to administer these agents. Since the same amount would be paid for the procedure whether or not contrast is used, this proposal would create a financial disincentive to the use of a contrast agent, even when its use would be medically appropriate. In my opinion, contrast use is less than optimal even with the current payement system. I believe in both stress echo and transthoracic echo, these agents are underutilized (for a variety of reasons). If the cost of these agents is not reimbursed, a strong financial disincentive will be created to contrast use,creating an additional barrier to their use to the detriment of patient care. These agents have been proven to improve image quality and thus diagnostic accuracy of echocardiography and in particular stress echo. While these agents are costly, they save money by reducing the frequency of inconclusive / inadequate studies, which reduces the need for other (potentially more expensive / invasive tests) to clarify a diagnosis. Diagnostic uncertainty will lead to more tests which will increase overall costs to the system. To pay the same amount for a study with or without a contrast agent simply makes no sense and if implemented will result in a strong financial disincentive to their use. I hope that CMS will reconsider this proposal and allow us to continue to provide high quality care to our patients.

Submitter : Mrs. CORRINE RENAULT **Date:** 09/01/2007

Organization : ASE

Category : Other Health Care Professional

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a cardiac sonographer who frequently performs stress echocardiography. In some cases, a contrast agent is critical to obtain a diagnostic test.

If contrast agents are not reimbursable, they will not be used. This will result in many non-diagnostic examinations. Patients will then be referred for more costly procedures to make an accurate diagnosis. Essentially, Medicare will end up paying for two separate tests for one diagnosis; ischemia.

Stress testing is not without risk. Patients with severe coronary artery disease risk life-threatening dysrhythmmias, myocardial infarction, and even death every time they undergo provocative testing. A non-diagnostic procedure followed by additional provocative testing to rule out ischemia doubles that risk.

At this moment, ultrasound technology has leapfrogged. Sadly, many of these technologies are not utilized simply because they are not reimbursed. Please don't let this happen to contrast. It will be a great disservice to my patients and will result in greater expense to Medicare.

Submitter : Ms. Deborah Wagoner **Date:** 09/01/2007

Organization : Ms. Deborah Wagoner

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I work with a private practice group of physicians doing echocardiograms and am seeing the financial cost and burden that medicare cuts are putting on their ability to continue to provide quality patient care. The cost of accreditation,maintaining up to date equipment, and having qualified personal to run them is being demanded by your and other agencies. What I see happening by you bundling charges and now not wanting to pay separate fees for contrast agents is that the doctors are going to be forced to use more expensive procedures like nuclear stresses,CT angiography,etc. to better determine how to care and manage their patients. Or even yet the patients just don't get the quality that they really need. Why should the physicians have to absorb these costs? We personally do not use contrast in echo unless it is absolutely necessary. But, if that patient had bypass and is extremely obese and we need to see his wall motion to be certain of the patency of his grafts we will use contrast; which is much less expensive than a nuclear stress or CT angio or heart cath. I am not understanding how this is going to help cut cost for the patient or for you and all I see happening is the quality of care for the patient continue to go down. What do you see happening when you continue to cut the resources we have to use to provide the quality that the physicians I work for demand? I am asking you to not eliminate separate payment for contrast agents used in outpatient settings. This will force us not to use contrast agents and have to use more expensive means to care for the patient.Echocardiograms are alot more inexpensive than most procedures and are very useful in the diagnosis,maintanence, and care of patients. If it was you or your family what would you want done for you? Why do you keep cutting the cost of echocardiograms?

Your consideration and response to this matter would be deeply appreciated. My email address is dlwagon@hotmail.com

Submitter : Ms. carol johnson **Date:** 09/01/2007

Organization : Ms. carol johnson

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

I will soon be eligible for medicare and I pray that the radioimmuntherapy drugs, Bexxar and or Zevelin will be available to me should I need the treatment in the future. Please!

Submitter : Mrs. Mary Adams **Date:** 09/01/2007

Organization : Mrs. Mary Adams

Category : Individual

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Re: CMS-1392-P
Gentlemen:
I am writing to protest the proposed changes in reimbursement for 1-131 Bexxar & Y90 Zevalin. These are a class of drugs known as radioimmunotherapy although given as a single treatment, the proposed reimbursement for all components of the treatment amounts to approx. 1/2 their cost, leaving hospitals unreimbursed for the remaining cost. This will have dire consequences for patients, for it will effectively deny them access to these drugs.
I have not been treated as yet with RIT but it will be the next drug I will need to treat my Non-Hodgkins lymphoma.
Traditional treatments require much longer treatment periods and cause significantly more side effects which add to both cost of the treatment and reduction in patient productivity and they are less effective than RIT.
If the proposed reimbursement change is adopted, hospitals will not subsidize the treatment and patients will no longer have access.
How many millions of dollars will be wasted on their development? How many patients will die?
So I urge you to consider the patients first and to deny the proposed changes in reimbursement to these drugs.
Thankyou,
Mary Adams
Lithia, Florida

Submitter : Mr. Kenneth Olsavsky **Date:** 09/01/2007

Organization : University Hospitals of Cleveland

Category : Other Technician

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Contrast should continue to be charged as a separatc itcm. I am a cardiac sonographer who uses contrast in a large hospital facility. Our amount of usage is about 15 - 20% of our total patients. This isnt a high usage item so it doesnt make sense to spread this cost over the other 80% of patients. Additionally, echo cardiographic costs are broken into components and charged accordingly. With echo, the three component costs are 2D, Color and Doppler. So if echo is composed of all or some of thc component costs, burying the contrast cost amongst all echos is inconsistent to current billing practices. Additionally, I believc the costs of contrast wont bc built into operational budget resources which will probably result in operational management personnel to discourage too much use of contrast. This places a risk on the patients because physicians may miss significant pathology due to the lack of use of contrast. Billing contrast as a separate item will allow us to usc this product when it can be most helpful in providing the best medical care possible for the healing of our patients. Since we currently bill separately and are using it on about 20% of our patients, you can see this isnt bcing used abusively nor are there any financial influences with commercial supplicrs.

Submitter : **Dr. Diane Wallis** **Date: 09/03/2007**

Organization : **Midwest Heart Specialists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a practicing cardiologist in the midwest, I would like to express my concern about the proposal to eliminate separate payment for echo contrast agents for hospital outpatients. This is predominately used for patients undergoing stress echocardiography. As many physicians are becoming cost consious, more and more stress echoes are being ordered by primary care physicians instead of stress thalliums. Unfortunately, I have to read these studies, many of whom are done in the obese, and contrast is necessary to even read the study. There is much pressure by hospitals to limit our access to material that is not reimbursed. Not only would patient access to studies using contrast would be severely limited, this would cause the conversion of the test to the more expensive nuclear thallium study, inconvenience to the patient, rescheduling, and additional costs to Medicare. I can assure you that the hospitals will not allow contrast if it is not being paid for under OPPS.

This proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.

Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

It is also my understanding that CMS is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

Thank you.

Sincerely,

Diane E. Wallis, MD

Submitter : **Date: 09/03/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am a practicing cardiologist at Edward Hospital in Naperville, Illinois, and at our institution we perform both contrast enhanced and non-contrast enhanced echocardiographic studies. I am concerned that eliminating appropriate reimbursement for the contrast enhanced studies will drastically limit their availability in the Medicare population. Literally decades of laboratory and clinical research have gone into the development of these helpful clinical agents, which when used appropriately, clearly enhance the diagnostic accurracy of the non-invasive study and decrease the likelihood of a patient requiring a more dangerous and costly invasive procedure. At our institution contrast is used in less than 5% of our greater than 10,000 yearly studies. To refuse separate payment for this valuable service is nothing short of extortion! The attempt of the CMS to systematically bundle medical services is nothing more than deliberate cost containment and the practice is wrong. Optimal care and the medical advances that lead to this care come with a cost. The old adage "You can't have your cake and eat it too" seems quite appropriate here. As a government entity you are asking for the best but are unwillingly to pay for the quality. Since when has that become the American Way?

Submitter : Dr. Steven Fera **Date:** 09/03/2007

Organization : RI Chapter, American College of Cardiology.

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

The current CMS proposal to eliminate separate payment for contrast agents used in ECHO procedures serves to provide a financial disincentive to use these agents, even though they are medically appropriate and improve the likelihood of accurate diagnosis. Patients whose studies are determined to be technically inadequate(in the absence of contrast use) are likely to be referred for other, more costly tests including invasive tests. I strongly recommend that this proposal be tabled and that separate payment continue for contrast agents used in ECHO exams.
Steven R Fera MD, FACC
Governor, RI Chapter- American College of Cardiology

Submitter : **Dr. stephen doggett** **Date: 09/04/2007**

Organization : **Dr. stephen doggett**

Category : **Physician**

Issue Areas/Comments

Brachytherapy

Brachytherapy

Request to maintain payment for brachytherapy technical codes for physician provided services in an ASC setting.

CMS-1392-P-320-Attach-1.DOC

#320

Re: CMS-1392-P

9-3-07

I am writing in regards to the Medicare Ambulatory Surgical Center (ASC) Payment System 2008 Proposed and Final Rule Summary.

I am asking that the current policy of paying a physician for the technical components of a service he provides in an ASC be maintained.

I am a radiation oncologist that provides **permanent seed prostate brachytherapy (55875)** to Medicare patients in the hospital as well as the ASC setting.
I have been asked by several more ASC's to provide prostate brachytherapy services specifically because they would like to offer this valuable service to their Medicare patients but do not have the patient volume to afford the capital equipment outlay or new staff.

I will be able to provide prostate brachytherapy services to a larger number of Medicare patients if I am able to continue to bill for the technical portions of the below codes in the ASC setting.

Under current policy, I have been paid for the technical components for the following codes I provide in an ASC:
77336
76965
77328
77370
77332
77295
77300
77470
77790
I provide the ultrasound machine, the treatment planning computer and the ultrasound stepper and stabilizer. Additionally, I act as the ultrasound technician and the physicist who performs the computerized intraoperative treatment plan..

Because I bring this equipment and operative skill to each ASC, the ASC does not have to make a 6 figure capital equipment expenditure and does not need to hire an ultrasound tech nor a physicist. The technical revenue from the above codes allows me to amortize the cost of the equipment utilized and to compensate me for the ultrasound and physics work performed.

I will be able to provide prostate brachytherapy services to a larger number of Medicare patients if I am able to continue to bill for the technical portions of the above codes in the ASC setting.

Thank you kindly for your attention .

Sincerely,

Stephen Doggett MD
14642 Newport Ave #470
Tustin CA 92780
drdoggett@nocancer.com

Submitter : **Dr. stephen doggett** **Date: 09/04/2007**

Organization : **Dr. stephen doggett**

Category : **Physician**

Issue Areas/Comments

Brachytherapy

Brachytherapy

I am writing in regards to the Medicare Ambulatory Surgical Center (ASC) Payment System 2008 Proposed and Final Rule Summary.

I am asking that the current policy of paying a physician for the technical components of a service he provides in an ASC be maintained.

I am a radiation oncologist that provides permanent seed prostate brachytherapy (55875) to Medicare patients in the hospital as well as the ASC setting.
I have been asked by several more ASC s to provide prostate brachytherapy services specifically because they would like to offer this valuable service to their Medicare patients but do not have the patient volume to afford the capital equipment outlay or new staff.

I will be able to provide prostate brachytherapy services to a larger number of Medicare patients if I am able to continue to bill for the technical portions of the below codes in the ASC setting.

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Because I bring this equipment and operative skill to each ASC, the ASC does not have to make a 6 figure capital equipment expenditure and does not need to hire an ultrasound tech nor a physicist. The technical revenue from the above codes allows me to amortize the cost of the equipment utilized and to compensate me for the ultrasound and physics work performed.

I will be able to provide prostate brachytherapy services to a larger number of Medicare patients if I am able to continue to bill for the technical portions of the above codes in the ASC setting.

Thank you kindly for your attention .

Sincerely,

Stephen Doggett MD
14642 Newport Ave #470
Tustin CA 92780
drdoggett@nocancer.com

Submitter : Ms. Wanda Burns **Date:** 09/04/2007

Organization : Albemarle Hospital

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

Contrast agents are already underutiliized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. Underutilization of contrast agents is not in the best interests of any patient including Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and more costly diagnostic testing.

Submitter : David Spearman **Date:** 09/04/2007

Organization : RadAmerica II, LLC

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-323-Attach-1.PDF

#323

September 4, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Rule (File Code: CMS-1392-P)

Dear Administrator Weems:

Thank you for the opportunity to comment on the proposed rule for the hospital outpatient prospective payment system for calendar year (CY) 2008, CMS-1392-P "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates."

We manage radiation oncology centers in the Baltimore – Washington area. Our centers utilize both linear accelerators and an image-guided robotic stereotactic radiosurgery system. Please feel free to contact me if you or your staff would like to visit a facility employing this technology in the Baltimore area.

Background

Linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments to tumors over several weeks while sparing normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT). In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1950's and 1960's, frame-based stereotactic radiosurgery (SRS) was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual positioning of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image-guided robotic stereotactic radiosurgery (r-SRS) was developed. This technology provides two significant advantages over traditional radiosurgery: (1) no head or body frames are required, and (2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body with a significant decrease in the amount of radiation delivered to normal tissue.

Proposed Treatment of Image-guided Stereotactic Radiosurgery

At present, the OPPS payment system groups SRS in three ambulatory payment classifications (APCs). For CY 2008, however, the Centers for Medicare & Medicaid Services (CMS) has proposed to include two disparate technologies together with r-SRS in these APCs. We strongly disagree with this proposal, because we believe that it does not maintain the degree of coherence in clinical and resource terms that CMS usually maintains and that is exhibited by other APCs.

The two technologies are ultrasound ablation of uterine fibroids with magnetic resonance guidance (MRgFUS) and magnetoencephalography (MEG). Neither of these technologies is similar to SRS, and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

MRgFUS is not similar to SRS. MRgFUS is a system by which high intensity focused ultrasound heats and destroys uterine fibroid tissue using sound waves. The mechanism of treatment for MRgFUS is most similar to that of Radiofrequency Ablation (RFA). Both MRgFUS and RFA ablate tissue by raising the temperature high enough to lead to cell death. By contrast, stereotactic radiosurgery utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body (for instance, in the brain, lung, or spine). Because of the longer duration of treatment, the requirements for monitoring and adjusting to patient movement are much greater.

Furthermore, the two technologies differ significantly in resource utilization. Unfortunately, claims information provides little reliable guidance on this point. MRgFUS is performed on very few Medicare patients and, therefore, very few claims are available. In CY 2005, for example, only two claims were submitted with a HCPCS code associated with MRgFUS.

The nature of the two treatments, however, provides a strong indication of resource differences. When performing MRgFUS, the treatment table containing the ultrasound transducer used to perform MRgFUS is rolled into conventional MRI equipment and the table is docked directly onto an existing MR scanner. The same MRI machine used to provide MRgFUS is also used to perform conventional MRI procedures and, therefore, does not represent an additional capital expense for the hospital. Moreover, no separate build-out is needed to house the equipment, since an existing diagnostic suite is used to perform MRgFUS. In comparison, stereotactic radiosurgery requires a lead-shielded vault, complete with special weighted mounting. SRS systems are dedicated to the treatment of tumors and select disorders with high dose radiation; they are not used to perform other procedures that could mitigate resource requirements. Additionally, SRS treatment times are longer. Therefore, both operating and capital expenses are commensurately larger.

We therefore urge reconsideration of the proposal to move MRgFUS into stereotactic radiosurgery APCs. We agree with the agency's assessment in the CY 2007 OPPS final rule that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Magnetoencephalography (MEG)

Similarly, MEG is also substantially dissimilar to SRS. MEG is a diagnostic imaging technique used to measure magnetic fields produced by electrical activity in the brain. MEG, also known as Magnetic Source Imaging (MSI), is much like Magnetic Resonance Imaging (MRI). Both MEG and MRI produce internal images by recording magnetic signals and are used to provide information to aid in diagnosis. Their use is limited to obtaining information about the brain for diagnostic purposes. SRS, on the other hand, is a therapeutic medical procedure that utilizes large, precisely targeted doses of radiation to destroy tumors and treat select disorders anywhere in the body. MEG is also performed on very few Medicare beneficiaries. Between CY 2002 and 2005, no more than 23 claims were submitted for one MEG CPT code. The other two MEG CPT codes together accounted for only eight claims during those years

In light of the significant differences between a diagnostic tool such as MEG and a therapeutic medical procedure such as SRS, we request CMS reconsider its proposal to assign MEG to the

stereotactic radiosurgery APCs. Moreover, we agree with the agency's previous comments indicating that resource and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

SRS Treatment Delivery Services

We support CMS's proposal to continue use of HCPCS codes G0173, G0251, G0339, and G0340. We agree with the assessment that these codes are more specific in their descriptors than available CPT codes, and that hospital claims data continue to reflect significantly different use of hospital resources. Adoption of a smaller set of CPT codes with less specific descriptors would not appropriately reflect the resource costs of these procedures to hospitals and would result in violations of the two times rule.

For CY 2004, CMS created two HCPCS codes, G0339 and G0340, in order to accurately distinguish image-guided robotic SRS systems from other forms of linear accelerator-based SRS systems and to account for the cost variation in delivering these services (CMS-1392-P). And, while there is now three years of hospital claims data, examination of the data reveals ongoing confusion among hospital providers about appropriate coding, resulting in cost and utilization data for SRS systems of all types being captured in the image-guided robotic SRS codes.

Since the agency's intent for CY 2008 is to continue using the G-codes for reporting LINAC-based SRS treatment delivery services under the OPPS, and to ensure appropriate payment to hospitals for the different facility resources associated with providing these services, we respectfully suggest minor revisions be made to the coding descriptors for clarification purposes. We believe that coding confusion and thus inappropriate payments relate to the concept of 'image-guided robotics.' We believe that clarification of the descriptors is necessary in order to achieve the results intended by the agency's 2004 revisions, and we would be grateful for the opportunity to work together to accomplish these goals.

Conclusion

In summary, we urge CMS to:

Not adopt its proposal to assign MRgFUS to the APCs for SRS. As indicated in the CY 2007 OPPS final rule, retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Not adopt its proposal to assign MEG to the APCs for SRS. As recommended by CMS in the August 2005 APC Panel Meeting, resources and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

Retain the SRS HCPCS codes, G0173, G0251, G0339, and G0340. Further, we request that CMS clarify the associated code descriptors to achieve the agency's goal of distinguishing image-guided robotic stereotactic radiosurgery (r-SRS) systems from other LINAC systems.

Sincerely,

David Spearman, President
RadAmerica II, LLC
Tele: 410-682-6800

Submitter : **Dr. Larry Bachle** **Date: 09/04/2007**

Organization : **Center for Wound Care & Hybaric Medicine of CRMC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

August 31, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392 P
Mail Stop C4 26 05
7500 Security Boulevard
Baltimore, MD 21244 1850

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
The Center for Wound Care and Hyperbarics of Charlotte Regional Medical Center appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. The Center for Wound Care and Hyperbarics of Charlotte Regional Medical Center is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf. We have reviewed our charges for skin repair procedures and have updated the charges for CPT codes 15340 and 15341 to include cost into for the surgical site preparation which was previously billed under CPT code 15000.
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Kim Mobley at (941)764-9560.
Sincerely,
Larry Bachle, D.O.
Medical Director
Wound Care and Hyperbaric Medicine

Submitter : Dr. John Kresl **Date:** 09/04/2007

Organization : St. Joseph's Hospital and Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-325-Attach-1.PDF

#325

St. Joseph's Hospital and Medical Center
CHW

350 West Thomas Road
Phoenix, AZ 85013
602 406 3000 Telephone

A CHW ministry sponsored by Dignity Health

Herb B. Kuhn, Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS proposed changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Director Kuhn:

Our hospital wishes to thank CMS for the opportunity to provide appropriate comments in response to the proposed 2008 Hospital Outpatient Prospective Payment System and 2008 Payment rates released by CMS on July 16, 2007.

We wish to address the CMS APC assignment for a new technology made effective in program transmittal 1259 dated June 1, 2007. A new technology assignment was approved by CMS specific to the Implantation of the DVS Dosimeter for treatment of cancer patients.

We appreciate that CMS has correctly determined that this technology is new and requires the development of a new APC assignment; however, CMS has made a significant error in the APC assignment for this new procedure and technology.

The new technology code (**C9728**) approved by CMS should include the cost of the implant procedure as well as the DVS sensors. The code assignment made has excluded the cost of the sensors and only accounts for the cost of the implant procedure. In addition, the existing code for implantation into the prostate (**55876**) also excludes the cost of the DVS sensors.

It is our understanding that the purpose of the new technology APC application is to permit hospitals to utilize new technology appropriately to provide care for beneficiaries, and to provide the hospitals a mechanism for reimbursement of new technology. The APC assignments for C9728 and 55876 do not account for the cost of the DVS technology, and the proposed 2008 HOPPS payment system does not offer a mechanism for reporting the DVS technology cost.

We encourage CMS to develop a code that will permit hospitals to report the cost of the technology associated with these two procedures so that cancer patients may have access to this new technology as CMS intended under the APC new technology process.

Thank you in advance for your time and consideration for this important clinical and hospital reimbursement issue.

Sincerely,

Hospital

cc: Carol M. Bazell, M.D., Director, Division of Outpatient Care (***Carol.Bazell@cms.hhs.gov***)

Submitter : Dr. Miguel A. Quinones **Date:** 09/04/2007

Organization : The Methodist Hospital

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

September 4, 2007

Dear CMS Member,

This is in response to CMS proposal to eliminate separate payment for contrast agents used in echo procedures performed in hospital outpatient settings beginning in 2008.

I am a practicing physician, cardiologist at a large teaching hospital and have been intimately involved with echocardiography since 1972. I have published extensively in this area and consider myself one of the leading experts in the field. I am also very much aware of the concept of incorporating new technologies under the umbrella of older ones as the new one is used every time the older one is applied. The proposal to eliminate separate payments for ultrasound contrast agents assumes that their use has become a routine with every cardiac ultrasound procedure. This could not be farthest from the truth. Echocardiography is still practiced without the use of contrast agents in the vast majority of cases, including stress echocardiography. The following are several important reasons for which you should not proceed with this proposal:

1. Contrast agents are only used to enhance the quality of an image when it is suboptimal to assess cardiac function. Currently, these agents are underutilized. Their underutilization means that many echocardiographic studies are still of suboptimal quality and thus, the physician orders another imaging test (adding to cost of care) to obtain the information needed to manage his or her patient. The appropriate use of contrast often obviates the need for a second imaging test. At the current low rate of utilization, it makes economic sense for CMS to encourage rather than discourage the use of contrast.
2. The present contrast code allows the facility to recuperate the cost of the agent without profit. (These costs are currently high relative to the overall cost of the procedure) Furthermore, using contrast adds time to the procedure and requires additional personnel. Thus, there is no current economic incentive to use contrast. The primary incentive is to improve quality. Even at current reimbursement rate, many facilities loose some income when applying contrast to an echocardiographic procedure. If Medicare stops reimbursing for the cost of a contrast agent, there will be significant economic lost to the facility and this will discourage their use. This will result in an increase of other imaging (including invasive) procedures.
3. The reduction in the use of contrast agents that will result if your proposal comes through is so large that it is likely that the companies making these agents will stop altogether and place their emphasis in some other technology. Even with the current utilization, these agents are not making significant profits for their makers. The disappearance of this new and exciting technology would be a terrible disservice to the medical community and to our patients.
4. Finally, if CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, and this would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

I hope that you will seriously consider the above when making a final determination. The development of contrast agents has been a major technological advancement that improves quality and helps us serve patients better, but we are still struggling to convince the medical community that using these agents, even though it does not bring additional profit, is the right thing to do. I ask that you do not destroy this great technology before it has had time to make a global impact in improving care and reducing cost.

Sincerely,

Miguel A. Qui?ones, MD, FACC
Professor of Medicine
Weill Cornell Medical College
Chairman, Department of Cardiology
The Methodist Hospital
Medical Director, Methodist DeBakey Heart Center
6550 Fannin, Suite 1901
Houston, TX, 77030

Submitter : Dr. Charles Herzog **Date:** 09/04/2007

Organization : United States Data Renal System (USRDS)

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am the medical director of the echocardiography laboratory at Hennepin County Medical Center in Minneapolis, Minnesota. I supervise an ICAEL-accredited laboratory and have had a primary clinical and research interest in echocardiography during my 23 years as an attending cardiologist at Hennepin County Medical Center. My major interest in clinical research focuses on heart disease and end stage renal disease (ESRD). Our clinical laboratory has performed stress echocardiography for more than 15 years; the one primary focus for which the laboratory was established was to perform non-invasive evaluation of patients with end stage renal disease for cardiac screening before elective renal transplant. Besides serving as the medical director of the cardiac ultrasound laboratory at Hennepin County Medical Center and attending cardiologist, I am also a professor of medicine at the University of Minnesota. My research appointment is director of the Cardiovascular Special Studies Center of the United States Renal Data System.

I have recently learned that CMS is proposing to eliminate separate payments for echo contrast agents (eg; Definity, also known as Perflutren). Under this proposal, reimbursement would be identical whether or not a contrast agent for left ventricular opacification is viewed. In my roll as echo lab director, I have personally interpreted more than 30,000 echocardiographic studies. Reflecting our special clinical and research interest, we have also performed more Dobutamine stress echocardiograms in patients with end stage renal disease than any other clinical laboratory in the world. As lab director, I have found that echo contrast agents used for LV opacification play a key clinical role in increasing diagnostic accuracy of assessment of global or regional systolic performance of the left ventricle in patients with difficult imaging. This particularly applies to patients with end stage renal disease (who frequently have severe concentric left ventricular hypertrophy and small LV volumes). Stress imaging can be very challenging in this patient population and the use of echo contrast has served to markedly improve the level of non-invasive imaging (and attendant quality of care) for patients with difficult imaging, of whom ESRD patients are a good example.

Our medical center is a safety net hospital and we serve an underserved population. We also have a disproportionately large number of patients with end stage renal disease cared for at our hospital both in the inpatient and outpatient setting. If the CMS proposal to eliminate separate payment for echo contrast agents were finalized, our patient population would no longer have ready access to echo contrast agents and thus would obtain inferior cardiology care in my opinion. We have reviewed our recent contrast expenditures, and we project a cost of approximately $300,000 a year contributable to contrast agents in our echo lab. If CMS were to eliminate separate reimbursement for echo contrast agents, Hennepin County Medical Center would not be able to continue to provide contrast agents to patients without reimbursement as we project our annual cost to be approximately $300,000 a year.

In summary, the CMS proposal to eliminate separate payments for echo contrast agents represents a serious threat to patient care and I strongly advise that this proposal be rejected. I would be happy to further discuss this issue with CMS representatives.

Charles A Herzog, M.D., F.A.C.C.

Submitter : Ms. Lorrie Fane **Date:** 09/04/2007

Organization : Hennepin County Medical Center Echo Lab

Category : Hospital

Issue Areas/Comments

Impact

Impact

Please see attached note regarding CMS-1392-P

CMS-1392-P-328-Attach-1.DOC

#328

Leslie V. Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

August 23, 2007

To Whom It May Concern:

I am the Cardiology Non-Invasive Lab Manager at Hennepin County Medical Center in Minneapolis, Minnesota. We do a large volume of echocardiograms and stress echocardiograms, 80% of which we do using the contrast-imaging agent Definity (Perflutren – Bristol Myers Squibb).

I understand that Medicare is proposing to eliminate separate payment for echo contrast agents. Under this proposal, reimbursement would be identical whether or not a contrast agent was used. We are a safety-net hospital and serve an under-served population. If this proposal passes, our patients would no longer have access to contrast agents, and thus obtain less accurate results from echocardiography. We believe that this is a disservice to patients, in particular low-income patients, as the non-contrast echocardiogram would often be sub-standard and additional testing would become necessary. With contrast costing nearly $300,000 a year, our hospital could not continue to provide contrast to patients without reimbursement.

I truly hope that you will take patient care and safety into account as you proceed with this decision. If I can answer any questions for you, please feel free to contact me.

Thank you,

Lorrie Fane
RDMS, RDCS
Manager, Non-Invasive Lab
Cardiology, O5
Hennepin County Medical Center
612-873-6307
lorraine.fane@co.hennepin.mn.us

Submitter : **Ms. Jean Corvinus** **Date: 09/04/2007**

Organization : **Frisbie Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

OPPS Impact

OPPS Impact

My comment is relevent to what I believe is missing from your proposed OP Quality Initiative. Smoking Cessation, Immunizations for Pneumovax and Influenza, and dietary counseling for DM patients. Thanks

Submitter : Dr. Joseph Rienzi **Date:** 09/04/2007

Organization : Advanced Imaging Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Attached please find letter re CMS 1385-P
Thank you
Joseph P. Rienzi, MD

Submitter : Ms. Patricia Wagstaff **Date:** 09/04/2007

Organization : Medical University of South Carolina

Category : Individual

Issue Areas/Comments

Quality Data

Quality Data

The algorithms should build in exit points for patients for HF and Hgbn A1C who have been previously selected for the same measure during either a previous quarter or a different clinic in this quarter. Prioritization should also be provided as to which visit in that quarter is to be abstracted.

Submitter : Dr. michael traurig **Date:** 09/04/2007

Organization : self

Category : Physician

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

We commend CMS for its work to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging
guidance and monitoring, percutaneous, laser, first vein treated). I am concerned with the element of equipment expense. New technologies frequently require the purchase of capital equipment. This cost of capital, to be absorbed into the cost of doing business, must be compensated in a manner that is affordable to the provider (in all practice settings) and reasonable to the payor.

Based on the CMS utilization formula for equipment cost per minute, I am finding a discrepancy in the equipment expense.

The Federal Register, Volume 72, July 12, 2007 identifies equipment expense for all physicians at 4.08. Based on the CMS equation:

(1/(minutes/yr * usage)) * price * ((interest rate/(1-(1/(1 + interest rate) * life of equipment)))) + Maintenance)

The allowed equipment expense is 4.08. When calculated using the ASP for the equipment used, the calculation is 4.75.

Payment for CPT code 36478, in the hospital outpatient department is in APC 0092 with an unadjusted national average payment of $1,684.02. Other procedures in that category include:
a. 37650: Ligation femoral vein
b. 37760: Ligation of perforator veins
c. 37765: Stab phlebectomy of varicose veins
We are requesting that 36478 be moved to APC 0091 with an unadjusted national average payment of is $2,780.84.Other procedures in this category include:
d. 37700: Ligation and division of long Saphenous vein at SFJ or distal interruptions
e. 37718: Ligation, division and stripping, short Saphenous vein
f. 37722: Ligation, division and stripping GSV from SFJ to knee or below
g. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
h. 36478: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

We believe CPT code 36478 is more clinically related to procedures in APC 0092 than to APC 0091.

In previous years, low cost laser fibers (not matched to the laser for compatibility) were available from various companies. March 28, 2007, a successfully litigated patent infringement suit resulted in these fibers being removed from the market. Although there has been no increase in fiber cost, the potential to reduce cost through the use unmatched fibers has been removed. Ensured compatibility between laser and fiber enhances patient safety. We believe resource consumption for CPT code 36478 is more closely related to APC 0091.

We are requesting that you move CPT code 36478 from APC 0092 to APC 0091.

CPT code 36478 has been moved form ASC group 9 to ASC group 8. We are requesting that CPT code 36478 be placed back into group 9.

Submitter : Mrs. Meghan Leverenz **Date:** 09/04/2007

Organization : Heart and Vascular Lake County

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am currently an echo tech at Heart and Vascular Center of Lake County and I use contrast agents. If seperate payment for echo contrast agents is eliminated for hosptial outpatients I believe it will reduce patient access to echo contrast agents. Underutilization of contrast agents is not in the best interest of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

CMS-1392-P-333 Medicare

Submitter : Mrs. Meghan Leverenz **Date & Time:** 09/04/2007

Organization : Heart and Vascular Lake County

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am currently an echo tech at Heart and Vascular Center of Lake County and I use contrast agents. If seperate payment for echo contrast agents is eliminated for hosptial outpatients I believe it will reduce patient access to echo contrast agents. Underutilization of contrast agents is not in the best interest of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

CMS-1392-P-334 Medicare

Submitter : Ms. Laura Foster **Date & Time:** 09/04/2007

Organization : Arizona Health Sciences Center, University Medical

Category : Other Technician

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

As a Registered Diagnostic Cardiac Sonographer who uses the contrast agent Definity on a daily basis to improve visualization of the heart, I am concerned about the proposed changes to the reimbursement of this agent by bundling the cost into the procedure. I believe that this may cause a disincentive to use this valuable diagnostic enhancement tool.

CMS-1392-P-335 Medicare

Submitter : Dr. Aksel Nordestgaard **Date & Time:** 09/04/2007

Organization : Northwest Vein Center

Category : Physician

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

We commend CMS for its work to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser, first vein treated). I am concerned with the element of equipment expense. New technologies frequently require the purchase of capital equipment. This cost of capital, to be absorbed into the cost of doing business, must be compensated in a manner that is affordable to the provider (in all practice settings) and reasonable to the payor.

Based on the CMS utilization formula for equipment cost per minute, I am finding a discrepancy in the equipment expense.

The Federal Register, Volume 72, July 12, 2007 identifies equipment expense for all physicians at 4.08. Based on the CMS equation:

(1/(minutes/yr * usage)) * price * ((interest rate/(1-(1/(1 + interest rate) * life of equipment)))) + Maintenance)

The allowed equipment expense is 4.08. When calculated using the ASP for the equipment used, the calculation is 4.75.

Payment for CPT code 36478, in the hospital outpatient department is in APC 0092 with an unadjusted national average payment of $1,684.02. Other procedures in that category include:
a. 37650: Ligation femoral vein
b. 37760: Ligation of perforator veins
c. 37765: Stab phlebectomy of varicose veins
We are requesting that 36478 be moved to APC 0091 with an unadjusted national average payment of is $2,780.84.Other procedures in this category include:
d. 37700: Ligation and division of long Saphenous vein at SFJ or distal interruptions
e. 37718: Ligation, division and stripping, short Saphenous vein
f. 37722: Ligation, division and stripping GSV from SFJ to knee or below
g. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
h. 36475: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

We believe CPT code 36478 is more clinically related to procedures in APC 0092 than to APC 0091.

In previous years, low cost laser fibers (not matched to the laser for compatibility) were available from various companies. March 28, 2007, a successfully litigated patent infringement suit resulted in these fibers being removed from the market. Although there has been no increase in fiber cost, the potential to reduce cost through the use unmatched fibers has been removed. Ensured compatibility between laser and fiber enhances patient safety. We believe resource consumption for CPT code 36478 is more closely related to APC 0091.

We are requesting that you move CPT code 36478 from APC 0092 to APC 0091.

CPT code 36478 has been moved form ASC group 9 to ASC group 8. We are requesting that CPT code 36478 be placed back into group 9.
Sincerely
Aksel G. Nordestgaard, MD
Northwest Vein Center
Gig Harbor
WA

Submitter : Stephen Belcher **Date:** 09/04/2007

Organization : University of Colorado Hospital

Category : Other Technician

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a practicing sonographer at the University of Colorado Hospital and am concerned about a proposed combination of billing of contrast agent with the principal procedure billed. Currently, contrast is billed separately and contrast agents are quite expensive relative to the procedures for which they are used. Combining the billing of the contrast agent with the procedure would produce a financial disincentive to using contrast agents, even when their use is medically appropriate. This disincentive would result in the underutilization of contrast agents. Underutilization will increase the prevalence of inconclusive diagnoses, which would result in an increase in more invasive and costly follow up tests. The ultimate result of this would be a reduction in the quality of care for the Medicare patient population and an increase in cost to the Medicare program. Please allow the continued separate billing of contrast agents. Thank you for your time.

Submitter : Ms. Jodie Coscia **Date:** 09/04/2007

Organization : ASE

Category : Other Health Care Professional

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am writing to strongly urge you to continue to provide separate reimbursement for echo contrast agents in 2008. I am a Cardiac Sonographer currently using echo contrast. Our populations is growing in limited studies due to body habitus and other reasons. Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests. Thank you for your time and consideration.
Jodie Coscia,RCS

Submitter : **Mrs. celeste mikulics** **Date: 09/04/2007**

Organization : **Sharp Grossmont Hospital Wound Healing Center**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Skin Substitute

August 31, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392 P
Mail Stop C4 26 05
7500 Security Boulevard
Baltimore, MD 21244 1850

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
Sharp Grossmont Hospital, Wound Care and HBO appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Sharp Gossmont Hospital is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf
We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Celeste Mikulics at 619-740-4160.
Sincerely,
Celeste M. Mikulics, RN. MSN, FNP

Submitter : **Dr. Moshe Bacharach** **Date: 09/04/2007**

Organization : **Ocean Cardiology PA**

Category : **Physician**

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am a cardiologists. My offiee echo lab, which is ICAEL certified for the past 5 years is using contrast agents in order to achieve high quality echo images. The contarst agent is very expensive hence it is being used only on select patients. The proposal to denies payment for such studies is not reasonable. No cardiologist will be ready to get a cut in echo payments and in addition to pay close to $150.00 for the contrast agent. The direct impact will result in poor studies and miss diagnosis and miss treatment. It is unfortunate that CMS makes life so difficult for doctors and cares so little about good quality medicine.

Submitter : Dr. Robert Carnevale **Date:** 09/04/2007

Organization : Medical Director Coastal Medical, Inc Prov, RI

Category : Physician

Issue Areas/Comments

OPPS Impact

OPPS Impact

CMS is proposing to eliminate separate payment for contrast agents used in echo procedures performed in hospital outpatient settings beginning in 2008. Payment for contrast agents would be packaged into the amount received for the principal procedure billed with the contrast agent. Since the same amount would be paid for the procedure whether or not contrast is used, this proposal would create an untenable financial disincentive to use a contrast agent. This change could not have been approved by knowledgeable cardiologist. I believe that they are mistaking saline contrast (for which there is no charge) with a pharmaceutical contrast which is currently being marketted as "Definity". This is an expensive agent which in many, many cases is used to avoid alternative imaging modalities such as cardiac MRI, CT and nuclear perfusion. This proposed change is a simply a mistake. We must pass this charge on to the patient since current reimbursement rates do not cover overhead now. To take this agent out of our diagnostic tool box will hurt patients. Kindly look at this one again because it does not make financial or clinical sense. Your response to me would be appreciated

Robert Carnevale MD FACC FASE, FACP
Medical Director Coastal Medical Inc
Clinical Assistant Professor
Warren Alpert School of Medicine at Brown University
Providence RI
e mail: robert_carnevale@brown.edu

Submitter : Mrs. JANET BURHOP **Date:** 09/04/2007

Organization : AURORA MEDICAL CENTER/AURORA HEALTHCARE

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

I FEEL THAT IMAGING ENHANCERS FOR ECHOCARDIOGRAPHY SHOULD BE REIMBURSED SEPARATE OF THE EXAM. THE USAGE OF THESE AGENTS IS ALREADY DONE WITH A VERY CRITICAL GROUP OF PATIENTS NEEDING AGENTS FOR BETTER VISUALIZATION OF THEIR HEART WALLS.WE ARE TRYING TO AVOID OTHER MORE COSTLY AND POSSIBLY UNCOMFORTABLE EXAMS TO OUR PATIENTS TO ACHIEVE WHAT WE ARE ABLE TO DO WITH CONTRAST AGENTS.PLEASE CONSIDER THE EFFECTIVENESS OF THESE AGENTS AND COMFORT LEVEL OF THE PATIENT--THEY ARE THE CONSUMER. THANK YOU VERY MUCH.

JANET C. BURHOP, RDCS
AURORA HEALTHCARE
KENOSHA, WI.

Submitter : **Dr. Yazid Fadl** **Date: 09/04/2007**

Organization : **Methodist Cardiology Physicians**

Category : **Physician**

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

08/30/2007

To Whom It May Concern:

I am a practicing cardiologist and the Medical Director of the Echocardiography Laboratory for a group of six cardiologists practicing under the name Methodist Cardiologist Physicians. I am also double boarded in cardiology and echocardiography. We perform hundreds of stress echocardiograms every year in between the three offices that we currently run. Our offices span different geographic areas of the greater Indianapolis, Indiana area.
We currently use echo-contrast agents for more technically challenging patients in order to help define the heart walls better and to improve the sensitivity of the test. Indeed, I have also performed independent research on this topic and I have given presentations at national meetings regarding the beneficial effects of using echo-contrast in reducing the false positive rate of stress echocardiograms. My research correlates well to what clinicians find in every day practice, which is if a study is technically limited and contrast is not used, that patient is more likely to undergo more invasive followup procedures, which will increase overall expenditures and cost. My research has shown that contrast agents are being underutilized, and if they are increased, this will only help to further reduce false positive rates and limit the amount of unnecessary invasive procedures such as cardiac catheterizations. In addition, contrast agents are relatively costly when compared to the echocardiogram procedure itself and this will create a further financial disincentive if the reimbursement was to be packaged together.
Based on both clinical research as well as day-to-day practice seen by thousands of cardiologists, it appears logical to not bundle echo-contrast reimbursement with the study itself, as this will further discourage physicians from using contrast and is only deleterious to both the patients overall healthcare as well as to the increasing cost of healthcare expenditure.

Sincerely,

Yazid Fadl, MD, MPH

Submitter : **Dr. Lisa Renner** **Date: 09/05/2007**

Organization : **Proud daughter of Bob**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Payment for Therapeutic Radiopharmaceuticals

Dear Sir or Madam,

I am very concerned that the proposed cuts in Medicare reimbursement for Therapeutic Radiopharmaceuticals will risk the lives of Americans like my father. My father is a very healthy and athletic 70 year old man who works full-time as a printing broker. He was just diagnosed with Stage 4 Follicular Lymphoma.

Therapeutic radiopharmaceuticals greatly improve complete response rates and insure long term survival for people like my father. He will have fewer side effects with this treatment. He is less likely to require expensive diagnostic studies and more rounds of chemotherapy related to recurrence of his cancer. He will be able to work and pay taxes rather than being forced to retire and draw on Social Security.

Your generous support of cancer research has led to many treatment breakthroughs. Cost effectiveness studies also funded by Congress show that radiopharmaceutical therapies are money saving.

You will insure life saving and less expensive treatment for people like my father by approving payments for therapeutic radiopharmaceuticals. You are supporting your promise that research funding is used efficiently and fairly for all and not just those with private insurance.
Thanks for your consideration, Lisa Renner, MD

Submitter : Dr. Julius Gardin **Date:** 09/05/2007

Organization : St. John Hospital and Medical Center

Category : Physician

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am writing to subjections to the CMS proposal to eliminate separate payment for contrast agents in echocardiography procedures performed in hospital out patient settings. I am a practicing cardiologist at St. John Hospital and Medical Center who currently orders tests with echo contrast agents and also interprets studies performed using contrast agents. I have a strong concern that if separate payment for echo contrast agents is eliminated of hospital out patients, patient access to the studies using contrast would be severely limited and Medicare expenditures for more invasive follow-up procedures may increase. Let me cite a few additional points:

1. Cost of the contrast agent added to the current cost of the echocardiography procedure still results in a test which is less expensive and more cost effective, when indicated, than are nuclear cardiology procedures.

2. The savings in patient time and convenience as well as in cost, by adding contrast to a suboptimal echocardiographic study to produce a diagnostic quality study, make the appropriate addition of contrast to the procedure very cost effective.

3. Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.

4. Underutilization of contrast agents is not in the best interests of Medicare pateitns or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

5. Contrast agents are relatively costly in comparison with the echo procedure with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

6. If CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures.

In Summary, I urge you to maintain separate payments for contrast echoes used in echocardiography procedures for appropriate indications in hospital out patient settings.

Sincerely,

Julius M. Gardin, MD
Vice-Chair, Department of Medicine
St. John. Hospital and Medical Center

Submitter : Ms. Kathy Konishi **Date:** 09/05/2007

Organization : Intermountain Healthcare

Category : Other Health Care Provider

Issue Areas/Comments

Quality Data

Quality Data

#1. Proposed measure PQRI #1 Hemoglobin A 1c Poor Control in Type 1 or 2 Diabetes Mellitus is an intermediate measure of outcome. This outcome measure is largely determined by patient behaviors in situations and circumstances outside of the control of the hospital, clinic or physician. As such, we express our concern about this measure and would recommend that it not be included.

#2. Data Collection and Submission Requirements: Performance Measurement System vendors have, by agreement, 120 days prior to implementation date to receive the complete and final documentation for a performance measurement in the inpatient quality measures. The proposed time line will not provide 120 days for vendors to program. The one month data reporting for January represents an increased vendor burden as does the shortened time frame to submit the January data (120 days instead of the current 135 days). Additionally, the shortened timeframe for reporting January data increases hospital burdens at the same that the hospitals must implement a new process for data collection and abstraction.

Submitter : **Date: 09/05/2007**

Organization : **St. John Hospital and Medical Center**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Packaged Services

Packaged Services

Please continue to provide separate reimbursement for echo contrast agents. As a health care provider for the poor and vulnerable in the great state of Michigan, contrast use is necessary in patients with poor endocardial definition on an echocardiogram. Limiting the use of contrast would uneccessarily increase the need to do expensive Invasive procedures on a greater number of patients. Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.
Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures. IF CMS nonetheless decides to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast-enhanced procedures. It is extremely important to reconsider this proposed change.

Submitter : Mrs. Laura Griego **Date:** 09/05/2007

Organization : Mountain View Regional Medical Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Skin Substitute

September 5, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392 P
Mail Stop C4 26 05
7500 Security Boulevard
Baltimore, MD 21244 1850

ATTN: CMS-1392-P
Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective
Payment System and CY 2008 Payment Rates; Skin Repair Procedures
Dear Administrator Weems:
[Hospital] appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. [Hospital] is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.
We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.
In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf s CPT procedure codes do not account for the actual clinical resource use in our experience.
We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.
Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf.We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.
Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact _Laura Griego at (505) 556-6855.
Sincerely,

Laura Griego RN Clinical Manager Mountain View Regional Medical Center

Submitter : **Date: 09/05/2007**

Organization :

Category : Physician

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

See attached comment letter.

CMS-1392-P-348-Attach-1.DOC

#348

[PHYSICIAN'S LETTERHEAD]

VIA Electronic Submission to http://www.cms.hhs.gov/eRulemaking

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1392-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

RE: Proposed 2008 Changes to the Hospital Outpatient Prospective Payment System CMS-1392-P. Packaging: Intravascular Ultrasound

Dear Administrator:

The purpose of this letter is to submit comments to CMS on the Proposed Rule updating the Medicare Outpatient Prospective Payment System (OPPS). I support CMS's ongoing policy efforts to create payment incentives which promote more efficient delivery of hospital outpatient services, including CMS's packaging policies with respect to certain minor component services that are generally performed with another primary procedure. As a practicing interventional cardiologist for the past ____ years, however, I am acutely interested in CMS policy changes that could negatively impact my patients' access to certain services. Based on my experience, I believe that CMS's proposed treatment of intravascular ultrasound (IVUS) and/or Functional Measurement (FM) procedures (37250, 37251, 75946, 92978, 92979, 93571, and 93572) as intraoperative services is inappropriate for the reasons explained below. In contrast to CMS's proposal, **I urge CMS to exclude IVUS and FM from its packaging proposal and continue to pay separately for these services**.

Overview of IVUS and FM

IVUS is a tomographic imaging methodology that allows visualization of the inner wall of the coronary arteries through ultrasound technology. The progressive accumulation of plaque within the artery wall leads to stenosis (narrowing) of the artery (known as coronary artery lesions) and the risk of heart attack. IVUS imaging allows a physician to precisely determine both plaque volume and degree of stenosis within the wall of the artery. Although it is performed during coronary angiography, it is only used in selective cases. It is especially useful where angiographic images do not visualize lumen segments adequately. **IVUS is also used therapeutically to assess the effectiveness of treatments of stenosis (such as angioplasty, with or without stents), and the results of medical therapy over time**.

FM is a guide wire based technology that analyzes pressure and flow parameters from inside of the vessel. FM measures blood flow so we can judge stenosis severity. FM is also used in conjunction with angiography. The measurement provides physicians with specific clinical guidance to determine appropriate therapy.

In the limited percentage of cases where angiographic imaging produces ambiguity or is considered unreliable, the information gathered from IVUS and FM can guide patient

management. IVUS and FM are also indicated to guide certain percutaneous coronary intervention (PCI) procedures to ensure proper geographic placement and sizing which has been proven to reduce subsequent complications.

Policy Concerns

CMS's proposed packaging of IVUS and/or FM with the payment rates for the associated ambulatory payment classifications (APCs) would limit my patients' access to these interventional tools and would thus jeopardize my ability to manage and treat their heart disease effectively and efficiently. Moreover, it is inconsistent with both CMS's rationale for packaging intraoperative procedures and CMS's overall goal of promoting efficient delivery of healthcare through payment policy.

According to CMS' proposed rule, packaging IVUS and FM would result in decreased reimbursement for certain IVUS or FM related APCs and increased reimbursement for others. For example, although reimbursement for APCs 80 (diagnostic cardiac catheterization) and 104 (transcatheter placement of intracoronary stents) would increase by $250 and $300 respectively, reimbursement for APC 83 (coronary angioplasty) would decrease by $700. Accordingly, I question whether these reimbursement adjustments have been applied appropriately and in accordance with actual hospital costs to perform IVUS or FM. Based on the fact that the codes for IVUS and FM have only been in existence for a few years and the claims data is still emerging, appropriately apportioning costs for the purpose of packaging reimbursement for IVUS and FM may not yet be possible and CMS's packaging proposal for these services is thus premature.

In fact, performing IVUS or FM imposes a significant additional expense on the hospital (about $2,000 per procedure in total costs). Hospitals would have to bear these costs if the adjusted APC rates do not appropriately cover the cost of both the primary procedure and the use of IVUS or FM. Therefore, if CMS's proposal becomes final, it would provide a significant financial incentive for hospitals to discourage utilization of IVUS and FM (even in clinically appropriate cases) and would discourage hospitals' investment in these beneficial technologies, in turn, limiting access to them to the detriment of patient care.

In the proposed rule, CMS's stated goal with respect to packaging of intraoperative services is to package reimbursement "for supportive dependent diagnostic testing or other minor procedures performed during independent procedures" that are "usually or always performed" with the primary procedure and not "sometimes or only rarely performed." 72 Fed. Reg. at 42659 - 60. Based on my experience, I do not believe that packaging payment for IVUS and FM furthers such a goal. Although IVUS and FM are performed during invasive coronary angiography in conjunction with either diagnostic exams or PCI's, they are by no means always *usually or always performed*, nor are they considered to be *minor* or *supportive* diagnostic procedures. For a variety of clinical reasons, an interventional cardiologist may believe that IVUS and/or FM are *not* appropriate or necessary for an individual patient, even if the primary diagnostic angiogram or PCI is indicated and performed. For example, in my practice IVUS or FM is clinically indicated in far less than 50% of diagnostic cardiac cath cases and cardiac angioplasty/stent cases. Further, these services consume significant resources such as time, staff, and supplies, and have unique therapeutic utility, separate and apart from the underlying primary procedure.

Indeed, IVUS and FM are tools to help interventional cardiologists make definitive therapeutic decisions in order to optimize the treatment and/or clinical management of the patient's condition. Limitations on the appropriate use of these technologies may lead to sub-optimal, and costlier-than-necessary care. Not only would this place undue physical burdens on certain patients and their families, but it would unnecessarily create financial burdens for the Medicare program and thus undermine CMS's interest in cost-efficiency.

Recommendation

For the reasons explained above, I believe that CMS should reconsider its proposal to package IVUS and FM technology with primary procedures and continue its current policy of separately reimbursing for these procedures.

Thank you for your consideration of these comments.

Very truly yours,

_____

cc: Dr. William Rogers (Director, CMS Physicians' Regulatory Issues Team) (William.Rogers@cms.hhs.gov)

Dr. Carol Bazell (Director, CMS Division of Hospital Outpatient Care (carol.bazell@cms.hhs.gov)

Submitter : Mrs. Lynn Golumbic **Date:** 09/05/2007

Organization : InSightec

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-349-Attach-1.PDF

#349

InSightec
Bringing therapy into focus

September 5, 2007

Herb B. Kuhn, Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1392-P; Hospital Outpatient Prospective Payment System and CY2008 Payment Rates

COMMENT REFERENCE: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Administrator Kuhn:

After reviewing the proposed rule regarding changes to the Hospital Outpatient Prospective Payment System payment rates for calendar year 2008, we would like to thank the Centers for Medicare and Medicaid Services (CMS) for the reclassification and recognition of MRgFUS as radiosurgery. We respectfully submit the following comments regarding the APC assignment of the MRgFUS procedure.

InSightec was founded in 1999 when GE Healthcare and Elbit Medical Imaging transferred proprietary technology to the company to enable it to concentrate on development of MR guided focused ultrasound surgery technology. InSightec developed the ExAblate 2000 that integrates continuous Magnetic Resonance Imaging with focused ultrasound energy as a treatment modality that offers non-invasive procedures and provides therapeutic alternatives to patients around the globe. ExAblate is currently used to treat patients with uterine fibroids during a procedure referred to as Magnetic Resonance guided Focused Ultrasound (MRgFUS). This procedure is an outpatient procedure that enables the patient to return home immediately and to work within one to two days, compared to surgical treatments which involve several days of hospitalization and weeks of recovery.

The proposed rule has placed MRgFUS into APC 0067, Level III Stereotactic Radiosurgery, with a proposed payment rate of $3918.43. To date, the MRgFUS procedure, which is reported with CPT codes 0071T and 0072T, has been assigned to clinical APCs 0195 and 0202. Over the past two years we have worked with CMS to provide cost and procedure data that would lead to a more clinically and resource appropriate APC. CMS followed the APC panel recommendation to map the MRgFUS procedure codes to a more clinically appropriate APC. Again, we would like to thank CMS for recognizing that MRgFUS is a radiosurgery procedure.

APC classifications are intended to appropriately group services that are similar both clinically and in terms of the resources they require. The total treatment time for a MRgFUS procedure ranges from 120-300 minutes. This reflects both the treatment delivery as well as the treatment planning component times.

2777 Stemmons Fwy, Suite 940, Dallas, Texas 75207, Tel: (1) 214-630-2000, Fax: (1) 214-630-2900

The proposed APC 0067 provides appropriate payment for Stereotactic Radiosurgery (SRS), however, SRS procedures permit providers to report treatment planning and management codes in addition to the primary procedure, where MRgFUS procedure codes include treatment planning immediately prior to the procedure. **MRgFUS treatment planning is a critical component of treatment which cannot be performed without the planning**. APC 0067 does not consider the cost of the required MRgFUS treatment planning. As it is necessary to plan the treatment to effectively deliver therapy, the cost of treatment planning must be captured as part of the APC assignment. UB92 claims from hospital sites that also perform SRS range from $21,000- 28,000, which includes treatment planning. This information has been provided to CMS.

As recommended previously, the most appropriate APC assignment based upon MRgFUS resource utilization is APC 0127, Level IV Stereotactic Radiosurgery. This would permit hospitals to provide the MRgFUS procedure with more appropriate consideration of the time and resources required for treatment planning AND treatment delivery. In addition, this would permit CMS to fulfill the basic intent of APC system: *Services in each APC are similar clinically and in terms of the resources they require*.

We respectfully request that CPT codes 0071T and 0072T be reassigned to APC 0127. This will enable hospitals to receive reimbursement for MRgFUS that more accurately reflects the costs incurred in providing this important treatment to patients suffering from uterine fibroids. It should be emphasized that oftentimes the only other option for patients is invasive surgery, which is accompanied by greater clinical risks as well as economic costs that exceed $9,000. In addition to the clinical benefits of the procedure, patients who undergo MRgFUS have fewer disability days (decreased days of missed work or days in bed) and lower use of medical resources.

In summary, we urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127, with the proposed payment rate of $7,864.15, which more accurately reflects the clinical and economic resources utilized by the hospital.

Again, we would like to thank you for recognizing the value of the MRgFUS procedure and its similarities to Stereotactic Radiosurgery and greatly appreciate your careful consideration of our recommendations.

Respectfully,

Lynn Golumbic

Lynn Golumbic
Director of Marketing and Reimbursement
InSightec Inc.

Submitter : Ms. LaChondra Nevins **Date:** 09/05/2007

Organization : Stormont Vail WoundCare Center

Category : Hospital

Issue Areas/Comments

Wound Care Services

Wound Care Services

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf?. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our physician often orders Apligraf? to help facilitate healing. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf?. These two codes replaced three 15342, 15343, and 15000, which were used to describe the work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf?. We recommend that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf?. This is consistent with other skin substitute products.

CMS-1392-P-350-Attach-1.DOC

#350

September 5, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Dear Mr. Weems:

On behalf of the Stormont-Vail WoundCare Center I would like to take this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for 2008. I am primarily concerned with Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Stormont-Vail WoundCare Center is the leading wound care center in Topeka and we treat several Medicare beneficiaries for diabetic foot and venous leg ulcers. We often use Skin Repair procedures when treating our patients to improve quality of care for diabetics and other patients that suffer from chronic leg and foot ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. As stated above our physician often orders Apligraf® to help facilitate healing. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf®. These two codes replaced three 15342, 15343, and 15000, which were used to describe the work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf®. We recommend that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf®. This is consistent with other skin substitute products.

Thank you for your consideration. If you would like to discuss this issue further, please feel free to contact me at 785-368-0411.

Sincerely,

LaChondra M. Nevins, MPA, MBA
Program Director

Submitter : **Date: 09/05/2007**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Hospital CoPs
File code CMS-1392-P

Sirs,
I would like to comment on this proposed requirement that all patients receiving anesthesia have a postanesthetic note prior to discharge from the PACU. In a small rural hospital such as ours, we CRNA's aren't always immediately available to write such a note due to us doing another anesthetic or pre-oping another patient. The only way I can see this rule being adhered to is if we are allowed to write the note when we report to the PACU nurse. I don't believe that is the intent of this proposal. Therefore, I wish that you would reconsider this proposal because we will not be able to follow this quideline if it remains the way it is.
Thank you,
Lyle Wernimont CRNA

Submitter : Dr. Charles Pollick **Date:** 09/05/2007

Organization : Los Angeles Cardiology Associates

Category : Physician

Issue Areas/Comments

Packaging Drugs and Biologicals

Packaging Drugs and Biologicals

I am a practicing cardiologist and currently use echo contrast agents. I am concerned that if separate payment for echo contrast agents is eliminated for hospital outpatients, patient access to studies using contrast would be severely limited and Medicare expenditures for more invasive follow-up procedures may increase.

In addition:

Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate.

Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests.

Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.

Therefore, I believe that this proposal should be dropped and that contrast agents should continue to be eligible for separate payment.

Submitter : Mr. John Barnas **Date:** 09/05/2007

Organization : Michigan Center for Rural Health

Category : Other Association

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

As I read this, and have had it confirmed, provider-based has no restrictions based on what was proposed so ANY service is subject to elimination. At a minimum, please exclude provider-based RHCs from the rule.

Submitter : Denise Williams **Date:** 09/05/2007

Organization : Provider Roundtable

Category : Hospital

Issue Areas/Comments

Bone Marrow and Stem Cell Processing Services

Bone Marrow and Stem Cell Processing Services

See attachment

CMS-1392-P-354-Attach-1.DOC

#354

Asante Health System, OR
Avera Health, SD
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Erlanger Medical Center, TN
Forrest General Hospital, MS
Health First, Inc., FL
Lovelace Health System, NM
Mercy Medical Center, IA
Our Lady of the Lake Regional Medical Center, LA
Palomar Pomerado Health, CA
Saint Joseph's Hospital, WI
St. Joseph's/Candler Health System, GA
Saint Mary's Hospital, MN
Sheltering Arms Rehabilitation Hospitals, VA
Sisters of Mercy Health System, MO
Twin Lakes Regional Medical Center, KY
University of Colorado Hospital, CO
University Health System, TX
Vanguard Health System, TN

The Provider Roundtable (PRT) is a group of providers representing 20 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

Bone Marrow and Stem Cell Processing Services

The Provider Roundtable supports CMS' proposal for CY2008 to discontinue recognition of HCPCs code G0267 (Bone marrow or peripheral stem cell harvest) and to recognize the six CPT codes that are more specific. The PRT agrees that use of these codes will provide more specific claims data and more accurate payment, while also requiring one set of codes for all payers for these services.

If CMS staff have questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052

Submitter : **Denise Williams** **Date: 09/05/2007**

Organization : **Provider Roundtable**

Category : **Hospital**

Issue Areas/Comments

Drug Administration

Drug Administration

see attachment on consultation codes

CMS-1392-P-355-Attach-1.DOC

#355

Asante Health System, OR
Avera Health, SD
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Erlanger Medical Center, TN
Forrest General Hospital, MS
Health First, Inc., FL
Lovelace Health System, NM
Mercy Medical Center, IA
Our Lady of the Lake Regional Medical Center, LA
Palomar Pomerado Health, CA
Saint Joseph's Hospital, WI
St. Joseph's/Candler Health System, GA
Saint Mary's Hospital, MN
Sheltering Arms Rehabilitation Hospitals, VA
Sisters of Mercy Health System, MO
Twin Lakes Regional Medical Center, KY
University of Colorado Hospital, CO
University Health System, TX
Vanguard Health System, TN

The Provider Roundtable (PRT) is a group of providers representing 20 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

The PRT supports CMS' proposal to inactivate CPT codes 99241 – 9924 for consultation visit codes under OPPS and reflect those resources in their internal hospital visit guidelines.

If CMS staff have questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville, TN
(615) 665-6052