Submitter : **Dr. Dennis Newton** **Date: 09/08/2005**

Organization : **Samaritan Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advanced bioengineered tissue therapy that is indicated for venous leg ulcers and dibetic foot ulcers. It is important element in advanced wound care. This proposed ruling would drastically limit the care that I provide and decrease the availability of this FDA approved product for my patients. Furthermore, by decreasing the availability of this product it would increase the rate of healing and add to the costs of delivering care to this group of patients.

Submitter : Barb Fagerlin **Date:** 09/08/2005

Organization : Samaritan Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Patient access to Apligraf is important. The proposed ruling would jeopardize the availability of this FDA approved advanced technology for my patients. Therefore, I am requesting that this ruling be rejected.

Submitter : **Barb Nester** **Date: 09/08/2005**

Organization : **Samaritan Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

I am requesting that this proposed ruling on the bioengineered product, Apligraf be rejected. Apligraf is an advanced bioengineered tissue and is only FDA approved product for both venous leg ulcers and diabetic foot ulcers. This ruling would severly limit the availability of the product for my patients and add to the costs of delivering wound care.

Submitter : Dede Eakle **Date:** 09/08/2005

Organization : Samaritan Hospital Wound Care Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

As a member of the Wound, Ostomy, & Continence Nursing Society and a clinician at a specialized wound care center, I am requesting that the proposed ruling on Apligraf be rejected. By passing this ruling, it would serverly limit the availability of Apligraf to patients with venous leg ulcers and diabetic foot ulcers. Therefore, it would delay wound healing and increase costs to the healthcare delivery system.

Submitter : **Ms. Brenda Wessel** **Date: 09/08/2005**

Organization : **Dorsey Surgical Associates,P.A.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please correct 2006 reimbursement C1305 we use this for Diabetic foot venous leg ulcer. Please keep this so we may use this in our office so we can help our patients.

Submitter : Ellen Uruhart, RN, MSN, FN **Date:** 09/08/2005

Organization : Samaritan Hospital Wound Care Clinic

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule contains errors which would seriously undermine wound care in the United States. As a director of a wound clinic and a nurse practioner, the proposed ruling for the advanced wound care product, Apligraf, would serverly limit the availibitly of this product. Apligraf is the only product that is FDA approved for both venous leg ulcers and diabetic foot ulcers. Apligraf is utilized in this group of patients in a lot of instances when all else has failed. Thereby, by limiting the availability of this product a large number of these wounds would not heal. This would lead to an increased number of amputations and add to the costs of the health care delivery system.

Submitter : **Ms. Brenda Wessel** **Date: 09/08/2005**

Organization : **Dorsey Surgical Associates,P.A.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please correct 2006 reimbursement C1305 we use this for Diabetic foot venous leg ulcer. Please keep this so we may use this in our office so we can help our patients.

Submitter : **Ms. T. Kimberly Harlan** **Date: 09/08/2005**

Organization : **North Kansas City Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please correct the recognized error in the 2006 reimbursement for c1305. Appligraft and Dermagraft give our healthcare professionals extra weapons to treat diabetic foot ulcers and venous statis ulcers. We need to make sure that Appligraft and Dermagraft are available for use 2006.

Submitter : **Dr. A. Enrique Whittwell** **Date: 09/08/2005**

Organization : **Jackson South Wound Care Center**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Although the proposed rule is intended to provide reimbursement of ASP +8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.
Apligraf- 2005 outpatient rate is $1,130.88; 2006 proposed outpatient rate is $766.84.
Dermagraft- 2005 outpatient rate is $529.54; 2006 proposed outpatient rate is $368.32.

Reimbursment at this rate would jeopardize patient access to Apligraf and dermagraft and that would have a very negative impact on quality of care

Submitter : **Ms. Jenny Schwartzberg** **Date: 09/08/2005**

Organization : **Ms. Jenny Schwartzberg**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,

I am a cochlear implant recipient, and as such I have a personal interest in the proposed : 'Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates,' which includes changes to the outpatient cochlear implant reimbursement rate for 2006. The new rate would reduce payment by 14 percent from the established 2005 rate of $25,307 to $21,739.

This deeply concerns me. I know from personal experience how valuable a cochlear implant is. In my case I was born profoundly deaf and received a cochlear implant in 1991. Over the years my ability to listen and use my new hearing has developed until at the present day I can recognize words, phrases and sentences without looking at people in order to lipread. This ability is not consistent and is dependent on being in a quiet environment, but it has vastly increased my overall level of comfort and consistency in communication and understanding of others' speech.

The improvement in hearing is much more marked for cochlear implant recipients who are children, especially very young children. However, cochlear implants are extraordinarily useful at all ages though the resulting abilities to hear and comprehend what one is hearing varies depending on various factors.

Any effort to decrease funding for cochlear implants should be firmly resisted. They are expensive, and they are not one-time costs, since there are ongoing upgrades in cochlear processors, ongoing battery costs, auditory therapy costs, speech therapy costs, repair and insurance costs. There is a continued expense, and few people can truly afford the continued expense, which is why more of these expenses should be reimbursable under Medicare. The quality of life with the implant is so valuable and so important that it absolutely must be made available to as many people as possible. Cost cutting efforts in Medicare reimbursements for any aspect of the Cochlear Implant process are incredibly shortsighted and foolish.

Respectfully yours,

Jenny Schwartzberg

Submitter : **Mrs. Judith Turner R.N.** **Date: 09/08/2005**

Organization : **Jackson South Wound Care Center**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is an advance bioengineered tissue based therapy indicated for the treatment of venous leg ulcers and diabetic ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for the treatment of venous leg ulcers.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

Submitter : **Mrs. Lisa Taylor** **Date: 09/08/2005**

Organization : **Oakwood Wound Care**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

September 8, 2005

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates -- Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs

Dear Mr. Kuhn:

Who is submitting this public comment to bring to your attention an error in the proposed rule, CMS-1501-P, ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201).

These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. These products have preserved and improved the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft.

As you know, in the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product.

However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Accordingly, both products experienced a significant decrease in payment:

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

There may have been some confusion in the proposed rule because the products are reimbursed in the physician?s office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively.

Thank you for your attention to this issue and we look forward to working with you to correct the issue in the final rule.

Sincerely,

Lisa Taylor
Oakwood Wound Care Center Taylor

Submitter : **Ms. Lydia Gregoret** **Date: 09/08/2005**

Organization : **Ms. Lydia Gregoret**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Please reconsider the proposal to reduce the outpatient cochlear implant reimbursement rate from $25,307 to $21,739. The cochlear implant has opened up a whole world to my son. It is truly a miraculous device. If this change occurs, fewer people will be able to benefit from this technology because even the current rate does not adequately reimburse surgeons and hospitals. Already, in some states like Rhode Island, children who are deaf and on Medicaid can't get cochlear implants at all because there is no pediatric CI center in the state and out-of-state clinics will not accept these children as patients due to the low reimbursement rate. Hospitals will be less willing to perform surgeries on Medicare patients and ALL cochlear implant patients, not just those under Medicare or Medicaid, will be indirectly affected, as the cochlear implant programs and departments rely on their hospital's good will to perform implant surgeries that are a net loss to the hospital. With rising costs of health care, I am really sad that you are actually thinking of lowering the reimbursement rate. It is truly unconscionable.

Submitter : **Dr. Michael Thomas** **Date: 09/08/2005**

Organization : **Memorial Hermann Baptist Beaumont Wound Healing Ce**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir / Madam,
I really like the apligraf as a very effective tool to heal wounds. In my opinion is has cut down the time to heal considerably. It is a clear cost saver and ahs been greatly appreciated by patients.
Michael Thomas, MD

Submitter : **Mrs. Francisca Arnal RN Coordinator** **Date: 09/08/2005**

Organization : **Kendall Regional Medical Center**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calender Year 2006 Payment Rates" contains errors which seriously undermine wound care in the United States.

Submitter : **Mrs. Judy Simpson** **Date: 09/08/2005**

Organization : **Memorial Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

? Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
? Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug
? Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32
? Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

? We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Mrs. Betsy Dresch** **Date: 09/08/2005**

Organization : **Memorial Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

? Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
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? We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. David Halpern** **Date: 09/08/2005**

Organization : **Memorial Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
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We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. Carlos Trabanco** **Date: 09/08/2005**

Organization : **Kendall Regional Medical Center**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Although the proposed rule is intended to provide reimbursement of ASP +8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP +8%

Submitter : **Mrs. Margie Marino** **Date: 09/08/2005**

Organization : **Memorial Hermann Beaumont Wound Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is great. I have seen many success stories. I understand the reimbursment for 2006 is under review. It is my hope that CMS will do the right thing and ensure that reimbursement for Apligraf is sufficient to cover its cost!! Margie Marino, LVN

Submitter : **Mrs. Shaunette Patterson** **Date: 09/08/2005**

Organization : **Memoriual Hermann Wound Care Beaumont**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Apligraf is great. I have seen many success stories. I understand the reimbursment for 2006 is under review. It is my hope that CMS will do the right thing and ensure that reimbursement for Apligraf is sufficient to cover its cost. Shaunette Patterson R.N.

Submitter : **Dr. Hungh Huynh** **Date: 09/08/2005**

Organization : **Tomball Regional Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,

The proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States.

Apligraft is an advanced bioengineered tissue based therapy indicated for treatment of venous leg ulcers and diabetic foot ulcers. It is an important element of advanced wound care, shown to speed up healing rates and reduce amputations in severely affected patients. It is the only tissue based therapy approved for treatment of venous leg ulcers.

Reimbursement at the 2006 outpatient proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on the quality of care.

I would like to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+8%

Regards,
Hungh Huynh, MD

Submitter : **Dr. E. P. Descant** **Date: 09/08/2005**

Organization : **Tomball Regional Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,

The proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States.

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Reimbursement at the 2006 outpatient proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on the quality of care.

I would like to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+8%

Regards,
E. Paul Descant, MD

Submitter : **Dr. Jeremy Moran** **Date: 09/08/2005**

Organization : **Tomball Regional Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,

The proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States.

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Reimbursement at the 2006 outpatient proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on the quality of care.

I would like to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+8%

Regards,
Jeremy Moran, DPM

Submitter : **Mrs. Charlotte Ballard** **Date: 09/08/2005**

Organization : **Tomball Regional Hospital**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,

The proposed rule CMS-1501-P "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors which would seriously undermine wound care in the United States.

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Reimbursement at the 2006 outpatient proposed rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on the quality of care.

I would like to petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specific covered drug, at ASP+8%

Regards,
Charlotte Ballard, NP

Submitter : **Dr. Douglas Jordan** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States.
Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug
Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. J Thomas Logsdon** **Date: 09/08/2005**

Organization : **Dr. J Thomas Logsdon**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-256-Attach-1.DOC

Submitter : **Dr. Donald Vierling** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
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We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. Timothy Ranval** **Date: 09/08/2005**

Organization : **Dr. Timothy Ranval**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-258-Attach-1.DOC

Submitter : **Mrs. Diane Morgan** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
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Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Ms. Deanna Galloway** **Date: 09/08/2005**

Organization : **Curative Health Services**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-260-Attach-1.DOC

Submitter : **Dr. Jason Banister** **Date: 09/08/2005**

Organization : **Dr. Jason Banister**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-1501-P-261-Attach-1.DOC

Submitter : **Mrs. Esther Gonzalez** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates contains errors which would seriously undermine wound care in the United States
Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug

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Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Mrs. Elizabeth Ann Mansfield** **Date: 09/08/2005**

Organization : **Lourdes Wound Care Center**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : **Mrs. Melanie Poulin** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
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We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. Doug Cohen** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates contains errors which would seriously undermine wound care in the United States
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We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Dr. Anne Kolker** **Date: 09/08/2005**

Organization : **Memorial Sloan Kettering Hospital and Cancer Cente**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed changes are detrimental to the teaching of Anesthesia residents

CMS-1501-P-266-Attach-1.WPD

CMS-1501-P-266-Attach-2.WPD

Submitter : **Mrs. Donna Ritter** **Date: 09/08/2005**

Organization : **Regional Wound Care at Bayonet Point**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule CMS-1501-P ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Paymemt Rates? contains errors which would seriously undermine wound care in the United States
Apligraf and Dermagraft are currently reimbursed in the hospital prospective payment system as a specified covered drug

Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

Reimbursement at this rate would jeopardize patient access to Apligraf and Dermagraft and that would have a very negative impact on quality of care.

We petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%.

Submitter : **Ms. Wendy Wieber** **Date: 09/08/2005**

Organization : **NC Early Intervention for D/HH**

Category : **Speech-Language Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I work with many children who are on Medicaide who receive Cochlear Implants. Without them they would have NO access to spoken language--no possibility of academic success and unltimatley meaningful employment. If Medicaide can pay now, future costs (SSI etc) will be reduced. Reducing reimbursement to hospitals and surgeons will reduce incentive to perform these important surgeries.

Cochlear implants dramatically improve the quality of life, self-sufficiency and independence of the Medicare population who receive them, and are cost effective as demonstrated by evidence-based literature and their acceptance among medical professionals and insurance providers.
CMS has been responsive working with providers and manufacturers to ensure adequate reimbursement rates, and has recognized the impact payment rates have on access to care and this life-enhancing technology for persons that are deaf and hard of hearing.
The proposed reimbursement level of $21,739 would have a negative impact on Medicare beneficiary access to cochlear implantation.
The proposed rate limit will reduce the number of surgeries performed by implant centers, causing shortages of qualified clinical personnel to perform audiological services and (re)habilitation necessary for implant recipients to achieve maximum benefit.
Actual device costs are much higher than the proposed rate, and the methodology hospital outpatient payment systems currently use to compute reimbursement makes it difficult for CMS to accurately track those costs.
Please consider accurate external device cost data as determined the Lewin Group study and recalculate the relative weight of APC 0259. Alternatively, CMS could set the 2006 reimbursement rate at the 2005 rate, adjusted for inflation and updated factors applied to all Ambulatory Payment Classifications (APCs).

Submitter : **Louise Sheridan** **Date: 09/08/2005**

Organization : **Louise Sheridan**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Cochlear implants dramatically improve the quality of life, self-sufficiency and independence of the Medicare population who receive them, and are cost effective as demonstrated by evidence-based literature and their acceptance among medical professionals and insurance providers.
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Actual device costs are much higher than the proposed rate, and the methodology hospital outpatient payment systems currently use to compute reimbursement makes it difficult for CMS to accurately track those costs.
I request that CMS substitute accurate external device cost data as determined the Lewin Group study and recalculate the relative weight of APC 0259. Alternatively, CMS could set the 2006 reimbursement rate at the 2005 rate, adjusted for inflation and updated factors applied to all Ambulatory Payment Classifications (APCs).

Submitter : **Dr. Robert Sorrentino** **Date: 09/08/2005**

Organization : **Medical College of Georgia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Medical College of Georgia
Section of Cardiovascular Diseases
Cardiac Arrhythmia Service

9/8/05

To CMS

As a major health care provider in our area, we at the Medical College of Georgia implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. I am writing to express my concerns about the proposed Outpatient Payment rule for calendar Year 2006.

In the proposed rule, the payment rates for procedures involving ICDs were significantly decreased. As a health care provider of these services to Medicare beneficiaries, these payment reductions are a serious concern. Changes should be made to the 2006 proposed payment rates for ICDs that are more closely aligned with the real cost of providing these services. The 2006 proposes a 14.1% payment decrease relative to 2005 payments for ICD APCs 0107 and 0108 resulting in an unsustainable financial burden for our institution. The resulting APC rates are lower than our institution?s cost for the device itself, leaving us with an out-of-pocket loss for device acquisition and no payment for the procedure. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To fix this problem, we respectfully suggest that CMS base the 2006 payment rates for ICD implant procedures on the 2005 payment rates plus the 3.2% hospital update. We understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates, while not entirely adequate, would be more in line with our facility?s actual cost of performing these services.

In the proposed rule, CMS requested comments on the February 2005 APC Advisory Panel recommendation to increase the number of single procedure claims available for rate setting for APCs 0107 and 0108. Although the scenarios displayed in the proposed rule increase the number of single procedure claims, single procedure claims have shown no ability to provide appropriate payment in the last five years and we are not able to support this proposal.

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization devices (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase, the move to the new APC actually equates to a lower rate of reimbursement than in 2005 due to the change in the status indicator. In the proposed rule the status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

The assignment of status indicator ?T? does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and is not duplicative. The assignment of a status indicator ?T? does not make sense in an APC where the device cost is 90% of the procedure. The cost of the lead itself is not reduced by 50% when implanted along with other procedures. To address this problem, we request that CMS retain the ?S? status indicator for the left sided lead APC.

Thank you for this opportunity to provide comments.

Sincerely,

Robert A. Sorrentino, MD FACC
Professor of Medicine
Director of Arrhythmia Services
Section of Cardiovascular Diseases
Medical College of Georgia
Augusta, GA

Submitter : **Mr. Brian Owens** **Date: 09/08/2005**

Organization : **Health Alliance of Greater Cincinnati**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter from Brian Owens, RNC, LPCC, PCC, BSN, MA
VP, Behavioral Health Services
Health Alliance.

CMS-1501-P-271-Attach-1.DOC

Submitter : **Dr. Joseph Cavorsi** **Date: 09/09/2005**

Organization : **Dr. Joseph Cavorsi**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-272-Attach-1.DOC