

Submitter : Mr. Ken Jones
Organization : Quest Medical, Inc.
Category : Device Industry

Date: 01/02/2008

Issue Areas/Comments

HCPCS codes

HCPCS codes

68816 - Please see attachment for detail

CMS-1392-FC-109-Attach-1.PDF



December 21, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: ASC Payment Level for new CPT® 68816

Dear Administrator:

This correspondence is in reference to the proposed payment in the ASC setting for new CPT® code 68816. In the final rule, the interim payment is proposed at a fully implemented rate of \$433.69. The rate is irreconcilably below the existing CPT code 68815 rate, which if not adjusted will increase healthcare costs by; 1) shifting care to the less successful procedure, resulting in repeat interventions and 2) causing providers to shift patients from the ASC environment to the hospital.

Quest Medical

Quest Medical, Inc. develops, manufactures, and distributes medical devices for a variety of medical and surgical markets. The markets our products provide solutions for include cardiac surgery, ophthalmic surgery, oncology, IV fluid and anesthesia delivery, and hemodialysis.

Quest Medical makes several products for treatment of eye disorders, including several manual ophthalmic surgical devices used for less invasive treatments of occluded lacrimal ducts. LacriCATH® is our newest product line. The LacriCATH® balloon catheters are available in various sizes and configurations to accommodate both pediatric and adult patients. Pediatric ophthalmologists are the primary customers for this technology.

Balloon Catheter Dilation of the Nasolacrimal Duct

As background, the 68816 procedure is described as *Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation*. In this procedure, the typical patient is placed under anesthesia. The puncta are dilated. The lacrimal system is probed in the customary fashion, and the presence of the probe in the nose is confirmed. The probe is removed, and a balloon catheter is passed through the superior punctum, canalicular system and into the nasolacrimal duct down to the nasal floor. The presence of the balloon catheter in the nose is then confirmed. An inflation device is filled with sterile water or saline, connected to the balloon catheter, and the

QUEST Medical, Inc.
An Atrion company

balloon is inflated for 90 seconds. The balloon is then deflated by releasing the lock mechanism on the inflation device. The inflation procedure is repeated a second time for 60 seconds, again the balloon is deflated. The balloon is pulled proximally and positioned within the lacrimal sac and nasolacrimal duct. The balloon is inflated and deflated again using the same method described above. The catheter is then rotated clockwise to minimize the profile of the deflated balloon and is gently withdrawn from the lacrimal system. The lacrimal system may be irrigated using a fluorescein stained fluid, which is recovered in the nose.

The procedure has gained prominence. In the largest series reported, patients received balloon treatment after failed probing. Patients experienced duct clearance in a single treatment. In all cases, those patients receiving a stent instead of a balloon required a second physician encounter to remove the stent after the end of the global period. In addition, balloon treatment was complication free (compared to a 20% rate for stents). Complications involved a separate intervention.

At a meeting with CMS, the issue of restenosis was discussed. In our experience, restenosis is not an issue for these patients. Quest Medical would be surprised if insurers have any measurable expenses associated with restenosis, which is in contrast to other areas where balloons are used and restenosis is a common and very expensive consequence of treatment. Once the tear ducts are clear, they do not tend to reocclude and there is no retreatment. Because restenosis is not a clinical or economic issue for nasolacrimal balloon catheter dilation, it has not been the subject of randomized trial. It simply does not represent a valid endpoint for clinical study for this patient group.

While Medicare beneficiaries are only a small fraction of treated patients, the Medicare ASC fee schedule represents a benchmark for establishing private insurer payment. Although the LacriCATH[®] technology is valuable and critical for patients, the market size is modest compared to many covered technologies. The current market for this technology is less than \$5 million, which represents fewer than 100 pacemakers or implantable neurostimulators.

History of Coding and Setting of Care Experience

Efforts to secure payment using an unlisted HCPCS code were time consuming and not particularly successful. The AMA awarded new CPT 68816 effective in 2008 to recognize the resource intensity, cost, and clinical differences of the balloon catheter procedure. The challenge has been adequate ASC facility payment to permit adoption of the procedure in this environment. Until the implementation of 68816 (effective in 2008), the balloon catheter procedure has been reported using 68815, *Probing of nasolacrimal duct, with or without irrigation; with insertion of tube or stent*. The 2007 ASC payment for 68815 is \$446. Because the balloon catheter alone costs \$306, ASCs have not been supportive of this procedure in that setting. In contrast, the 2007 OPPS payment is \$1,053; therefore, the balloon catheter procedure has been typically steered toward the hospital outpatient department environment.

2008 Ambulatory Surgery Center Payment

Our understanding is that the 2008 interim ASC payment rate that CMS published for 68816 was based upon performing this procedure in an office setting. While it is theoretically possible to perform this procedure in the physician office setting, the procedure is typically performed in the outpatient/ambulatory setting. Our goal, identified in response to physicians' requests, is to enable providers to regularly offer and provide this service to patients in the ASC setting. This is the preferred setting for the procedure (assuming adequate payment). However, the 2008 interim ASC payment level of \$434 for this procedure will not facilitate this. With the balloon catheter costing \$306, ASCs will not support the procedure due to facility resource concerns. Therefore, providers will continue to be forced to perform this procedure in the outpatient setting, unless CMS is able to provide a more appropriate payment to the ASC.

Summary Comment

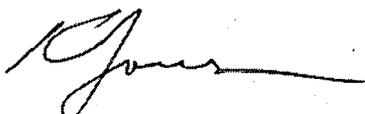
The importance of CMS assigning appropriate ASC payment is significant. Without appropriate ASC payment level, patients will be steered to the less effective, higher reimbursement treatments or to more costly care settings, possibly including avoidable hospital admissions.

We are requesting that CMS consider revising the interim ASC payment for 68816. More appropriate methodology for assigning payment to this code could involve using 65% of the OPPS payment rate (resulting in an ASC payment of \$775).

Alternatively, CMS may use CPT code 68815 as a similar cost procedure, with the exception of supply costs. The difference is supply costs with 68816 as compared to 68815 is approximately \$200. The difference in procedural supply costs is described in the supply cost data tables associated with the Physician Fee Schedule Final Rule.

Thank you for this opportunity to comment on payment for 68816. If you have any questions, please contact me at 800-627-0226.

Sincerely,



Ken Jones
President
Quest Medical, Inc.

Submitter : Ms. Mark Reinesto

Date: 01/02/2008

Organization : Ms. Mark Reinesto

Category : Individual

Issue Areas/Comments

GENERAL

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I am a patient who relies on interventional pain management physicians for my care. I am writing to you because of my grave concern for the future of patient access to this type of care. Based on my knowledge of the planned reduction in reimbursement, it is my firmly held belief that, unless Congress takes action soon, seniors will lose access to interventional pain management. If past actions are any guide, it is certain that Medicaid and third party payors will follow Medicare, cutting their reimbursement for these valuable services as well.

As a concerned patient, I write urging you to take steps to stop the pending physician reimbursement cuts and the devastating ASC cuts for interventional pain management procedures. I am extremely disappointed that Congress does not appear to be willing to take action prior to the holiday recess. This inaction could very well cause seniors to lose access to interventional pain management.

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Once again, thank you for all your help.
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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Sheri Hughes-Carlson

Date: 01/02/2008

Organization : Ms. Sheri Hughes-Carlson

Category : Individual

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Submitter : Mr. Walter Gross

Date: 01/02/2008

Organization : Mr. Walter Gross

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Debra Shea

Date: 01/02/2008

Organization : Ms. Debra Shea

Category : Individual

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Submitter : Mr. Joe Lennert

Date: 01/02/2008

Organization : Mr. Joe Lennert

Category : Individual

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Submitter : Mr. Philep M. Mann

Date: 01/02/2008

Organization : Mr. Philep M. Mann

Category : Individual

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Submitter : Ms. Diane Karson

Date: 01/02/2008

Organization : Ms. Diane Karson

Category : Individual

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Submitter : Ms. Marla Ellis

Date: 01/02/2008

Organization : Ms. Marla Ellis

Category : Individual

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Submitter : Mr. Donald E. Ellis
Organization : Mr. Donald E. Ellis
Category : Individual

Date: 01/02/2008

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Submitter : Mr. Dave Raeiwe

Date: 01/02/2008

Organization : Mr. Dave Raeiwe

Category : Individual

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Candis Lindner

Date: 01/02/2008

Organization : Ms. Candis Lindner

Category : Individual

Issue Areas/Comments

GENERAL

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Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Michael Rock

Date: 01/02/2008

Organization : Mr. Michael Rock

Category : Individual

Issue Areas/Comments

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Email address: _____

Submitter : Ms. Donna Spivey

Date: 01/02/2008

Organization : Ms. Donna Spivey

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Email address: _____

Submitter : Ms. Elizabeth Pence

Date: 01/02/2008

Organization : Ms. Elizabeth Pence

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Ms. Paula Perez
Organization : Ms. Paula Perez
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Submitter : Ms. Geraldine Riordan

Date: 01/02/2008

Organization : Ms. Geraldine Riordan

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Sandra Bendik

Date: 01/02/2008

Organization : Ms. Sandra Bendik

Category : Individual

Issue Areas/Comments

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Submitter : Mr. Timothy S. Bednarz

Date: 01/02/2008

Organization : Mr. Timothy S. Bednarz

Category : Individual

Issue Areas/Comments

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Submitter : Mr. Pete Beresheim

Date: 01/02/2008

Organization : Mr. Pete Beresheim

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Candice M. Schulz

Date: 01/02/2008

Organization : Ms. Candice M. Schulz

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Suzanne M. Sylvester

Date: 01/02/2008

Organization : Ms. Suzanne M. Sylvester

Category : Individual

Issue Areas/Comments

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Email address: _____

Submitter : Ms. Debra Beach

Date: 01/02/2008

Organization : Ms. Debra Beach

Category : Individual

Issue Areas/Comments

GENERAL

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Jaqueline Brown

Date: 01/02/2008

Organization : Ms. Jaqueline Brown

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Loretta A. Hoban
Organization : Ms. Loretta A. Hoban
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Bertha Corral

Date: 01/02/2008

Organization : Ms. Bertha Corral

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Rosaire O'Connor

Date: 01/02/2008

Organization : Ms. Rosaire O'Connor

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Charlotte Swalec

Date: 01/02/2008

Organization : Ms. Charlotte Swalec

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Michael Kroll
Organization : Mr. Michael Kroll
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

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Submitter : Ms. Carol A. Vukas

Date: 01/02/2008

Organization : Ms. Carol A. Vukas

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

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Submitter : Mr. Ken Quick

Date: 01/02/2008

Organization : Mr. Ken Quick

Category : Individual

Issue Areas/Comments

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Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Elizabeth L. Kloski-Song

Date: 01/02/2008

Organization : Ms. Elizabeth L. Kloski-Song

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Kristy Leparski

Date: 01/02/2008

Organization : Ms. Kristy Leparski

Category : Individual

Issue Areas/Comments

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Email address: _____

Submitter : Ms. Ronald J. Winchel

Date: 01/02/2008

Organization : Ms. Ronald J. Winchel

Category : Individual

Issue Areas/Comments

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For more information visit www.asipp.org

Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Arlene Heasley

Date: 01/02/2008

Organization : Ms. Arlene Heasley

Category : Individual

Issue Areas/Comments

GENERAL

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Eric Soappman

Date: 01/02/2008

Organization : Mr. Eric Soappman

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Deanna Vicario

Date: 01/02/2008

Organization : Ms. Deanna Vicario

Category : Individual

Issue Areas/Comments

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Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Cindy Hoedebecke

Date: 01/02/2008

Organization : Ms. Cindy Hoedebecke

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Margaret Ebert

Date: 01/02/2008

Organization : Ms. Margaret Ebert

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Lois E. Fitzmaurice

Date: 01/02/2008

Organization : Ms. Lois E. Fitzmaurice

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Steve Luloh

Date: 01/02/2008

Organization : Mr. Steve Luloh

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Kelly Kendzior

Date: 01/02/2008

Organization : Ms. Kelly Kendzior

Category : Individual

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Angela J. Morawa
Organization : Ms. Angela J. Morawa
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Ms. Mary Ann Ruckauf

Date: 01/02/2008

Organization : Ms. Mary Ann Ruckauf

Category : Individual

Issue Areas/Comments

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Email address: _____

Submitter : Ms. Robin A. Prarie

Date: 01/02/2008

Organization : Ms. Robin A. Prarie

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Email address: _____

Submitter : Ms. Kristin Moran

Date: 01/02/2008

Organization : Ms. Kristin Moran

Category : Individual

Issue Areas/Comments

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For more information visit www.asipp.org

Print Name: _____

Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Brad Fields

Date: 01/02/2008

Organization : Mr. Brad Fields

Category : Individual

Issue Areas/Comments

GENERAL

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Email address: _____

Submitter : Mr. Joseph F. Schiezler

Date: 01/02/2008

Organization : Mr. Joseph F. Schiezler

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Email address: _____

Submitter : Ms. Doris Fricka

Date: 01/02/2008

Organization : Ms. Doris Fricka

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Ms. Christina Kosac

Date: 01/02/2008

Organization : Ms. Christina Kosac

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Sharon Heagy

Date: 01/02/2008

Organization : Ms. Sharon Heagy

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Ms. Georgine Claude

Date: 01/02/2008

Organization : Ms. Georgine Claude

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Annette Lopez

Date: 01/02/2008

Organization : Ms. Annette Lopez

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Mr. David Shepard
Organization : Mr. David Shepard
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Submitter : Ms. Ethel Cockerhan

Date: 01/02/2008

Organization : Ms. Ethel Cockerhan

Category : Individual

Issue Areas/Comments

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Submitter : Ms. Patricia Hillyer
Organization : Ms. Patricia Hillyer
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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Submitter : Mr. Anthony R. Campana

Date: 01/02/2008

Organization : Mr. Anthony R. Campana

Category : Individual

Issue Areas/Comments

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Signature: _____ Date: _____

Email address: _____

Submitter : Mr. Mike Hareld

Date: 01/02/2008

Organization : Mr. Mike Hareld

Category : Individual

Issue Areas/Comments

GENERAL

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I am a patient who relies on interventional pain management physicians for my care. I am writing to you because of my grave concern for the future of patient access to this type of care. Based on my knowledge of the planned reduction in reimbursement, it is my firmly held belief that, unless Congress takes action soon, seniors will lose access to interventional pain management. If past actions are any guide, it is certain that Medicaid and third party payors will follow Medicare, cutting their reimbursement for these valuable services as well.

As a concerned patient, I write urging you to take steps to stop the pending physician reimbursement cuts and the devastating ASC cuts for interventional pain management procedures. I am extremely disappointed that Congress does not appear to be willing to take action prior to the holiday recess. This inaction could very well cause seniors to lose access to interventional pain management.

I understand that the physician payment fix should be for at least two years with a change in the law rather than yearly fix which will accumulate the cuts in the third year to 20% at one time. I also support modest cuts for Medicare Advantage Plan; however, we do not support complete elimination of Medicare Advantage Plans. This is especially true in Illinois as malpractice costs are rising for interventional pain management physicians. Based on these statistics it is obvious that physicians will have an extremely difficult time continuing to practice and offer the care that they are currently.

A second issue of concern relates to ambulatory surgery center payment cuts for interventional pain management procedures. This is one of the most effective locations for these procedures to be performed, along with physician offices. Since the Government has decided to reduce payments to offices and ASCs, we will be forced to return to the hospital setting. This is, without a doubt, a less effective, more inefficient, and more expensive setting. It appears to be criminal to punish both of the most effective interventional pain management settings, namely the offices, and ASCs, with draconian cuts. If this is allowed to stand, it will significantly affect our access to these valuable services which have significantly improved our quality of life.

Although we appreciate the bills introduced by Honorable Mike Crapo (R-ID) in the Senate and Honorable Kendrick Meek (D-17th FI) and Wally Herger (R-2nd CA) in the House; these unfortunately will not fix the ASC issue for interventional pain management. They also would be extremely expensive and consequently, we request a temporary reprieve for interventional procedures performed in ASCs by a carve-out for 9 procedures which will cost \$8 million in the year 2008 and a total of \$34 million by 2010.

Please act immediately, as these issues are extremely important to the American public, namely your voters. I am very much interested in hearing your response and hoping for your support on these important issues.

Once again, thank you for all your help.
For more information visit www.asipp.org

Print Name: _____

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Submitter : Mr. William McPhail

Date: 01/02/2008

Organization : Mr. William McPhail

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Mr. James Desper

Date: 01/02/2008

Organization : Mr. James Desper

Category : Individual

Issue Areas/Comments

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Print Name: _____

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Submitter : Mr. Steven J. Sauck
Organization : Mr. Steven J. Sauck
Category : Individual

Date: 01/02/2008

Issue Areas/Comments

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